

Clinical Laboratory Improvement Amendments (CLIA) High-Level Overview

I. BACKGROUND

Congress implemented CLIA to improve the quality and safety of laboratory services. CLIA requires all laboratories and providers that perform tests (including waived tests) for health assessment or for the diagnosis, prevention, or treatment of disease or health impairment to comply with specific federal quality standards. This requirement applies even if only a single test is being performed. Refer to the CMS CLIA website for detailed information on CMS requirements @ their website below and searching "CLIA" @ <http://www.cms.gov/>

The Centers for Medicare & Medicaid Services (CMS) regulates certain laboratory testing through the Clinical Laboratory Improvement Amendments (CLIA). Wisconsin Medicaid adheres to the regulation by ensuring providers billing and/or rendering services regulated by CLIA are properly certified by CMS. In interChange, the provider records are updated with the appropriate CLIA certifications and the claims are monitored by a system edit.

A provider who performs tests for the above stated purposes is considered a laboratory under CLIA and must obtain a CLIA certificate from the federal Centers for Medicare and Medicaid Services (CMS) indicating that the laboratory is qualified to perform a category of tests. The type of certificate CMS issues is determined by both the complexity of tests performed and the qualifications of staff performing the tests. Certifications cannot be retroactively dated by CMS so providers should plan on getting a certificate before trying to get compensation for laboratory procedures.

For information on attaining a Certificate, please see the "How to obtain a CLIA Certificate" brochure available at CMS' site. Having a Medicaid (MA) Certificate does not replace a CLIA Certificate.

As a reminder, once issued a Certificate, Providers will need to send a copy of it to:

ForwardHealth
Provider Maintenance
313 Blettner Blvd
Madison WI 53714-2405

II. REQUIREMENTS

1. The system shall only allow valid Types of Certificates (TOC) for providers that are effective for the date(s) of service

2. The system shall only allow valid TOC for providers. The valid TOCs are:

A. Certificate of Compliance (COC)

- This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.

- This TOC will allow all kinds of tests to be performed as listed in the attached

Appendixes A, F, and G.

B. Certificate of Waiver (CW)

- This certificate is issued to a laboratory to perform only waived tests.

- This TOC will allow only tests from Appendix G.

- Certain tests on the Waived list, from Appendix G, will also require a modifier to be present on the claim/encounter at the detail level. This is to distinguish those procedures done by Providers who have a lab and are performing them versus others who may only be a specimen collection site and/or are using only prepackaged tests. These tests generally are considered low to moderate complexity as well by CMS.

C. Certificate of Accreditation (COA)

- This is a certificate that is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.

- This TOC will allow all kinds of tests to be performed as listed in the attached Appendixes A, F, and G.

D. Certificate for Provider-Performed Microscopy Procedures (PPMP)

- This certificate is issued to a laboratory in which a physician, mid-level practitioner, or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests.

- This TOC will allow only tests from Appendix F & G.

E. Certificate of Registration (COR)

- This certificate is issued to a laboratory and enables the entity to conduct moderate- or high-complexity laboratory testing, or both, until the entity is determined by survey to be in compliance with the CLIA regulations.

- This TOC will allow all kinds of tests to be performed as listed in the attached Appendixes A, F, and G.

3. The system shall only allow valid Categorization of Tests (COT) for procedure codes. The valid COTs are:

- A. Tests Subject to CLIA Edits
- B. Waived Tests
- C. PPMP Tests
- D. Tests Excluded from CLIA Edits

4. The system shall monitor claims details for allowable testing in relation to the provider's TOC. The TOCs and allowed COTs are:

- A. COC - All Tests
- B. CW - Waived Tests only
- C. COA - All Tests
- D. PPMP & Waived Tests only
- E. COR - All Tests

III. PROCESSING BACKGROUND

All HCPCS Codes (Healthcare Common Procedure Coding System Codes) have an assigned Laboratory Procedure Code by the American Medical Association (AMA). The AMA's HCPCS Code set for tests subject to CLIA Edits is in Appendix A.

The associated Laboratory Certification Codes are in Appendix B. These are offered for information purposes only and are not factored into Encounter processing.

For the most up to date listing of HCPCS Codes Subject to CLIA, as well as Provider-Performed Microscopy Procedures and other Waived Tests, please visit the CMS website - <http://www.cms.gov/>

The application a Provider sends to CMS (see Appendix C) outlines what tests they'll be performing and are seeking certification for. These align directly with the "Requirements" section on pages 2-3 of this document. The Forward Health processing system will automatically check each HCPCs Code against a a Provider's certification type for that procedure code (HCPCs or CPT).

IV. PROCESSING ERRORS

Claims will deny for CLIA reasons associated with one of two EOB's:

-EOB 0793: Denied. Provider must have a CLIA Number to bill laboratory procedures. There is no certification on file for said billing Provider.

-EOB 0794: Procedure not allowed for CLIA certification type. The Provider doesn't have the correct certification type for that Procedure Code. One possible resolution to this would be for the Provider to apply for different type of certification with CMS as it would relate to the "Requirements" section on pages 2-3. If they believe they have the correct certification on file already, it can be checked by looking at the CLIA Extract or contacting Provider Services @ (800) 947-9627.

The CLIA Extract report is an invaluable tool in resolving issues. This report maps out the NPI and associated MCD ID for each provider. This will also map out what certification type the provider has. If there is an issue, look up the provider by their NPI and MCD ID, and compare that to the associated HCPCs Procedure Code they used on the claim and as defined in this manual. If NPIs and/or MCD IDs are shared, it can not pinpoint to a specific service location as a claim looks for one based on the Taxonomy and Zip Code that was submitted.

V. ADDITIONAL INFORMATION

For more information on this topic, see the following:

-Section 14 of the Encounter User Guide: abridged and added here as Appendix D

-Offers CLIA basics and information on the CLIA Extract available on a weekly basis to Managed Care Organizations.

-Wisconsin's Department of Health Services FAQ on the topic of CLIA – Appendix E

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2014 CPT-4 and HCPCS Codes Subject to CLIA Edits

Includes non-waived and non-PPMP tests

Laboratory certification codes are for informational purposes only.

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Applicable FARS/DFARS Apply to Government Use.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
G0103		Psa, screening	310
G0123		Screen cerv/vag thin layer	630
G0124		Screen c/v thin layer by MD	630
G0141		Scr c/v cyto,autosys and md	630
G0143		Scr c/v cyto,thinlayer,rescr	630
G0144		Scr c/v cyto,thinlayer,rescr	630
G0145		Scr c/v cyto,thinlayer,rescr	630
G0147		Scr c/v cyto, automated sys	630
G0148		Scr c/v cyto, autosys, rescr	630
G0306		CBC/diffwbc w/o platelet	400
G0307		CBC without platelet	400
G0328		Fecal blood scrn immunoassay	310, 400
G0416		Sat biopsy prostate 1-20 spc	610
G0416	TC	Sat biopsy prostate 1-20 spc	610
G0416	26	Sat biopsy prostate 1-20 spc	610
G0417		Sat biopsy prostate 21-40	610
G0417	TC	Sat biopsy prostate 21-40	610
G0417	26	Sat biopsy prostate 21-40	610
G0418		Sat biopsy prostate 41-60	610
G0418	TC	Sat biopsy prostate 41-60	610
G0418	26	Sat biopsy prostate 41-60	610
G0419		Sat biopsy prostate: >60	610
G0419	TC	Sat biopsy prostate: >60	610
G0419	26	Sat biopsy prostate: >60	610
G0431		Drug screen multip class	340
G0432		EIA HIV-1/HIV-2 screen	140, 220
G0433		ELISA HIV-1/HIV-2 screen	140, 220
G0434		Drug screen multi drug class	340
G0435		Oral HIV-1/HIV-2 screen	140, 220
G0461		Immunohisto/cyto chem 1st st - Effective 1/1/2014	220, 610
G0462		Immunohisto/cyto chem add - Effective 1/1/2014	220, 610
G9143		Warfarin respon genetic test	220, 310
P3000		Screen pap by tech w md supv	630
P3001		Screening pap smear by phys	630
P7001		Culture bacterial urine	110
0103T		Holotranscobalamin, quantitative	310
0111T		Long-chain omega-3 fatty acids in red blood cell membranes	310
17311		Mohs, 1 stage, h/n/hf/g	610
17312		Mohs addl stage	610
17313		Mohs, 1 stage, t/a/l	610

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
17314		Mohs, addl stage, t/a/l	610
17315		Mohs surg, addl block	610
78110		Plasma volume, single	800
78110	TC	Plasma volume, single	800
78110	26	Plasma volume single	800
78111		Plasma volume, multiple	800
78111	TC	Plasma volume, multiple	800
78111	26	Plasma volume multiple	800
78120		Red cell mass, single	800
78120	TC	Red cell mass, single	800
78120	26	Red cell mass single	800
78121		Red cell mass, multiple	800
78121	TC	Red cell mass, multiple	800
78121	26	Red cell mass multiple	800
78122		Blood volume	800
78122	TC	Blood volume	800
78122	26	Blood volume	800
78130		Red cell survival study	800
78130	TC	Red cell survival study	800
78130	26	Red cell survival study	800
78191		Platelet survival	800
78191	TC	Platelet survival	800
78191	26	Platelet survival	800
78270		Vit B-12 absorption exam	800
78270	TC	Vit B-12 absorption exam	800
78270	26	Vit B-12 absorption exam	800
78271		Vit B-12 absorp exam, int fac	800
78271	TC	Vit B-12 absorp exam, int fac	800
78271	26	Vit b-12 absrp exam int fac	800
78272		Vit B-12 absorp, combined	800
78272	TC	Vit B-12 absorp, combined	800
78272	26	Vit b-12 absorp combined	800
80047		Basic metabolic panel (Calcium, ionized)	310
80048		Basic metabolic panel total ca	310
80050		General health panel	310, 330, 400
80051		Electrolyte panel	310
80053		Comprehen metabolic panel	310
80055		Obstetric panel	210, 220, 400, 530
80061		Lipid panel	310
80069		Renal function panel	310
80074		Acute hepatitis panel	220
80076		Hepatic function panel	310
80100		Drug screen, qualitate/multi	340
80101		Drug screen, single - Not payable by Medicare	340
80102		Drug confirmation	340
80103		Drug analysis tissue prep	340
80104		Drug scrn 1+ class nonchromo - Not payable by Medicare	340
80150		Assay of amikacin	340
80152		Assay of amitriptyline	340
80154		Assay of benzodiazepines	340
80155		Drug screen quant caffeine - Effective 1/1/2014	340
80156		Assay, carbamazepine, total	340

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
80157		Assay, carbamazepine, free	340
80158		Assay of cyclosporine	340
80159		Drug screen quant clozapine - Effective 1/1/2014	340
80160		Assay of desipramine	340
80162		Assay of digoxin	340
80164		Assay, dipropylacetic acid	340
80166		Assay of doxepin	340
80168		Assay of ethosuximide	340
80169		Drug screen quant everolimus - Effective 1/1/2014	340
80170		Assay of gentamicin	340
80171		Drug screen quant gabapentin - Effective 1/1/2014	340
80172		Assay of gold	340
80173		Assay of haloperidol	340
80174		Assay of imipramine	340
80175		Drug screen quan lamotrigine - Effective 1/1/2014	340
80176		Assay of lidocaine	340
80177		Drug scrn quan levetiracetam - Effective 1/1/2014	340
80178		Assay of lithium	340
80180		Drug scrn quan mycophenolate - Effective 1/1/2014	340
80182		Assay of nortriptyline	340
80183		Drug scrn quant oxcarbazepin - Effective 1/1/2014	340
80184		Assay of phenobarbital	340
80185		Assay of phenytoin, total	340
80186		Assay of phenytoin, free	340
80188		Assay of primidone	340
80190		Assay of procainamide	340
80192		Assay of procainamide	340
80194		Assay of quinidine	340
80195		Assay of sirolimus	340
80196		Assay of salicylate	340
80197		Assay of tacrolimus	340
80198		Assay of theophylline	340
80199		Drug screen quant tiagabine - Effective 1/1/2014	340
80200		Assay of tobramycin	340
80201		Assay of topiramate	340
80202		Assay of vancomycin	340
80203		Drug screen quant zonisamide - Effective 1/1/2014	340
80299		Quantitative assay, drug	340
80400		Acth stimulation panel	330
80402		Acth stimulation panel	330
80406		Acth stimulation panel	330
80408		Aldosterone suppression eval	330
80410		Calcitonin stimul panel	330
80412		CRH stimulation panel	330
80414		Testosterone response	330
80415		Estradiol response panel	330
80416		Renin stimulation panel	330
80417		Renin stimulation panel	330
80418		Pituitary evaluation panel	330
80420		Dexamethasone panel	330
80422		Glucagon tolerance panel	310, 330
80424		Glucagon tolerance panel	310, 330

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
80426		Gonadotropin hormone panel	330
80428		Growth hormone panel	330
80430		Growth hormone panel	310, 330
80432		Insulin suppression panel	310, 330
80434		Insulin tolerance panel	310, 330
80435		Insulin tolerance panel	310, 330
80436		Metyrapone panel	330
80438		TRH stimulation panel	330
80439		TRH stimulation panel	330
80440		TRH stimulation panel	330
81003		Urinalysis, auto, w/o scope	320
81005		Urinalysis	320
81007		Urine screen for bacteria	110
81099		Urinalysis test procedure	320
81200		Aspa gene	220, 310
81201		Apc gene full sequence	220, 310
81202		Apc gene known fam variants	220, 310
81203		Apc gene dup/delet variants	220, 310
81205		Bckdhb gene	220, 310
81206		Bcr/abl1 gene major bp	220, 310, 900
81207		Bcr/abl1 gene minor bp	220, 310, 900
81208		Bcr/abl1 gene other bp	220, 310, 900
81209		Blm gene	220, 310
81210		Braf gene	220, 310
81211		Brca1&2 seq & com dup/del	220, 310
81212		Brca1&2 185&5385&6174 var	220, 310
81213		Brca1&2 uncom dup/del var	220, 310
81214		Brca1 full seq & com dup/del	220, 310
81215		Brca1 gene known fam variant	220, 310
81216		Brca2 gene full sequence	220, 310
81217		Brca2 gene known fam variant	220, 310
81220		Cftr gene com variants	220, 310
81221		Cftr gene known fam variants	220, 310
81222		Cftr gene dup/delet variants	220, 310
81223		Cftr gene full sequence	220, 310
81224		Cftr gene intron poly t	220, 310
81225		Cyp2c19 gene com variants	220, 310
81226		Cyp2d6 gene com variants	220, 310
81227		Cyp2c9 gene com variants	220, 310
81228		Cytogen micarray copy nmbr	220, 310, 900
81229		Cytogen m array copy no&snp	220, 310, 900
81235		Egfr gene com variants	220, 310
81240		F2 gene	400
81241		F5 gene	400
81242		Fancc gene	220, 400
81243		Fmr1 gene detection	220, 900
81244		Fmr1 gene characterization	220, 900
81245		Flt3 gene	220, 310, 900
81250		G6pc gene	220, 310
81251		Gba gene	220, 310
81252		Gjb2 gene full sequence	220, 310
81253		Gjb2 gene known fam variants	220, 310

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
81254		Gjb6 gene com variants	220, 310
81255		Hexa gene	220, 310
81256		Hfe gene	310, 400
81257		Hba1/hba2 gene	310, 400
81260		Ikbkap gene	310
81261		Igh gene rearrange amp meth	220, 310, 900
81262		Igh gene rearrang dir probe	220, 310, 900
81263		Igh vari regional mutation	220, 310, 900
81264		Igk rearrangeabn clonal pop	220, 310, 900
81265		Str markers specimen anal	010, 220
81266		Str markers spec anal addl	010, 220
81267		Chimerism anal no cell selec	010, 220
81268		Chimerism anal w/cell select	010, 220
81270		Jak2 gene	220, 310, 900
81275		Kras gene	220, 310, 900
81280		Long qt synd gene full seq	220, 310
81281		Long qt synd known fam var	220, 310
81282		Long qt syn gene dup/dlt var	220, 310
81287		Mgmt gene methylation anal - Effective 1/1/2014	220, 310
81290		Mcoln1 gene	220, 310
81291		Mthfr gene	400
81292		Mlh1 gene full seq	220, 310
81293		Mlh1 gene known variants	220, 310
81294		Mlh1 gene dup/delete variant	220, 310
81295		Msh2 gene full seq	220, 310
81296		Msh2 gene known variants	220, 310
81297		Msh2 gene dup/delete variant	220, 310
81298		Msh6 gene full seq	220, 310
81299		Msh6 gene known variants	220, 310
81300		Msh6 gene dup/delete variant	220, 310
81301		Microsatellite instability	220, 310
81302		Mecp2 gene full seq	220, 310
81303		Mecp2 gene known variant	220, 310
81304		Mecp2 gene dup/delet variant	220, 310
81310		Npm1 gene	220, 310, 900
81315		Pml/raralpha com breakpoints	220, 310, 900
81316		Pml/raralpha 1 breakpoint	220, 310, 900
81317		Pms2 gene full seq analysis	220, 310, 900
81318		Pms2 known familial variants	220, 310, 900
81319		Pms2 gene dup/delet variants	220, 310, 900
81321		Pten gene full sequence	220, 310
81322		Pten gene known fam variant	220, 310
81323		Pten gene dup/delet variant	220, 310
81324		Pmp22 gene dup/delet	220, 310
81325		Pmp22 gene full sequence	220, 310
81326		Pmp22 gene known fam variant	220, 310
81330		Smpd1 gene common variants	220, 310
81331		Snrpn/ube3a gene	220, 310
81332		Serpina1 gene	220, 310
81340		Trb@ gene rearrange amplify	220, 310, 900
81341		Trb@ gene rearrange dirprobe	220, 310, 900
81342		Trg gene rearrangement anal	220, 310, 900

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
81350		Ugt1a1 gene	220, 310
81355		Vkorc1 gene	220, 400
81370		Hla i & ii typing lr	010
81371		Hla i & ii type verify lr	010
81372		Hla i typing complete lr	010
81373		Hla i typing 1 locus lr	010
81374		Hla i typing 1 antigen lr	010
81375		Hla ii typing ag equiv lr	010
81376		Hla ii typing 1 locus lr	010
81377		Hla ii type 1 ag equiv lr	010
81378		Hla i & ii typing hr	010
81379		Hla i typing complete hr	010
81380		Hla i typing 1 locus hr	010
81381		Hla i typing 1 allele hr	010
81382		Hla ii typing 1 loc hr	010
81383		Hla ii typing 1 allele hr	010
81400		Mopath procedure level 1	610
81401		Mopath procedure level 2	610
81402		Mopath procedure level 3	610
81403		Mopath procedure level 4	610
81404		Mopath procedure level 5	610
81405		Mopath procedure level 6	610
81406		Mopath procedure level 7	610
81407		Mopath procedure level 8	610
81408		Mopath procedure level 9	610
81479		Unlisted molecular pathology	010, 220, 310, 610
81500		Onco (ovar) two proteins - Not payable by Medicare	310
81503		Onco (ovar) five proteins - Not payable by Medicare	310
81504		Oncology tissue of origin - Effective 1/1/2014	220, 310
81506		Endo assay seven anal - Not payable by Medicare	220, 310, 330
81507		Fetal aneuploidy trisom risk - Effective 1/1/2014	220, 900
81508		Ftl cgen abnor two proteins - Not payable by Medicare	310, 330
81509		Ftl cgen abnor 3 proteins - Not payable by Medicare	310, 330
81510		Ftl cgen abnor three anal - Not payable by Medicare	220, 310, 330
81511		Ftl cgen abnor four anal - Not payable by Medicare	220, 310, 330
81512		Ftl cgen abnor five anal - Not payable by Medicare	220, 310, 330
81599		Unlisted maaa - Not payable by Medicare	220, 310, 330
82000		Assay of blood acetaldehyde	340
82003		Assay of acetaminophen	340
82009		Test for acetone/ketones	310
82010		Acetone assay	310
82013		Acetylcholinesterase assay	310
82016		Acylcarnitines, qual	310
82017		Acylcarnitines, quant	310
82024		Assay of acth	330
82030		Assay of adp & amp	310, 330
82040		Assay of serum albumin	310
82042		Assay of urine albumin	310
82043		Microalbumin, quantitative	310
82044		Microalbumin, semiquant	310
82045		Albumin, ischemia modified	310
82055		Assay of ethanol	340

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
82085		Assay of aldolase	310
82088		Assay of aldosterone	330
82101		Assay of urine alkaloids	340
82103		Alpha-1-antitrypsin, total	220
82104		Alpha-1-antitrypsin, pheno	220
82105		Alpha-fetoprotein, serum	220, 310
82106		Alpha-fetoprotein, amniotic	220, 310
82107		Alpha-fetoprotein I3	220, 310
82108		Assay of aluminum	340
82120		Amines, vaginal fluid qual	310
82127		Amino acid, single qual	310
82128		Amino acids, mult qual	310
82131		Amino acids, single quant	310
82135		Assay, aminolevulinic acid	330, 340
82136		Amino acids, quant, 2-5	310
82139		Amino acids, quan, 6 or more	310
82140		Assay of ammonia	310
82143		Amniotic fluid scan	310
82145		Assay of amphetamines	340
82150		Assay of amylase	310
82154		Androstanediol glucuronide	330
82157		Assay of androstenedione	330
82160		Assay of androsterone	330
82163		Assay of angiotensin II	330
82164		Angiotensin I enzyme test	310
82172		Assay of apolipoprotein	310
82175		Assay of arsenic	340
82180		Assay of ascorbic acid	310
82190		Atomic absorption	310, 340
82205		Assay of barbiturates	340
82232		Assay of beta-2 protein	220
82239		Bile acids, total	310
82240		Bile acids, cholyglycine	310
82247		Bilirubin, total	310
82248		Bilirubin, direct	310
82252		Fecal bilirubin test	310
82261		Assay of biotinidase	310
82271		Test for blood, other source	310
82274		Assay test for blood, fecal	310, 400
82286		Assay of bradykinin	310
82300		Assay of cadmium	340
82306		Assay of vitamin D	310
82308		Assay of calcitonin	330
82310		Assay of calcium	310
82330		Assay of calcium	310
82331		Calcium infusion test	310
82340		Assay of calcium in urine	310
82355		Calculus analysis, qual	310
82360		Calculus assay, quant	310
82365		Calculus spectroscopy	310
82370		X-ray assay, calculus	310
82373		Assay, c-d transfer measure	310

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
82374		Assay, blood carbon dioxide	310
82375		Assay, blood carbon monoxide	340
82376		Test for carbon monoxide	340
82378		Carcinoembryonic antigen	310
82379		Assay of carnitine	310
82380		Assay of carotene	310
82382		Assay, urine catecholamines	330
82383		Assay, blood catecholamines	330
82384		Assay, three catecholamines	330
82387		Assay of cathepsin-d	330
82390		Assay of ceruloplasmin	310
82397		Chemiluminescent assay	310, 330, 340
82415		Assay of chloramphenicol	340
82435		Assay of blood chloride	310
82436		Assay of urine chloride	310
82438		Assay, other fluid chlorides	310
82441		Test for chlorohydrocarbons	340
82465		Assay, bld/serum cholesterol	310
82480		Assay, serum cholinesterase	310
82482		Assay, rbc cholinesterase	310
82485		Assay, chondroitin sulfate	310
82486		Gas/liquid chromatography	310, 330, 340
82487		Paper chromatography	310, 330, 340
82488		Paper chromatography	310, 330, 340
82489		Thin layer chromatography	310, 330, 340
82491		Chromotography, quant, sing	310, 330, 340
82492		Chromotography, quant, mult	310, 330, 340
82495		Assay of chromium	340
82507		Assay of citrate	310
82520		Assay of cocaine	340
82523		Collagen crosslinks	310, 330
82525		Assay of copper	340
82528		Assay of corticosterone	330
82530		Cortisol, free	330
82533		Total cortisol	330
82540		Assay of creatine	310
82541		Column chromatography, qual	310, 330, 340
82542		Column chromatography, quant	310, 330, 340
82543		Column chromatograph/isotope	310, 330, 340
82544		Column chromatograph/isotope	310, 330, 340
82550		Assay of ck (cpk)	310
82552		Assay of cpk in blood	310
82553		Creatine, MB fraction	310
82554		Creatine, isoforms	310
82565		Assay of creatinine	310
82570		Assay of urine creatinine	310
82575		Creatinine clearance test	310
82585		Assay of cryofibrinogen	400
82595		Assay of cryoglobulin	310
82600		Assay of cyanide	340
82607		Vitamin B-12	310
82608		B-12 binding capacity	310

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
82610		Cystatin C	310
82615		Test for urine cystines	310
82626		Dehydroepiandrosterone	330
82627		Dehydroepiandrosterone	330
82633		Desoxycorticosterone	330
82634		Deoxycortisol	330
82638		Assay of dibucaine number	310
82646		Assay of dihydrocodeinone	340
82649		Assay of dihydromorphinone	340
82651		Assay of dihydrotestosterone	330
82652		Assay of dihydroxyvitamin d	310
82654		Assay of dimethadione	340
82656		Pancreatic elastase, fecal	310
82657		Enzyme cell activity	310
82658		Enzyme cell activity, ra	310
82664		Electrophoretic test	330, 340
82666		Assay of epiandrosterone	330
82668		Assay of erythropoietin	330
82670		Assay of estradiol	330
82671		Assay of estrogens	330
82672		Assay of estrogen	330
82677		Assay of estriol	330
82679		Assay of estrone	330
82690		Assay of ethchlorvynol	340
82693		Assay of ethylene glycol	340
82696		Assay of etiocholanolone	330
82705		Fats/lipids, feces, qual	310
82710		Fats/lipids, feces, quant	310
82715		Assay of fecal fat	310
82725		Assay of blood fatty acids	310
82726		Long chain fatty acids	310
82728		Assay of ferritin	310
82731		Assay of fetal fibronectin	310
82735		Assay of fluoride	340
82742		Assay of flurazepam	340
82746		Blood folic acid serum	310
82747		Assay of folic acid, rbc	310
82757		Assay of semen fructose	310
82759		Assay of rbc galactokinase	310
82760		Assay of galactose	310
82775		Assay galactose transferase	310
82776		Galactose transferase test	310
82777		Galectin 3	310
82784		Assay of gammaglobulin igm	220
82785		Assay of gammaglobulin ige	220
82787		Igg 1, 2, 3 or 4, each	220
82800		Blood pH	310
82803		Blood gases: pH, pO2 & pCO2	310
82805		Blood gases w/O2 saturation	310
82810		Blood gases, O2 sat only	310
82820		Hemoglobin-oxygen affinity	310
82930		Gastric analy w/ph ea spec	310

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
82938		Gastrin test	330
82941		Assay of gastrin	330
82943		Assay of glucagon	310, 330
82945		Glucose other fluid	310
82946		Glucagon tolerance test	310, 330
82947		Assay, glucose, blood quant	310
82948		Reagent strip/blood glucose	310
82950		Glucose test	310
82951		Glucose tolerance test (GTT)	310
82952		GTT-added samples	310
82953		Glucose-tolbutamide test	310
82955		Assay of g6pd enzyme	310
82960		Test for G6PD enzyme	310
82963		Assay of glucosidase	310
82965		Assay of gdh enzyme	310
82975		Assay of glutamine	310
82977		Assay of GGT	310
82978		Assay of glutathione	310
82979		Assay, rbc glutathione	310
82980		Assay of glutethimide	340
82985		Glycated protein	310
83001		Gonadotropin (FSH)	330
83002		Gonadotropin (LH)	330
83003		Assay, growth hormone (hgh)	330
83008		Assay of guanosine	310
83009		H pylori (c-13), blood	110
83010		Assay of haptoglobin, quant	310
83012		Assay of haptoglobins	310
83015		Heavy metal screen	340
83018		Quantitative screen, metals	340
83020		Hemoglobin electrophoresis	310, 400
83020	26	Hemoglobin electrophoresis	310, 400
83021		Hemoglobin chromatography	310, 400
83030		Fetal hemoglobin, chemical	310, 400
83033		Fetal hemoglobin assay, qual	310, 400
83036		Glycated hemoglobin test	310, 400
83045		Blood methemoglobin test	310, 400
83050		Blood methemoglobin assay	310, 400
83051		Assay of plasma hemoglobin	310, 400
83055		Blood sulfhemoglobin test	310, 400
83060		Blood sulfhemoglobin assay	310, 400
83065		Assay of hemoglobin heat	310, 400
83068		Hemoglobin stability screen	310, 400
83069		Assay of urine hemoglobin	320
83070		Assay of hemosiderin, qual	320, 400
83071		Assay of hemosiderin, quant	310
83080		Assay of b hexosaminidase	310
83088		Assay of histamine	340
83090		Assay of homocystine	310
83150		Assay of for hva	330
83491		Assay of corticosteroids	330
83497		Assay of 5-hiaa	330

HPCPS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
83498		Assay of progesterone	330
83499		Assay of progesterone	330
83500		Assay, free hydroxyproline	310, 330
83505		Assay, total hydroxyproline	310, 330
83516		Immunoassay, nonantibody	310, 330, 340
83518		Immunoassay, dipstick	310, 330, 340
83519		Immunoassay, nonantibody	220, 310, 330, 340
83520		Immunoassay, RIA	220, 310, 330, 340
83525		Assay of insulin	330
83527		Assay of insulin	330
83528		Assay of intrinsic factor	310
83540		Assay of iron	310
83550		Iron binding test	310
83570		Assay of idh enzyme	310
83582		Assay of ketogenic steroids	330
83586		Assay 17- ketosteroids	330
83593		Fractionation, ketosteroids	330
83605		Assay of lactic acid	310
83615		Lactate (LD) (LDH) enzyme	310
83625		Assay of Idh enzymes	310
83630		Lactoferrin, fecal (qual)	310
83631		Lactoferrin, fecal (quant)	310
83632		Placental lactogen	330
83633		Test urine for lactose	310
83634		Assay of urine for lactose	310
83655		Assay of lead	340
83661		L/s ratio, fetal lung	310
83662		Foam stability, fetal lung	310
83663		Fluoro polarize, fetal lung	310
83664		Lamellar bdy, fetal lung	310
83670		Assay of lap enzyme	310
83690		Assay of lipase	310
83695		Lipoprotein (a)	310
83698		Assay lipoprotein pla2	310
83700		Lipopro bld, electrophoretic	310
83701		Lipoprotein bld, hr fraction	310
83704		Lipoprotein bld, by nmr	310
83718		Assay of lipoprotein	310
83719		Assay of blood lipoprotein	310
83721		Assay of blood lipoprotein	310
83727		Assay of lrh hormone	330
83735		Assay of magnesium	310
83775		Assay of md enzyme	310
83785		Assay of manganese	310
83788		Mass spectrometry qual	310, 330, 340
83789		Mass spectrometry quant	310, 330, 340
83805		Assay of meprobamate	340
83825		Assay of mercury	340
83835		Assay of metanephrines	330
83840		Assay of methadone	340
83857		Assay of methemalbumin	310
83858		Assay of methsuximide	340

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
83861		Microfluid analy tears	310
83864		Mucopolysaccharides	310
83866		Mucopolysaccharides screen	310
83872		Assay synovial fluid mucin	310
83873		Assay of csf protein	310
83874		Assay of myoglobin	310
83876		Myeloperoxidase	310
83880		Natriuretic peptide	310
83883		Assay, nephelometry not spec	220, 310
83885		Assay of nickel	340
83887		Assay of nicotine	340
83915		Assay of nucleotidase	310
83916		Oligoclonal bands	220, 310
83918		Organic acids, total, quant	340
83919		Organic acids, qual, each	310, 340
83921		Organic acid, single, quant	340
83925		Assay of opiates	340
83930		Assay of blood osmolality	310
83935		Assay of urine osmolality	310
83937		Assay of osteocalcin	310
83945		Assay of oxalate	310
83950		Oncoprotein, her-2/neu	310
83951		Oncoprotein, dcp	310
83970		Assay of parathormone	330
83986		Assay of body fluid acidity	310
83992		Assay for phencyclidine	340
83993		Calprotectin, fecal	310
84022		Assay of phenothiazine	340
84030		Assay of blood pku	310
84035		Assay of phenylketones	310
84060		Assay acid phosphatase	310
84066		Assay prostate phosphatase	310
84075		Assay alkaline phosphatase	310
84078		Assay alkaline phosphatase	310
84080		Assay alkaline phosphatases	310
84081		Amniotic fluid enzyme test	310
84085		Assay of rbc pg6d enzyme	310
84087		Assay phosphohexose enzymes	310
84100		Assay of phosphorus	310
84105		Assay of urine phosphorus	310
84106		Test for porphobilinogen	310
84110		Assay of porphobilinogen	310
84112		Placenta alpha micro ig c/v	310
84119		Test urine for porphyrins	310
84120		Assay of urine porphyrins	310
84126		Assay of feces porphyrins	310
84127		Assay of feces porphyrins	310
84132		Assay of serum potassium	310
84133		Assay of urine potassium	310
84134		Assay of prealbumin	310
84135		Assay of pregnanediol	330
84138		Assay of pregnanetriol	330

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
84140		Assay of pregnenolone	330
84143		Assay of 17-hydroxypregнено	330
84144		Assay of progesterone	330
84145		Procalcitonin (pct)	330
84146		Assay of prolactin	330
84150		Assay of prostaglandin	310
84152		Assay of psa, complexed	310
84153		Assay of psa, total	310
84154		Assay of psa, free	310
84155		Assay of protein, serum	310
84156		Assay of protein, urine	310
84157		Assay of protein, other	310
84160		Assay of protein, any source	310
84163		Pappa, serum	310
84165		Protein electrophoresis, serum	310
84165	26	Protein electrophoresis, serum	310
84166		Protein electrophoresis, urine/csf	310
84166	26	Protein electrophoresis, urine, csf	310
84181		Western blot test	220
84181	26	Western blot test	220
84182		Protein, western blot test	220
84182	26	Protein, western blot test	220
84202		Assay RBC protoporphyrin	310
84203		Test RBC protoporphyrin	310
84206		Assay of proinsulin	330
84207		Assay of vitamin b-6	310
84210		Assay of pyruvate	310
84220		Assay of pyruvate kinase	310
84228		Assay of quinine	340
84233		Assay of estrogen	330
84234		Assay of progesterone	330
84235		Assay of endocrine hormone	330
84238		Assay, nonendocrine receptor	220, 330
84244		Assay of renin	330
84252		Assay of vitamin b-2	310
84255		Assay of selenium	340
84260		Assay of serotonin	310, 330
84270		Assay of sex hormone globul	330
84275		Assay of sialic acid	310
84285		Assay of silica	340
84295		Assay of serum sodium	310
84300		Assay of urine sodium	310
84302		Assay of sweat sodium	310
84305		Assay of somatomedin	330
84307		Assay of somatostatin	330
84311		Spectrophotometry	140, 220, 310, 400
84315		Body fluid specific gravity	310
84375		Chromatogram assay, sugars	310
84376		Sugars, single, qual	310
84377		Sugars, multiple, qual	310
84378		Sugars single quant	310
84379		Sugars multiple quant	310

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
84392		Assay of urine sulfate	310
84402		Assay of testosterone	330
84403		Assay of total testosterone	330
84425		Assay of vitamin b-1	310
84430		Assay of thiocyanate	340
84431		Thromboxane, urine	310
84432		Assay of thyroglobulin	310
84436		Assay of total thyroxine	330
84437		Assay of neonatal thyroxine	330
84439		Assay of free thyroxine	330
84442		Assay of thyroid activity	330
84443		Assay thyroid stim hormone	330
84445		Assay of tsi	330
84446		Assay of vitamin e	310
84449		Assay of transcortin	310
84450		Transferase (AST) (SGOT)	310
84460		Alanine amino (ALT) (SGPT)	310
84466		Assay of transferrin	310
84478		Assay of triglycerides	310
84479		Assay of thyroid (t3 or t4)	330
84480		Assay, triiodothyronine (t3)	330
84481		Free assay (FT-3)	330
84482		Reverse assay (t3)	330
84484		Assay of troponin, quant	310
84485		Assay duodenal fluid trypsin	310
84488		Test feces for trypsin	310
84490		Assay of feces for trypsin	310
84510		Assay of tyrosine	310
84512		Assay of troponin, qual	310
84520		Assay of urea nitrogen	310
84525		Urea nitrogen semi-quant	310
84540		Assay of urine/urea-n	310
84545		Urea-N clearance test	310
84550		Assay of blood/uric acid	310
84560		Assay of urine/uric acid	310
84577		Assay of feces/urobilinogen	310
84578		Test urine urobilinogen	320
84580		Assay of urine urobilinogen	310
84583		Assay of urine urobilinogen	320
84585		Assay of urine vma	330
84586		Assay of vip	330
84588		Assay of vasopressin	330
84590		Assay of vitamin a	310
84591		Assay of nos vitamin	310
84597		Assay of vitamin k	310
84600		Assay of volatiles	340
84620		Xylose tolerance test	310
84630		Assay of zinc	310
84681		Assay of c-peptide	310
84702		Chorionic gonadotropin test	330
84703		Chorionic gonadotropin assay	330
84704		hCG, free beta chain test	330

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
84999		Clinical chemistry test	310, 330, 340
85002		Bleeding time test	400
85004		Automated diff WBC count	400
85007		BI smear w/diff WBC count	400
85008		BI smear w/o diff WBC count	400
85009		Manual diff WBC count b-coat	400
85014		Hematocrit	400
85018		Hemoglobin	400
85025		Complete CBC w/auto diff WBC	400
85027		Complete CBC, automated	400
85032		Manual cell count, each	400
85041		Automated RBC count	400
85044		Manual reticulocyte count	400
85045		Automated reticulocyte count	400
85046		Reticyte/hgb concentrate	400
85048		Automated leukocyte count	400
85049		Automated platelet count	400
85055		Reticulated platelet assay	400
85060		Blood smear interpretation	400, 610
85097		Bone marrow interpretation	400, 610
85130		Chromogenic substrate assay	400
85170		Blood clot retraction	400
85175		Blood clot lysis time	400
85210		Blood clot factor II test	400
85220		Blood clot factor V test	400
85230		Blood clot factor VII test	400
85240		Blood clot factor VIII test	400
85244		Blood clot factor VIII test	400
85245		Blood clot factor VIII test	400
85246		Blood clot factor VIII test	400
85247		Blood clot factor VIII test	400
85250		Blood clot factor IX test	400
85260		Blood clot factor X test	400
85270		Blood clot factor XI test	400
85280		Blood clot factor XII test	400
85290		Blood clot factor XIII test	400
85291		Blood clot factor XIII test	400
85292		Blood clot factor assay	400
85293		Blood clot factor assay	400
85300		Antithrombin III test	400
85301		Antithrombin III test	400
85302		Blood clot inhibitor antigen	400
85303		Blood clot inhibitor test	400
85305		Blood clot inhibitor assay	400
85306		Blood clot inhibitor test	400
85307		Assay activated protein c	400
85335		Factor inhibitor test	400
85337		Thrombomodulin	400
85345		Coagulation time	400
85347		Coagulation time	400
85348		Coagulation time	400
85360		Euglobulin lysis	400

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
85362		Fibrin degradation products	400
85366		Fibrinogen test	400
85370		Fibrinogen test	400
85378		Fibrin degrade, semiquant	400
85379		Fibrin degradation, quant	400
85380		Fibrin degradation, vte	400
85384		Fibrinogen	400
85385		Fibrinogen	400
85390		Fibrinolysins screen	400
85390	26	Fibrinolysins screen	400
85396		Clotting assay, whole blood	400
85397		Clotting funct activity	400
85400		Fibrinolytic plasmin	400
85410		Fibrinolytic antiplasmin	400
85415		Fibrinolytic plasminogen	400
85420		Fibrinolytic plasminogen	400
85421		Fibrinolytic plasminogen	400
85441		Heinz bodies, direct	400
85445		Heinz bodies, induced	400
85460		Hemoglobin, fetal	400
85461		Hemoglobin, fetal	400
85475		Hemolysin	220
85520		Heparin assay	400
85525		Heparin neutralization	400
85530		Heparin-protamine tolerance	400
85536		Iron stain peripheral blood	400
85540		Wbc alkaline phosphatase	400
85547		RBC mechanical fragility	400
85549		Muramidase	310
85555		RBC osmotic fragility	400
85557		RBC osmotic fragility	400
85576		Blood platelet aggregation	400
85576	26	Blood platelet aggregation	400
85597		Platelet neutralization	400
85598		Hexagonal phosph pltit neutrl	220, 400
85610		Prothrombin time	400
85611		Prothrombin test	400
85612		Viper venom prothrombin time	400
85613		Russell viper venom, diluted	400
85635		Reptilase test	400
85652		Rbc sed rate, automated	400
85660		RBC sickle cell test	400
85670		Thrombin time, plasma	400
85675		Thrombin time, titer	400
85705		Thromboplastin inhibition	400
85730		Thromboplastin time, partial	400
85732		Thromboplastin time, partial	400
85810		Blood viscosity examination	310, 400
85999		Hematology procedure	400
86000		Agglutinins, febrile	220
86001		Allergen specific IgG	220
86003		Allergen specific IgE	220

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
86005		Allergen specific IgE	220
86021		WBC antibody identification	010
86022		Platelet antibodies	220
86023		Immunoglobulin assay	220, 520, 530
86038		Antinuclear antibodies	220
86039		Antinuclear antibodies (ANA)	220
86060		Antistreptolysin o, titer	220
86063		Antistreptolysin o, screen	220
86140		C-reactive protein	220
86141		C-reactive protein, hs	220
86146		Glycoprotein antibody	220
86147		Cardiolipin antibody	210
86148		Phospholipid antibody	220
86152		Cell enumeration & id	220, 400, 610
86153		Cell enumeration phys interp	220, 400, 610
86153	26	Cell enumeration phys interp	220, 400, 610
86155		Chemotaxis assay	220
86156		Cold agglutinin, screen	220
86157		Cold agglutinin, titer	220
86160		Complement, antigen	220
86161		Complement/function activity	220
86162		Complement, total (CH50)	220
86171		Complement fixation, each	220
86185		Counterimmunoelectrophoresis	220
86200		CCP antibody	220
86215		Deoxyribonuclease, antibody	220
86225		DNA antibody	220
86226		DNA antibody, single strand	220
86235		Nuclear antigen antibody	220
86243		Fc receptor	220
86255		Fluorescent antibody, screen	220
86255	26	Fluorescent antibody, screen	220
86256		Fluorescent antibody, titer	220
86256	26	Fluorescent antibody, titer	220
86277		Growth hormone antibody	220
86280		Hemagglutination inhibition	220
86294		Immunoassay, tumor, qual	220, 310
86300		Immunoassay, tumor, ca 15-3	220, 310
86301		Immunoassay, tumor, ca 19-9	220, 310
86304		Immunoassay, tumor, ca 125	220, 310
86305		Human epididymis protein 4	210, 310
86308		Heterophile antibodies	220
86309		Heterophile antibodies	220
86310		Heterophile antibodies	220
86316		Immunoassay, tumor other	220, 310
86317		Immunoassay,infectious agent	220
86318		Immunoassay,infectious agent	220
86320		Serum immunoelectrophoresis	220
86320	26	Serum immunoelectrophoresis	220
86325		Other immunoelectrophoresis	220
86325	26	Other immunoelectrophoresis	220
86327		Immunoelectrophoresis assay	220

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
86327	26	Immunoelectrophoresis assay	220
86329		Immunodiffusion	220
86331		Immunodiffusion ouchterlony	220
86332		Immune complex assay	220
86334		Immunofixation e-phoresis, serum	220
86334	26	Immunofixation e-phoresis, serum	220
86335		Immunofixation e-phoresis/urine/csf	220
86335	26	Immunofixation e-phoresis/urine/csf	220
86336		Inhibin A	220, 330
86337		Insulin antibodies	220
86340		Intrinsic factor antibody	220
86341		Islet cell antibody	220
86343		Leukocyte histamine release	220
86344		Leukocyte phagocytosis	220
86352		Cell function assay w/stim	220
86353		Lymphocyte transformation	010, 220
86355		B cells, total count	220
86356		Mononuclear cell antigen	220
86357		Nk cells, total count	220
86359		T cells, total count	220
86360		T cell, absolute count/ratio	220
86361		T cell, absolute count	220
86367		Stem cells, total count	220
86376		Microsomal antibody	220
86378		Migration inhibitory factor	220
86382		Neutralization test, viral	220
86384		Nitroblue tetrazolium dye	220
86386		Nuclear matrix protein 22	220, 310
86403		Particle agglutination test	220
86406		Particle agglutination test	220
86430		Rheumatoid factor test	220
86431		Rheumatoid factor, quant	220
86480		Tb test, cell immun measure	220
86481		Tb ag response t-cell susp	220
86590		Streptokinase, antibody	220
86592		Blood serology, qualitative	210
86593		Blood serology, quantitative	210
86602		Antinomyces antibody	220
86603		Adenovirus antibody	220
86606		Aspergillus antibody	220
86609		Bacterium antibody	220
86611		Bartonella antibody	220
86612		Blastomyces antibody	220
86615		Bordetella antibody	220
86617		Lyme disease antibody	220
86618		Lyme disease antibody	220
86619		Borrelia antibody	220
86622		Brucella antibody	220
86625		Campylobacter antibody	220
86628		Candida antibody	220
86631		Chlamydia antibody	220
86632		Chlamydia igm antibody	220

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
86635		Coccidioides antibody	220
86638		Q fever antibody	220
86641		Cryptococcus antibody	220
86644		CMV antibody	220
86645		CMV antibody, IgM	220
86648		Diphtheria antibody	220
86651		Encephalitis antibody	220
86652		Encephalitis antibody	220
86653		Encephalitis antibody	220
86654		Encephalitis antibody	220
86658		Enterovirus antibody	220
86663		Epstein-barr antibody	220
86664		Epstein-barr antibody	220
86665		Epstein-barr antibody	220
86666		Ehrlichia antibody	220
86668		Francisella tularensis	220
86671		Fungus antibody	220
86674		Giardia lamblia antibody	220
86677		Helicobacter pylori	220
86682		Helminth antibody	220
86684		Hemophilus influenza	220
86687		Htlv-i antibody	220
86688		Htlv-ii antibody	220
86689		HTLV/HIV confirmatory test	220
86692		Hepatitis, delta agent	220
86694		Herpes simplex test	220
86695		Herpes simplex test	220
86696		Herpes simplex type 2	220
86698		Histoplasma	220
86701		HIV-1	220
86702		HIV-2	220
86703		HIV-1/HIV-2, single assay	220
86704		Hep b core antibody, total	220
86705		Hep b core antibody, igm	220
86706		Hep b surface antibody	220
86707		Hep be antibody	220
86708		Hep a antibody, total	220
86709		Hep a antibody, igm	220
86710		Influenza virus antibody	220
86711		John cunningham antibody	220
86713		Legionella antibody	220
86717		Leishmania antibody	220
86720		Leptospira antibody	220
86723		Listeria monocytogenes ab	220
86727		Lymph choriomeningitis ab	220
86729		Lympho venereum antibody	220
86732		Mucormycosis antibody	220
86735		Mumps antibody	220
86738		Mycoplasma antibody	220
86741		Neisseria meningitidis	220
86744		Nocardia antibody	220
86747		Parvovirus antibody	220

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
86750		Malaria antibody	220
86753		Protozoa antibody nos	220
86756		Respiratory virus antibody	220
86757		Rickettsia antibody	220
86759		Rotavirus antibody	220
86762		Rubella antibody	220
86765		Rubeola antibody	220
86768		Salmonella antibody	220
86771		Shigella antibody	220
86774		Tetanus antibody	220
86777		Toxoplasma antibody	220
86778		Toxoplasma antibody, igm	220
86780		Treponema pallidum	210
86784		Trichinella antibody	220
86787		Varicella-zoster antibody	220
86788		West nile virus ab, igm	220
86789		West nile virus antibody	220
86790		Virus antibody nos	220
86793		Yersinia antibody	220
86800		Thyroglobulin antibody	220
86803		Hepatitis c ab test	220
86804		Hep c ab test, confirm	220
86805		Lymphocytotoxicity assay	010
86806		Lymphocytotoxicity assay	010
86807		Cytotoxic antibody screening	010
86808		Cytotoxic antibody screening	010
86812		HLA typing, A, B, or C	010
86813		HLA typing, A, B, or C	010
86816		HLA typing, DR/DQ	010
86817		HLA typing, DR/DQ	010
86821		Lymphocyte culture, mixed	010
86822		Lymphocyte culture, primed	010
86825		Hla x-match, non-cytotoxic	010
86826		Hla x-match, non-cyt add-on	010
86828		Hla class i&ii antibody qual	010
86829		Hla class i/ii antibody qual	010
86830		Hla class i phenotype qual	010
86831		Hla class ii phenotype qual	010
86832		Hla class i high defin qual	010
86833		Hla class ii high defin qual	010
86834		Hla class i semiquant panel	010
86835		Hla class ii semiquant panel	010
86849		Immunology procedure	220
86850		RBC antibody screen	520, 530
86860		RBC antibody elution	540
86870		RBC antibody identification	540
86880		Coombs test, direct	520, 530
86885		Coombs test, indirect, qual	520, 530
86886		Coombs test, indirect, titer	520, 530
86890		Autologous blood process	510, 530
86900		Blood typing, ABO	510
86901		Blood typing, Rh (D)	510

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
86902		Blood type antigen donor ea	550
86904		Blood typing, patient serum	550
86905		Blood typing, RBC antigens	550
86906		Blood typing, Rh phenotype	510
86920		Compatibility test, spin	550
86921		Compatibility test, incubate	550
86922		Compatibility test, antiglob	550
86940		Hemolysins/agglutinins, auto	540
86941		Hemolysins/agglutinins	540
86970		RBC pretreatment	520, 530, 540, 550
86971		RBC pretreatment	520, 530, 540, 550
86972		RBC pretreatment	520, 530, 540, 550
86975		RBC pretreatment, serum	540
86976		RBC pretreatment, serum	540
86977		RBC pretreatment, serum	540
86978		RBC pretreatment, serum	540
87001		Small animal inoculation	110, 140, 150
87003		Small animal inoculation	110, 140, 150
87015		Specimen concentration	115, 130
87040		Blood culture for bacteria	110
87045		Feces culture, bacteria	110
87046		Stool cultr, bacteria, each	110
87070		Culture, bacteria, other	110
87071		Culture bacteri aerobic othr	110
87073		Culture bacteria anaerobic	110
87075		Culture bacteria,except blood	110
87076		Culture anaerobe ident, each	110
87077		Culture aerobic identify	110
87081		Culture screen only	110
87084		Culture of specimen by kit	110
87086		Urine culture/colony count	110
87088		Urine bacteria culture	110
87101		Skin fungi culture	120
87102		Fungus isolation culture	120
87103		Blood fungus culture	120
87106		Fungi identification, yeast	120
87107		Fungi identification, mold	120
87109		Mycoplasma	110
87110		Chlamydia culture	110
87116		Mycobacteria culture	115
87118		Mycobacteric identification	115
87140		Culture type immunofluoresc	110, 120, 140
87143		Culture typing, glc/hplc	110, 115, 120
87147		Culture type, immunologic	110, 120, 140
87149		Culture type, nucleic acid	110, 115
87150		Dna/rna, amplified probe	110, 115, 120, 140
87152		Culture type pulse field gel	110, 115
87153		Dna/rna sequencing	110, 115, 120, 140
87158		Culture typing, added method	110, 115
87164		Dark field examination	110, 210
87164	26	Dark field examination	110, 210
87166		Dark field examination	110, 210

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
87168		Macroscopic exam arthropod	130
87169		Macacrosopic exam parasite	130
87172		Pinworm exam	130
87176		Tissue homogenization, cultr	150
87177		Ova and parasites smears	130
87181		Microbe susceptible, diffuse	110, 115, 120
87184		Microbe susceptible, disk	110, 115, 120
87185		Microbe susceptible, enzyme	110
87186		Microbe susceptible, mic	110, 115, 120
87187		Microbe susceptible, mlc	110, 120
87188		Microbe suscept, macrobroth	110, 115, 120
87190		Microbe suscept, mycobacteri	115
87197		Bactericidal level, serum	110
87205		Smear, gram stain	110, 120
87206		Smear, fluorescent/acid stai	110, 115, 120, 130,140
87207		Smear, special stain	130, 140
87207	26	Smear, special stain	130, 140
87209		Smear, complex stain	130
87210		Smear, wet mount, saline/ink	110, 120, 130
87220		Tissue exam for fungi	120, 130
87230		Assay, toxin or antitoxin	110
87250		Virus inoculate, eggs/animal	140
87252		Virus inoculation, tissue	140
87253		Virus inoculate tissue, addl	140
87254		Virus inoculation, shell via	140
87255		Genet virus isolate, HSV	140
87260		Adenovirus ag, if	140
87265		Pertussis ag, if	110
87267		Enterovirus antibody, DFA	220
87269		Giardia ag, if	130
87270		Chlamydia trachomatis ag, if	110
87271		Cytomegalovirus dfa	220
87272		Cryptosporidium ag, if	130
87273		Herpes simplex 2, ag, if	140
87274		Herpes simplex 1, ag, if	140
87275		Influenza b, ag, if	140
87276		Influenza a, ag, if	140
87277		Legionella micdadei, ag, if	110
87278		Legion pneumophilia ag, if	110
87279		Parainfluenza, ag, if	140
87280		Respiratory syncytial ag, if	140
87281		Pneumocystis carinii, ag, if	130
87283		Rubeola, ag, if	140
87285		Treponema pallidum, ag, if	110
87290		Varicella zoster, ag, if	140
87299		Antibody detection, nos, if	110, 115, 120, 130, 140
87300		Ag detection, polyval, if	110
87301		Adenovirus ag, eia	140
87305		Aspergillus ag, eia	120
87320		Chylmd trach ag, eia	110
87324		Clostridium ag, eia	110
87327		Cryptococcus neoform ag, eia	120

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
87328		Cryptosporidium ag, eia	130
87329		Giardia ag, eia	130
87332		Cytomegalovirus ag, eia	140
87335		E coli 0157 ag, eia	110
87336		Entamoeb hist dispr, ag, eia	130
87337		Entamoeb hist group, ag, eia	130
87338		Hpylori, stool, eia	110
87339		H pylori ag, eia	110
87340		Hepatitis b surface ag, eia	220
87341		Hepatitis b surface, ag, eia	220
87350		Hepatitis be ag, eia	220
87380		Hepatitis delta ag, eia	220
87385		Histoplasma capsul ag, eia	120
87389		Hiv-1 ag w/hiv-1 & hiv-2 ab	220
87390		Hiv-1 ag, eia	220
87391		Hiv-2 ag, eia	220
87400		Influenza a/b, ag, eia	140
87420		Resp syncytial ag, eia	140
87425		Rotavirus ag, eia	140
87427		Shiga-like toxin ag, eia	110
87430		Strep a ag, eia	110
87449		Ag detect nos, eia, mult	110, 120, 130, 140
87450		Ag detect nos, eia, single	110, 120, 130, 140
87451		Ag detect polyval, eia, mult	110, 120, 130
87470		Bartonella, dna, dir probe	110
87471		Bartonella, dna, amp probe	110
87472		Bartonella, dna, quant	110
87475		Lyme dis, dna, dir probe	110
87476		Lyme dis, dna, amp probe	110
87477		Lyme dis, dna, quant	110
87480		Candida, dna, dir probe	120
87481		Candida, dna, amp probe	120
87482		Candida, dna, quant	120
87485		Chylmd pneum, dna, dir probe	110
87486		Chylmd pneum, dna, amp probe	110
87487		Chylmd pneum, dna, quant	110
87490		Chylmd trach, dna, dir probe	110
87491		Chylmd trach, dna, amp probe	110
87492		Chylmd trach, dna, quant	110
87493		C diff amplified probe	110
87495		Cytomeg, dna, dir probe	140
87496		Cytomeg, dna, amp probe	140
87497		Cytomeg, dna, quant	140
87498		Enterovirus, dna, amp probe	140
87500		Vanomycin, dna, amp probe	110
87501		Influenza dna amp prob 1+	140
87502		Influenza dna amp probe	140
87503		Influenza dna amp prob addl	140
87510		Gardner vag, dna, dir probe	110
87511		Gardner vag, dna, amp probe	110
87512		Gardner vag, dna, quant	110
87515		Hepatitis b, dna, dir probe	220

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
87516		Hepatitis b, dna, amp probe	220
87517		Hepatitis b, dna, quant	220
87520		Hepatitis c, rna, dir probe	220
87521		Hepatitis c, rna, amp probe	220
87522		Hepatitis c, rna, quant	220
87525		Hepatitis g, dna, dir probe	220
87526		Hepatitis g, dna, amp probe	220
87527		Hepatitis g, dna, quant	220
87528		Hsv, dna, dir probe	140
87529		Hsv, dna, amp probe	140
87530		Hsv, dna, quant	140
87531		Hhv-6, dna, dir probe	140
87532		Hhv-6, dna, amp probe	140
87533		Hhv-6, dna, quant	140
87534		Hiv-1, dna, dir probe	140, 220
87535		Hiv-1, dna, amp probe	140, 220
87536		Hiv-1, dna, quant	140, 220
87537		Hiv-2, dna, dir probe	140, 220
87538		Hiv-2, dna, amp probe	140, 220
87539		Hiv-2, dna, quant	140, 220
87540		Legion pneumo, dna, dir prob	110
87541		Legion pneumo, dna, amp prob	110
87542		Legion pneumo, dna, quant	110
87550		Mycobacteria, dna, dir probe	115
87551		Mycobacteria, dna, amp probe	115
87552		Mycobacteria, dna, quant	115
87555		M.tuberculo, dna, dir probe	115
87556		M.tuberculo, dna, amp probe	115
87557		M.tuberculo, dna, quant	115
87560		M.avium-intra, dna, dir prob	115
87561		M.avium-intra, dna, amp prob	115
87562		M.avium-intra, dna, quant	115
87580		M.pneumon, dna, dir probe	110
87581		M.pneumon, dna, amp probe	110
87582		M.pneumon, dna, quant	110
87590		N.gonorrhoeae, dna, dir prob	110
87591		N.gonorrhoeae, dna, amp prob	110
87592		N.gonorrhoeae, dna, quant	110
87620		Hpv, dna, dir probe	140
87621		Hpv, dna, amp probe	140
87622		Hpv, dna, quant	140
87631		Resp virus 3-11 targets	140
87632		Resp virus 6-11 targets	140
87633		Resp virus 12-25 targets	140
87640		Staph a, dna, amp probe	110
87641		Mr-staph, dna, amp probe	110
87650		Strep a, dna, dir probe	110
87651		Strep a, dna, amp probe	110
87652		Strep a, dna, quant	110
87653		Strep b, dna, amp probe	110
87660		Trichomonas vagin, dir probe	130
87661		Trichomonas vaginalis amplif - Effective 1/1/2014	130

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
87797		Detect agent nos, dna, dir	110, 115, 120, 130, 140
87798		Detect agent nos, dna, amp	110, 115, 120, 130, 140
87799		Detect agent nos, dna, quant	110, 115, 120, 130, 140
87800		Detect agnt mult, dna, direc	110, 115, 120, 130, 140
87801		Detect agnt mult, dna, ampli	110, 115, 120, 130, 140
87802		Strep b assay w/optic	110
87803		Clostridium toxin a w/optic	110
87804		Influenza assay w/optic	140
87807		RSV assay w/optic	140
87808		Trichomonas assay w/optic	130
87809		Adenovirus assay w/optic	140
87810		Chylmd trach assay w/optic	110
87850		N. gonorrhoeae assay w/optic	110
87880		Strep a assay w/optic	110
87899		Agent nos assay w/optic	110
87901		Genotype, dna, hiv reverse t	140, 220
87902		Genotype, dna, hepatitis C	140, 220
87903		Phenotype, dna hiv w/culture	140, 220
87904		Phenotype, dna hiv w/clt add	140, 220
87905		Sialidase enzyme assay	110, 115, 120, 130
87906		Genotype dna hiv reverse t	140, 220
87910		Genotype cytomegalovirus	140
87912		Genotype dna hepatitis b	220
87999		Microbiology procedure	110, 115, 120, 130, 140
88104		Cytopathology, fluids	630
88104	TC	Cytopathology, fluids	630
88104	26	Cytopathology, fluids	630
88106		Cytopathology, fluids	630
88106	TC	Cytopathology, fluids	630
88106	26	Cytopathology, fluids	630
88108		Cytopath, concentrate tech	630
88108	TC	Cytopath, concentrate tech	630
88108	26	Cytopath, concentrate tech	630
88112		Cytopath, cell enhance tech	630
88112	TC	Cytopath, cell enhance tech	630
88112	26	Cytopath, cell enhance tech	630
88120		Cytp urne 3-5 probes ea spec	610, 900
88120	TC	Cytp urne 3-5 probes ea spec	610, 900
88120	26	Cytp urne 3-5 probes ea spec	610, 900
88121		Cytp urine 3-5 probes cmptr	610, 900
88121	TC	Cytp urine 3-5 probes cmptr	610, 900
88121	26	Cytp urine 3-5 probes cmptr	610, 900
88130		Sex chromatin identification	900
88140		Sex chromatin identification	900
88141		Cytopath, c/v, interpret	630
88142		Cytopath, c/v, thin layer	630
88143		Cytopath, c/v, thin layer redo	630
88147		Cytopath, c/v, automated	630
88148		Cytopath, c/v, auto rescreen	630
88150		Cytopath, c/v, manual	630
88152		Cytopath, c/v, auto redo	630
88153		Cytopath, c/v, redo	630

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
88154		Cytopath, c/v, select	630
88155		Cytopath, c/v, index add-on	630
88160		Cytopath smear, other source	630
88160	TC	Cytopath smear, other source	630
88160	26	Cytopath smear, other source	630
88161		Cytopath smear, other source	630
88161	TC	Cytopath smear, other source	630
88161	26	Cytopath smear, other source	630
88162		Cytopath smear, other source	630
88162	TC	Cytopath smear, other source	630
88162	26	Cytopath smear, other source	630
88164		Cytopath tbs, c/v, manual	630
88165		Cytopath tbs, c/v, redo	630
88166		Cytopath tbs, c/v, auto redo	630
88167		Cytopath tbs, c/v, select	630
88172		Cytp dx eval fna 1st ea site	610, 630
88172	TC	Cytp dx eval fna 1st ea site	610, 630
88172	26	Cytp dx eval fna 1st ea site	610, 630
88173		Cytopath eval, fna, report	610, 630
88173	TC	Cytopath eval, fna, report	610, 630
88173	26	Cytopath eval, fna, report	610, 630
88174		Cytopath, c/v auto, in fluid	630
88175		Cytopath, c/v auto fluid redo	630
88177		Cytp fna eval ea addl	610, 630
88177	TC	Cytp fna eval ea addl	610, 630
88177	26	Cytp fna eval ea addl	610, 630
88182		Cell marker study	220, 400, 610
88182	TC	Cell marker study	220, 400, 610
88182	26	Cell marker study	220, 400, 610
88184		Flowcytometry/tc, 1 marker	220, 400, 610
88185		Flowcytometry/tc, add-on	220, 400, 610
88187		Flowcytometry/read, 2-8	220, 400, 610
88188		Flowcytometry/read, 9-15	220, 400, 610
88189		Flowcytometry/read, 16 & >	220, 400, 610
88199		Cytopathology procedure	630
88199	TC	Cytopathology procedure	630
88199	26	Cytopathology procedure	630
88230		Tissue culture, lymphocyte	900
88233		Tissue culture, skin/biopsy	900
88235		Tissue culture, placenta	900
88237		Tissue culture, bone marrow	900
88239		Tissue culture, tumor	900
88245		Chromosome analysis, 20-25	900
88248		Chromosome analysis, 50-100	900
88249		Chromosome analysis, 100	900
88261		Chromosome analysis, 5	900
88262		Chromosome analysis, 15-20	900
88263		Chromosome analysis, 45	900
88264		Chromosome analysis, 20-25	900
88267		Chromosome analys, placenta	900
88269		Chromosome analys, amniotic	900
88271		Cytogenetics, dna probe	900

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
88272		Cytogenetics, 3-5	900
88273		Cytogenetics, 10-30	900
88274		Cytogenetics, 25-99	900
88275		Cytogenetics, 100-300	900
88280		Chromosome karyotype study	900
88283		Chromosome banding study	900
88285		Chromosome count, additional	900
88289		Chromosome study, additional	900
88291		Cyto/molecular report	900
88299		Cytogenetic study	900
88300		Surgical path, gross	610, 620
88300	TC	Surgical path, gross	610, 620
88300	26	Surgical path, gross	610, 620
88302		Tissue exam by pathologist	610, 620
88302	TC	Tissue exam by pathologist	610, 620
88302	26	Tissue exam by pathologist	610, 620
88304		Tissue exam by pathologist	610, 620
88304	26	Tissue exam by pathologist	610, 620
88305		Tissue exam by pathologist	610, 620, 630
88305	26	Tissue exam by pathologist	610, 620, 630
88307		Tissue exam by pathologist	610, 620
88307	TC	Tissue exam by pathologist	610, 620
88307	26	Tissue exam by pathologist	610, 620
88309		Tissue exam by pathologist	610, 620
88309	TC	Tissue exam by pathologist	610, 620
88309	26	Tissue exam by pathologist	610, 620
88312		Special stains	610, 620, 630
88312	26	Special stains	610, 620, 630
88313		Special stains	130, 610, 620, 630
88313	26	Special stains	130, 610, 620, 630
88314		Histochemical stain	610, 620, 630
88314	26	Histochemical stain	610, 620, 630
88319		Enzyme histochemistry	310, 630
88319	TC	Enzyme histochemistry	310, 630
88319	26	Enzyme histochemistry	310, 630
88321		Microslide consultation	610, 620, 630
88323		Microslide consultation	610, 620, 630
88323	TC	Microslide consultation	610, 620, 630
88323	26	Microslide consultation	610, 620, 630
88325		Comprehensive review of data	610, 620, 630
88331		Path consult intraop, 1 bloc	610, 620
88331	TC	Path consult intraop, 1 bloc	610, 620
88331	26	Path consult intraop, 1 bloc	610, 620
88332		Path consult intraop, add'l	610, 620
88332	TC	Path consult intraop, add'l	610, 620
88332	26	Path consult intraop, add'l	610, 620
88333		Intraop cyto path consult, 1	610, 620, 630
88333	TC	Intraop cyto path consult, 1	610, 620, 630
88333	26	Intraop cyto path consult, 1	610, 620, 630
88334		Intraop cyto path consult, 2	610, 620, 630
88334	TC	Intraop cyto path consult, 2	610, 620, 630
88334	26	Intraop cyto path consult, 2	610, 620, 630

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
88342		Immunohisto antibody slide - Not payable by Medicare	220, 610
88342	TC	Immunohisto antibody slide - Not payable by Medicare	220, 610
88342	26	Immunohisto antibody slide - Not payable by Medicare	220, 610
88343		Immunohisto antibod add slid - Not payable by Medicare - Effective 1/1/2014	220, 610
88343	TC	Immunohisto antibod add slid - Not payable by Medicare - Effective 1/1/2014	220, 610
88343	26	Immunohisto antibod add slid - Not payable by Medicare - Effective 1/1/2014	220, 610
88346		Immunofluorescent study	220, 610
88346	TC	Immunofluorescent study	220, 610
88346	26	Immunofluorescent study	220, 610
88347		Immunofluorescent study	220, 610
88347	TC	Immunofluorescent study	220, 610
88347	26	Immunofluorescent study	220, 610
88348		Electron microscopy	610, 620, 630
88348	TC	Electron microscopy	610, 620, 630
88348	26	Electron microscopy	610, 620, 630
88349		Scanning electron microscopy	610, 620, 630
88349	TC	Scanning electron microscopy	610, 620, 630
88349	26	Scanning electron microscopy	610, 620, 630
88355		Analysis, skeletal muscle	610
88355	TC	Analysis, skeletal muscle	610
88355	26	Analysis, skeletal muscle	610
88356		Analysis, nerve	610
88356	TC	Analysis, nerve	610
88356	26	Analysis, nerve	610
88358		Analysis, tumor	610
88358	TC	Analysis, tumor	610
88358	26	Analysis, tumor	610
88360		Tumor immunohistochem/manual	220, 610
88360	TC	Tumor immunohistochem/manual	220, 610
88360	26	Tumor immunohistochem/manual	220, 610
88361		Tumor immunohistochem/comput	220, 610
88361	TC	Tumor immunohistochem/comput	220, 610
88361	26	Tumor immunohistochem/comput	220, 610
88362		Nerve teasing preparations	610
88362	TC	Nerve teasing preparations	610
88362	26	Nerve teasing preparations	610
88363		Xm archive tissue molec anal	610, 630
88365		Insitu hybridization (fish)	610, 630, 900
88365	TC	Insitu hybridization (fish)	610, 630, 900
88365	26	Insitu hybridization (fish)	610, 630, 900
88367		Insitu hybridization, auto	610, 630, 900
88367	TC	Insitu hybridization, auto	610, 630, 900
88367	26	Insitu hybridization, auto	610, 630, 900
88368		Insitu hybridization, manual	610, 630, 900
88368	TC	Insitu hybridization, manual	610, 630, 900
88368	26	Insitu hybridization, manual	610, 630, 900
88371		Protein, western blot tissue	220, 610
88371	26	Protein, western blot tissue	220, 610
88372		Protein analysis w/probe	220, 610

HCPCS	MOD	DESCRIPTION	LABORATORY CERTIFICATION (LC) CODE
88372	26	Protein analysis w/probe	220, 610
88375		Optical endomicroscopy interp	610
88380		Microdissection	610
88380	TC	Microdissection	610
88380	26	Microdissection	610
88381		Microdissection, manual	610
88381	TC	Microdissection, manual	610
88381	26	Microdissection, manual	610
88387		Tiss exam molecular study	610
88387	TC	Tiss exam molecular study	610
88387	26	Tiss exam molecular study	610
88388		Tiss ex molecul study add-on	610
88388	TC	Tiss ex molecul study add-on	610
88388	26	Tiss ex molecul study add-on	610
88399		Surgical pathology procedure	610, 620
88399	TC	Surgical pathology procedure	610, 620
88399	26	Surgical pathology procedure	610, 620
89049		Chct for mal hyperthermia	610
89050		Body fluid cell count	400
89051		Body fluid cell count	400
89060		Exam synovial fluid crystals	310
89060	26	Exam synovial fluid crystals	310
89125		Specimen fat stain	310
89160		Exam feces for meat fibers	310
89230		Collect sweat for test	310
89240		Pathology lab procedure	610, 620, 630
89300		Semen analysis w/huhner	400
89310		Semen analysis w/count	400
89320		Semen anal vol/count/mot	400
89321		Semen analysis & motility	400
89322		Semen anal, strict criteria	400
89325		Sperm antibody test	220
89329		Sperm evaluation test	400
89330		Evaluation, cervical mucus	400
89331		Retrograde ejaculation anal	400

**LABORATORY CERTIFICATION (LC) CODES
CLIA SPECIALTY AND SUBSPECIALTY INFORMATION**

LC Code	Specialty - Subspecialty
010	Histocompatibility
110	Microbiology - Bacteriology
115	Microbiology - Mycobacteriology
120	Microbiology - Mycology
130	Microbiology - Parasitology
140	Microbiology - Virology
210	Diagnostic Immunology - Syphilis Serology
220	Diagnostic Immunology - General Immunology
310	Chemistry - Routine Chemistry
320	Chemistry - Urinalysis
330	Chemistry - Endocrinology
340	Chemistry - Toxicology
400	Hematology
510	Immunohematology - ABO Group & Rh type
520	Immunohematology - Antibody Detection (transfusion)
530	Immunohematology - Antibody Detection (non-transfusion)
540	Immunohematology - Antibody Identification
550	Immunohematology - Compatibility Testing
610	Pathology - Histopathology
620	Pathology - Oral Pathology
630	Pathology - Cytology
800	Radiobioassay
900	Clinical Cytogenetics

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION****I. GENERAL INFORMATION**

☐ Initial Application			☐ Survey			CLIA IDENTIFICATION NUMBER					
☐ Change in Certification Type						_____ D _____					
☐ Other Changes (<i>Specify</i>)			_____			(If an initial application leave blank, a number will be assigned)					
FACILITY NAME						FEDERAL TAX IDENTIFICATION NUMBER					
EMAIL ADDRESS						TELEPHONE NO. (<i>Include area code</i>)			FAX NO. (<i>Include area code</i>)		
FACILITY ADDRESS — <i>Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified</i>						MAILING/BILLING ADDRESS (<i>If different from street address</i>)					
NUMBER, STREET (<i>No P.O. Boxes</i>)						NUMBER, STREET					
CITY		STATE		ZIP CODE		CITY		STATE		ZIP CODE	
NAME OF DIRECTOR (<i>Last, First, Middle Initial</i>)						FOR OFFICE USE ONLY					
						Date Received _____					

II. TYPE OF CERTIFICATE REQUESTED (*Check only one*)

- ☐ Certificate of Waiver (*Complete Sections I – VI and IX – X*)
- ☐ Certificate for Provider Performed Microscopy Procedures (PPM) (*Complete Sections I – X*)
- ☐ Certificate of Compliance (*Complete Sections I – X*)
- ☐ Certificate of Accreditation (*Complete Sections I – X*) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes
- | | | |
|---|-------------------------------|-------------------------------|
| ☐ The Joint Commission | ☐ AOA | ☐ AABB |
| ☐ CAP | ☐ COLA | ☐ ASHI |

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- | | | |
|--|---|---|
| ☐ 01 Ambulance | ☐ 11 Health Main. Organization | ☐ 22 Practitioner Other (Specify) |
| ☐ 02 Ambulatory Surgery Center | ☐ 12 Home Health Agency | |
| ☐ 03 Ancillary Testing Site in Health Care Facility | ☐ 13 Hospice | ☐ 23 Prison |
| ☐ 04 Assisted Living Facility | ☐ 14 Hospital | ☐ 24 Public Health Laboratories |
| ☐ 05 Blood Bank | ☐ 15 Independent | ☐ 25 Rural Health Clinic |
| ☐ 06 Community Clinic | ☐ 16 Industrial | ☐ 26 School/Student Health Service |
| ☐ 07 Comp. Outpatient Rehab Facility | ☐ 17 Insurance | ☐ 27 Skilled Nursing Facility/
Nursing Facility |
| ☐ 08 End Stage Renal Disease
Dialysis Facility | ☐ 18 Intermediate Care Facility for
Mentally Retarded | ☐ 28 Tissue Bank/Repositories |
| ☐ 09 Federally Qualified
Health Center | ☐ 19 Mobile Laboratory | ☐ 29 Other (Specify) |
| ☐ 10 Health Fair | ☐ 20 Pharmacy | |
| | ☐ 21 Physician Office | |
- Is this a shared lab? ☐ Yes ☐ No

IV. HOURS OF LABORATORY TESTING (List times during which **laboratory testing** is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)**Are you applying for the multiple site exception?**

- ☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?

☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

☐ Yes ☐ No

If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

☐ Yes ☐ No

If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING (Including PPM testing)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	
HISTOCOMPATIBILITY			HEMATOLOGY			
☐ Transplant			☐ Hematology			
☐ Nontransplant			IMMUNOHEMATOLOGY			
MICROBIOLOGY			☐ ABO Group & Rh Group			
☐ Bacteriology		☐ Antibody Detection (transfusion)				
☐ Mycobacteriology		☐ Antibody Detection (nontransfusion)				
☐ Mycology		☐ Antibody Identification				
☐ Parasitology		☐ Compatibility Testing				
☐ Virology			PATHOLOGY			
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology			
☐ Syphilis Serology			☐ Oral Pathology			
☐ General Immunology		☐ Cytology				
CHEMISTRY			RADIOBIOASSAY			
☐ Routine			☐ Radiobioassay			
☐ Urinalysis			CLINICAL CYTOGENETICS			
☐ Endocrinology			☐ Clinical Cytogenetics			
☐ Toxicology			TOTAL ESTIMATED ANNUAL TEST VOLUME:			

IX. TYPE OF CONTROL**VOLUNTARY NONPROFIT**

- ☐ 01 Religious Affiliation
☐ 02 Private Nonprofit
☐ 03 Other Nonprofit

(Specify)

FOR PROFIT

- ☐ 04 Proprietary

GOVERNMENT

- ☐ 05 City
☐ 06 County
☐ 07 State
☐ 08 Federal
☐ 09 Other Government

(Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (*Sign in ink*)

DATE

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
 - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
 - **Credentials, and**
 - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a:

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization.

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

III. TYPE OF LABORATORY

Select your certificate type based on the highest level of test complexity performed by your laboratory. Laboratories performing non-waived tests can choose COA or COC based on the agency you wish to survey your laboratory.

A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund a laboratory's operations. The definition of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory's operation.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. Hospice and HHA could qualify for an exception i.e. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).

VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at:

<http://www.cms.gov/CLIA/downloads/waivetbl.pdf>

VII. PPM TESTING

Indicate the estimated annual test volume for all PPM tests performed. List can be found at:

<http://www.cms.gov/clia/downloads/ppmp.list.pdf>

VIII. NON-WAIVED TESTING (INCLUDING PPM)

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type of control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificate.

Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

VIII. NON-WAIVED TESTING

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALTIES

HISTOCOMPATIBILITY

HLA Typing (disease associated antigens)

MICROBIOLOGY

Bacteriology

Gram Stain

Culture

Susceptibility

Strep screen

Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology

Acid Fast Smear

Mycobacterial culture

Mycobacterial susceptibility

Mycology

Fungal Culture

DTM

KOH Preps

Parasitology

Direct Preps

Ova and Parasite Preps

Wet Preps

Virology

RSV (Not including waived kits)

HPV assay

Cell culture

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology

RPR

FTA, MHATP

General Immunology

Allergen testing

ANA

Antistreptolysin O

Antigen/Antibody (hepatitis, herpes, rubella, etc.)

Complement (C3, C4)

Immunoglobulin

HIV

Mononucleosis assay

Rheumatoid factor

Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

*Tumor markers can alternatively be listed under
Routine Chemistry instead of General Immunology.

HEMATOLOGY

Complete Blood Count (CBC)

WBC count

RBC count

Hemoglobin

Hematocrit (Not including spun micro)

Platelet count

Differential

Activated Clotting Time

Prothrombin time (Not including waived instruments)

Partial thromboplastin time

Fibrinogen

Reticulocyte count

Manual WBC by hemocytometer

Manual platelet by hemocytometer

Manual RBC by hemocytometer

Sperm count

IMMUNOHEMATOLOGY

ABO group

Rh(D) type

Antibody screening

Antibody identification

Compatibility testing

PATHOLOGY

Dermatopathology

Oral Pathology

PAP smear interpretations

Other Cytology tests

Histopathology

RADIOBIOASSAY

Red cell volume

Schilling test

CLINICAL CYTOGENETICS

Fragile X

Buccal smear

Prader-Willi syndrome

FISH studies for: neoplastic disorders, congenital disorders
or solid tumors.

CHEMISTRY

Routine Chemistry

Albumin
Ammonia
Alk Phos
ALT/SGPT
AST/SGOT
Amylase
Bilirubin
Blood gas (pH, pO₂, pCO₂)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO₂
Creatinine
Ferritin
Folate
GGT
Glucose (Not fingerstick)
Iron
LDH/LDH isoenzymes
Magnesium
Potassium
Protein, electrophoresis
Protein, total
PSA
Sodium
Triglycerides
Troponin
Uric acid
Vitamin B12

Endocrinology

Cortisol
HCG (serum pregnancy test)
T3
T3 Uptake
T4
T4, free
TSH

Toxicology

Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis**

Automated Urinalysis (Not including waived instruments)
Microscopic Urinalysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfosalicylic acid

** Dipstick urinalysis is counted in Section VI. WAIVED TESTING

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/subspecialties can be found at <http://www.cms.gov/CLIA/downloads/subject.to.CLIA.pdf> and <http://www.cms.gov/CLIA/downloads/lcCodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <http://www.cms.gov/CLIA/downloads/CLIA.SA.pdf>.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopia examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.

14 CLIA Processing Information

14.1 CLIA Introduction

Congress implemented CLIA to improve the quality and safety of laboratory services. CLIA requires all laboratories and providers that perform tests (including waived tests) for health assessment or for the diagnosis, prevention, or treatment of disease or health impairment to comply with specific federal quality standards. This requirement applies even if only a single test is being performed. Refer to the CMS CLIA website for detailed information on CMS requirements:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/>

14.2 CLIA Extract

HMOs receive a CLIA extract on a weekly basis. The layout for the CLIA report is included on the HMO Report Matrix available at:

www.forwardhealth.wi.gov/WIPortal/content/Managed%20Care%20Organization/reports_data/hmomatrix.htm.spage

The extract is posted to both the SFTP and Managed Care Portal.

14.3 CLIA Extract Fields

The following fields will be included in the CLIA extract:

- Medicaid Provider Number – proprietary provider ID pointing to unique provider service location.
- Provider NPI – National Provider Identifier for the Provider.
- CLIA Number – Provider Clinical Laboratory Improvement Act identification number.
- Certification Type – CLIA type certification code [Regular, Waiver, Accreditation, Provider-Performed Microscopy Procedure (PPMP), Partial Accredited, Registration].
- CLIA Start Date – start date of Provider's CLIA number.
- CLIA End Date – end date of Provider's CLIA number.
- Certification Effective Date – date this CLIA number is effective for this provider.
- Certification End Date – date this CLIA number is no longer effective for this provider.
- Lab Code – the CLIA lab code.
- Lab Effective Date – effective date of CLIA lab code.
- Lab End Date – end date of CLIA lab code.

Division of Quality Assurance
CLIA – Frequently Asked Questions
June 2013

Question	Answer	Federal requirement
1) Who needs a CLIA certificate?	Any facility where testing is performed on specimens collected from human beings for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of health, comes under the Federal CLIA requirements.	\$ 493.2 Definitions
2) What are the types of CLIA certificates?	There are four different CLIA certificates: • Certificate of Waiver • Provider Performed Microscopy • Certificate of Compliance • Certificate of Accreditation	\$ 493.5 Categories of tests by complexity
3) What does “CLIA Certificate of Waiver” mean?	This Certificate allows the laboratory to perform any test that has been categorized by the FDA as a “waived” method. An example of waived testing is many of the finger-stick blood glucose methods. This DOES NOT mean that the laboratory is waived from all CLIA requirements.	\$ 493.15 Laboratories performing waived tests
4) What are the requirements for a CLIA Certificate of Waiver?	Requirements include: • follow the manufacturer’s instructions for all tests performed; • agree to permit announced and unannounced inspections by CMS and its authorized agents; • notify the state agency within 30 days of any changes in – ○ Ownership ○ Name ○ Location, or ○ Director • Remit the Certificate of Waiver fee	\$ 493.35 Application for a Certificate of Waiver \$ 493.37 Requirements for a Certificate of Waiver, and \$ 493.39 Notification requirements for a Certificate of Waiver
5) How do I determine what type of CLIA Certificate is required?	If the only tests the lab performs are categorized by the FDA as “waived” methods, the laboratory will need to obtain a Certificate of Waiver. If the test menu includes waived, PPM procedures, moderate and/or high complexity methods, the determination of type of certificate is based on these three factors: • FDA categorization of the tests performed; • Qualifications of personnel performing the tests; and • For Compliance or Accreditation certificates, the agency that will be	\$ 493.15 \$ 493.43 Application for a Certificate for Provider Performed Microscopy or a Certificate of Compliance \$ 493.55 Application for a Certificate of Accreditation

Division of Quality Assurance
CLIA – Frequently Asked Questions
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	responsible for the survey/inspection.	
6) How do I apply for a CLIA certificate?	Complete the CLIA application form, CMS-116, and submit it to the state agency along with a copy of the Laboratory Director's State of Wisconsin license (see state agency contact info below). The CMS-116 can be accessed at: http://www.cms.gov/cmsforms/downloads/cms116.pdf Additional information is needed if applying for a Certificate of Compliance or Accreditation. Please note: Laboratory Director license verification printed from a public domain resource on the web are not acceptable.	\$ 493.35 \$ 493.43 \$ 493.55
7) Who can sign the CMS-116 form?	The CMS-116 form must be signed by either the Laboratory Director, the owner, or an authorized representative. If signed by an owner or authorized representative, please print the individual's name and title underneath their signature.	\$ 493.35 \$ 493.43 \$ 493.55
8) What if my Laboratory Director does not have State of Wisconsin licensure?	Contact the state agency for assistance.	NA
9) How is my certificate of Waiver renewed?	The federal contractor sends an invoice approximately 6 months prior to the certificate expiration date.	NA
How is my certificate of PPM renewed?	This invoice includes the fee coupon and the address that you submit your check to. DO NOT mail payment to the state agency.	
10) When do I receive my new certificate of Waiver?	After payment is received, the federal contractor mails out the new certificate shortly before the old one is due to expire. This may be the week your current certificate expires.	NA
11) How is my certificate of	The federal contractor sends an invoice for the compliance fee	NA

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Compliance renewed?	approximately 1 year prior to the expiration date. Once the compliance fee is paid, and not more than two weeks prior to the survey, the CLIA surveyor contacts the laboratory to announce the on-site survey date. After the compliance survey is completed and with a finding that all CLIA requirements are met, the federal contractor sends an invoice for the certificate fee. Once this certificate fee is paid, the federal contractor mails the new CLIA certificate.	
12) How is my certificate of Accreditation renewed?	The federal contractor sends an invoice for the certificate fee and validation fee approximately 6 months prior to the certificate expiration date. Once the certificate and validation fee is paid and shortly before the current certificate expires, the federal contractor sends the new CLIA certificate.	NA
13) Who do I send payment to?	The address for the federal contractor is: CLIA Laboratory Program PO Box 530882 Atlanta GA 30353-0882 Please include your CLIA number on the front of all checks sent to the contractor. DO NOT bundle fee payment to the contractor.	NA
14) What are the notification requirements for a PPM certificate? What are the notification requirements for a Certificate of Accreditation?	Notify the state agency within 30 days of any change in: • Ownership, • Name, • Location, and/or • Laboratory Director	§ 493.53 Notification requirements for laboratories issued a certificate for Provider Performed Microscopy § 493.63 Notification requirements for laboratories issued a certificate of Accreditation
15) What are the notification requirements for a Certificate of	Notify the state agency within 30 days of any change in: • Ownership,	§ 493.51 Notification requirements for laboratories issued a certificate

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Compliance?	• Name, • Location; • Director, or • Technical Supervisor Notify the state agency within 6 months of any addition or deletion of a test specialty.	of Compliance
16) How do I notify the state agency of changes to my CLIA certificate?	Written notification is required for all change requests. The CMS-116 form is required for: • status change to any certificate type other than Waiver • Laboratory Director change to a Certificate of PPM, Compliance or Accreditation • Reinstatement of a CLIA certificate The CMS-116 form can be accessed at: http://www.cms.gov/cmsforms/downloads/cms116.pdf All other changes - acceptable written documents include emails, faxes, or hard copy letters and must include the following: • CLIA number • Laboratory name • Change requested, and • Name and full contact info for the person requesting the change	SOM 6032 Notification of change in laboratory operations
17) How do I know that the state agency has processed my application request or change request?	The state agency sends a confirmation letter to the individual that submitted the application and/or change request. Processing is usually completed within two weeks of receipt of all necessary forms and licenses. Note: Providing an email address is appreciated as we prefer to send confirmation letters electronically. Retain this confirmation letter with your CLIA certificate.	NA
18) How can I keep current with CLIA requirements and state agency	Sign up for the Division of Quality Assurance's (DQA) email subscription services at: http://www.dhs.wisconsin.gov/rl_DSL/Listserv/signup.HTM	NA

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information?		
19) Where can I find more information about the CLIA regulations?	The CLIA regulations and related information can be found on the CMS website at: http://www.cms.gov/CLIA/	NA
20) Where can I find assistance in performing Waived testing?	The CDC has prepared information specifically for Waived testing. The program is called "Ready?, Set?, Test!". Further information is available at this link: http://www.cdc.gov/dls/waivedtests	NA
21) Who do I report problems to: Test system problems Complaints about laboratory services	Report to the FDA MedWatch program: http://www.fda.gov/Safety/MedWatch/default.htm Report to the state agency by: • phone 800.642.6552 • online complaint system available at: http://www.dhs.wisconsin.gov/bqaconsumer/HealthCareComplaints.htm	NA
22) What is the state agency contact info?	Mailing address is: DHS/DQA/BHS – CLIA Section 1 W Wilson St Rm 455 PO Box 2969 Madison WI 53701-2969 Ph # 608-266-7485 Fax # 608-264-9847 Email: angela.mack@dhs.wisconsin.gov , or DHSDQACLIA@wisconsin.gov	NA

Provider-performed Microscopy Procedures

Q0111 - Wet mounts, including preparations of vaginal, cervical or skin specimens

Q0112 - All potassium hydroxide (KOH) preparations

Q0113 - Pinworm examinations

Q0114 - Fern test

Q0115 - Post-coital direct, qualitative examinations of vaginal or cervical mucous

81015 - Urinalysis; microscopic only

81000 - Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy

81001 - Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)

81020 - Urinalysis; two or three glass test

89055 - Fecal leukocyte examination (Effective: January 1, 2004)

G0027 - Semen analysis; presence and/or motility of sperm excluding Huhner

89190 - Nasal smears for eosinophils

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-automated	Various	Monitors hemoglobin level in blood
84830	Ovulation tests by visual color comparison for human luteinizing hormone	Various	Detection of ovulation (optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia
85651	Erythrocyte sedimentation rate – non-automated	Various	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Abbott i-STAT Chem8+ Cartridge {Whole Blood}	i-STAT Corporation	Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
80048QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood} 2. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc Abaxis, Inc	Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen in whole blood
80051QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood} 2. Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc. Abaxis, Inc.	Measures carbon dioxide, chloride, potassium, and sodium in whole blood
80053QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood} 2. Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc. Abaxis, Inc.	Measures alanine amino transferase, aspartate amino transferase, albumin, total bilirubin, total calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, and urea nitrogen in whole blood

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	1. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)	Infopia Co., Ltd.	
	3. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	
	4. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System	Infopia Co., Ltd.	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80061QW, 82465QW 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW	Alere Cholestech LDX {Whole Blood}	Alere, Inc.	Measures alanine aminotransferase, aspartate aminotransferase, total cholesterol, HDL cholesterol, glucose, and triglycerides in whole blood
80069QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood} 2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and urea nitrogen in whole blood
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech QuickScreen One Step Amphetamine Test 2. BTNX Inc Rapid Response X-Press Drug Test Cassette Amp/Amphetamine 3. BTNX Inc Rapid Response X-Press Drug Test Strip Amp/Amphetamine 4. Wondfo Amphetamine Urine Test {Cup Format} 5. Wondfo Amphetamine Urine Test {Dip card Format}	Phamatech BTNX Inc. BTNX Inc. Guangzhou Wondfo Biotech Co., Ltd. Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of amphetamine in urine

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Secobarbital Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of barbiturates in urine
	2. Wondfo Secobarbital Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Oxazepam Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of benzodiazepines in urine
	2. Wondfo Oxazepam Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	2. Wondfo Oxazepam Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
	2. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	
	3. BTNX Inc Rapid Response X-Press Drug Test Cassette	BTNX Inc.	
	4. BTNX Inc Rapid Response X-Press Drug Test Strip	BTNX Inc.	
	5. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	ACON Laboratories, Inc.	
	6. Phamatech QuickScreen One Step THC Screening Test	Phamatech	
	7. Phamatech At Home Drug Test (Model 9078)	Phamatech	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	8. Phamatech At Home Drug Test (Model 9078T)	Phamatech	Screening test for the presence/detection of cannabinoids (THC) in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	9. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
	1. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Cup format}	BTNX Inc.	Screening test for the presence/detection of cocaine metabolites in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Dip card format}	BTNX Inc.	
	3. Phamatech At Home Drug Test (Model 9073)	Phamatech	
	4. Phamatech At Home Drug Test (Model 9073T)	Phamatech	Screening test for the presence/detection of cocaine metabolites in urine
	5. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Cup format}	BTNX Inc.	Screening test for the presence/detection of methadone in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Dip card format}	BTNX Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (ME/T/Methamphetamine) {Cup format}	BTNX Inc.	Screening test for the presence/detection of methamphetamines in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (ME/T/Methamphetamine) {Dip card format}	BTNX Inc.	
	3. Phamatech At Home Drug Test (Model 9068)	Phamatech	
	4. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine) {Cup format}	BTNX Inc.	Screening test for the presence/detection of 3,4-methylenedioxymethamphetamine HCl (MDMA) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine) {Dip card format}	BTNX Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine) {Cup format}	BTNX Inc.	Screening test for the presence/detection of morphine in urine at a cutoff concentration of 300ng/ml
	2. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine) {Dip card format}	BTNX Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Cup format}	BTNX Inc.	Screening test for the presence/detection of morphine in urine at a cutoff concentration of 2000ng/ml
	2. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Dip card format}	BTNX Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. CLIAwaived Inc. Instant Nicotine Detection Test	Mossman Associates, Inc.	Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer
	2. DyanGen NicCheck II Test Strips	DynaGen, Inc.	
	3. Mossman Associates, Inc. NicCheck I Test Strips	Mossman Associates, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Notriptyline{Cup format}	BTNX Inc.	Screening test for the presence/detection of notriptyline (major metabolite of tricyclic antidepressants) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Notriptyline{Dip card format}	BTNX Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9083)	Phamatech	Screening test for the presence/detection of opiates in urine
	2. Phamatech QuickScreen One Step Opiate Screening Test	Phamatech	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Cassette	BTNX Inc.	Screening test for the presence/detection of oxazepam (major metabolite of benzodiazepines) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Strip	BTNX Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Oxycodone Urine Test {Dip card format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of oxycodone in urine
	2. Wondfo Oxycodone Urine Test {Cup format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Cup format}	BTNX Inc.	Screening test for the presence/detection of phencyclidine (PCP) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Dip card format}	BTNX Inc.	
	3. Phamatech At Home Drug Test (Model 9133)	Phamatech	
	4. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Cassette	BTNX Inc.	Screening test for the presence/detection of secobarbital (major metabolite of barbiturates) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Strip	BTNX Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	
	3. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	
	4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	
	5. Wondfo Cannabinoids Urine Test {Cup Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	6. Wondfo Cannabinoids Urine Test {Dip card Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	7. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC)	Worldwide Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine
	2. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	3. Insight Medical Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. Insight Medical Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine
	5. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	6. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	
	7. Jant Pharmacal Accutest Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	8. Jant Pharmacal Accutest Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	
	9. Total Diagnostic Solutions Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	10. Total Diagnostic Solutions Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. ADC CLIA Waived Multiple Drug Test Card	ADC	Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and PCP in urine
	2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card	Advantage Diagnostics Corporation	
	3. Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Phamatech At Home Drug Test (Model 9150T)	Phamatech	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, and opiates in urine

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OP1-MET)	Worldwide Medical Corporation	Screening test for the presence/detection of THC, cocaine metabolites, opiates and methamphetamines in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine
	2. accutest Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	3. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)	ACON Laboratories, Inc.	
	4. Alere iCassette Drug Screen	Alere	
	5. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	6. iCassette Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	7. RediScreen Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	8. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}	Innovacon, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrtrue Single/Multi-Panel Drug Screen Cassette Tests	Chemtron Biotech, Inc	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, morphine, and PCP in urine
	2. Chemtron Biotech, Inc. Chemtrtrue Single/Multi-Panel Drug Screen Dip	Chemtron Biotech, Inc	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrtrue Single/Multi-Panel Drug Screen Cassette Tests	Chemtron Biotech, Inc	Screening test for the presence/detection of benzodiazepines, barbiturates, MDMA, methadone, opiates, and oxycodone in urine
	2. Chemtron Biotech, Inc. Chemtrtrue Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere Toxicology Service, Inc. Tox Screen Drugs of Abuse Test Cup*	Alere	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine
	2. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup	ACON Laboratories, Inc.	
	3. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Imnovacon, Inc.	
	4. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	
	5. Innovacon Integrated E-Z Split Key Cup II {Professional Use}	Imnovacon, Inc.	
	6. Noble Medical Inc. Split-Specimen Cup	ACON Laboratories, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	7. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II	Biosite Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine
	8. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use}	Innovacon, Inc.	
	9. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Multi-Drug Urine Test Cup {Cup Format}	Guangzhou wondfo Biotech Co., Ltd.	Screening test for the presence/detection of cocaine metabolites, methamphetamines, MDMA, morphine, methadone, PCP and tricyclic antidepressants in urine
	2. Wondfo Multi-Drug Urine Test Panel {Dip Card Format}		
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Branan Medical Corporation ToxCup Drug Screen Cup	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	2. Express Diagnostic Int'l Inc DrugCheck Waive RT (Model 9308z)	Phamatech, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere Toxicology Services Alere iCassette DX Drug Screen	Alere	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine
	2. Phamatech At Home 12 Drug Test (Model 9308T)*	Phamatech, Inc.	
	3. Phamatech At Home 12 Drug Test (Model 9308Z)*	Phamatech, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Innovacon Multi-Clin Drug Screen Test Device	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	2. Instant Technologies, Inc. iCassette DX Drug Screen Test	Alere	
	3. Inverness Medical Innovations Signify ER Drug Screen	Biosite Inc.	
	4. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device	Innovacon, Inc.	
	5. Abbott Diagnostics Signify ER Drug Screen Test	Innovacon, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	5. Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	6. Insight Medical Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	7. Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	8. Millenium Laboratories Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	9. Physicians' Test Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	10. On the Spot Drug Testing Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	11. Quik Test USA, Inc. Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	12. Screen Tox Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	13. Total Diagnostic Solutions Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Aventir Biotech LLC Home Check Multiple Drug Test Cup	Tianjin New Bay Bioresearch Co. Ltd.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, morphine, oxycodone, PCP and tricyclic antidepressants in urine
	2. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
	3. Medimpex United Inc. MedimpexQ Test Mult X Drug Cup Test	Tianjin New Bay Bioresearch Co. Ltd	
	4. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Amedica Biotech Amedica Drug Screen Test Cup	Amedica Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Amedica Biotech AmediCheck Instant Test Cup	Amedica Biotech, Inc.	
	3. Amedica Biotech Instant Test Cup	Amedica Biotech, Inc.	
	4. Ameditech, Inc ImmuTest Drug Screen Cup	Biosite Inc.	
	5. Branan Medical Corporation, FastTox Multiple Drug Dipcard	Branan Medical Corporation	
	6. CLIAwaived, Inc. Rapid Drug Test	Biosite Inc.	
	7. CLIAwaived, Inc. Rapid Drug Test Cup*	Alere	
	8. CLIAwaived, Inc. Rapid Drug Test Cup {OTC}	Biosite Inc.	
	9. CLIAwaived Inc. Rapid Dip Drug Test	Branan Medical Corporation	
	10. CLIAwaived Inc. Single Drug Dipstick Test	Branan Medical Corporation	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	11. Clinical Reference Laboratory, Inc. Intelligent Transport Cup*	Alere	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamine, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	12. Express Diagnostics, DrugCheck Waive Cup	Biosite Inc.	
	13. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
	14. Instant Technologies, iCup DX Drug Screen Cup	Biosite Inc.	
	15. Jant Pharmacal Corporation ACCUTEST Drug Test Cup	Amedica Biotech, Inc	
	16. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup	Biosite Inc.	
	17. NexScreen LLC, NexScreen Cup	Amedica Biotech, Inc.	
	18. Noble Medical Inc. NOBLE 1 Step Cup {OTC}*	Alere	
	19. Noble Medical Inc. NOBLE 1 Step Cup {OTC}	Biosite Inc.	
	20. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}*	Alere	
	21. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}	Biosite Inc.	
	22. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup	Biosite Inc.	
	23. Twin Spirit, Inc. DrugSmart Cup	Amedica Biotech, Inc.	
	24. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}*	Alere	
	25. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}	Biosite Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamine, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Branan Medical Corporation, QuickTox Drug Screen Dipcard	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamine, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
	1. Advin Multi-Drug Screen Test*	Advin Biotech	
	2. American Screening Corporation Discover Drug Test Cards	UCP Biosciences, Inc	
	3. American Screening Corporation Discover Multi-panel Drug Test Cups	UCP Biosciences, Inc	
	4. American Screening Corporation, Inc., Multi-Drug Testing Cards	UCP Biosciences, Inc	
	5. American Screening Corporation, Inc., Multi-Drug Testing Cups	UCP Biosciences, Inc	
	6. American Screening Corporation OneScreen Drug Test Cards	UCP Biosciences, Inc.	
	7. American Screening Corporation OneScreen Drug Test Cups	UCP Biosciences, Inc.	
	8. American Screening Corporation Reveal Multi-Drug Testing Cups	UCP Biosciences, Inc	
	9. Diagnostic Test Group Clarity Multi-Drug Test Cards	UCP Biosciences, Inc	
	10. Diagnostic Test Group Clarity Multiple Drug Screen Cards	UCP Biosciences, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	11. Diagnostic Test Group Clarity Multiple Drug Screen Cups	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamine, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
	12. Diagnostic Test Group Clarity Simple Drug Screening Cups	UCP Biosciences, Inc.	
	13. Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards	UCP Biosciences, Inc.	
	14. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups	UCP Biosciences, Inc.	
	15. UCP Biosciences, Inc. Drug Screening Test Cards	UCP Biosciences	
	16. UCP Biosciences, Inc. Drug Screening Test Cups	UCP Biosciences, Inc.	
	17. UCP Biosciences, Inc. Multiple Drug Screen Cups	UCP Biosciences	
	18. UCP Biosciences, Inc. U-Checker Drug Screening Test Cups	UCP Biosciences, Inc.	
	19. Ultimate Analysis Cup UA Cups	UCP Biosciences, Inc.	
	20. American Bio Medica Rapid TOX	American Bio Medica Corp.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. UCP Biosciences, Inc. UCP Compact Drug Test Cards	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	2. UCP Biosciences, Inc. UCP Compact Drug Test Cups	UCP Biosciences, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
80178QW	4. UCP Biosciences, Inc., UCP Home Drug Screening Test Cups* RelialAB Inc. InstaRead Lithium System {fingertstick or venipuncture whole blood}	UCP Biosciences, Inc. Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
81003QW	1. Acon Laboratories, Inc. Foresight U120 Urine Analyzer 2. Acon Laboratories, Inc. Insight U120 Urine Analyzer 3. Acon Mission U120 Urine Analyzer 4. Biosys Laboratories Optima Urine Analyzer 5. BTNX Rapid Response U120 Urine Analyzer 6. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated 7. CLIAwaived Inc. Automated Urinalysis Test System 8. Cole-Talor Marketing Inc. CTI-120 Urine Strip Analyzer 9. Consult diagnostics Urine Analyzer	Acon Laboratories, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. BioSys Laboratories, Inc. Acon Laboratories, Inc. Boehringer Mannheim Corporation Acon Laboratories, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. BioSys Laboratories, Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81003QW(cont.)	10. Germaine Laboratories Inc. AimStrip Urine Analyzer	Acon Laboratories, Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
	11. Henry Schein OneStepPlus Urine Analyzer	Macherey-Nagel GmbH & Co., Kg.	
	12. Henry Schein Urispec Plus Urine Analyzer*	Macherey-Nagel GmGH & Co., Kg.	
	13. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	14. Immunostics Inc., Detector Urinstrip+ Analyzer	Acon Laboratories, Inc.	
	15. Jant Pharmacal Corporation Accustrip URS Reader	Jant Pharmacal Corporation	
	16. McKesson 120 Urine Analyzer	Acon Laboratories, Inc.	
	17. Mediwatch urinewatch Urine Analyzer	Acon Laboratories, Inc.	
	18. Moore Medical, mooremedical Urine Analyzer U120	Acon Laboratories, Inc.	
	19. Physician Sales & Service, Inc. PSS Select Urine Analyzer	BioSys Laboratories, Inc.	
	20. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	21. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer MannheimCorporation	
	22. Stanbio Uri-Trak 120 Urine Analyzer	Acon Laboratories, Inc.	
	23. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
81003QW, 82044QW, 82570QW	Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	

Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81003QW, 82044QW, 82570QW, 84703QW	1. Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	Diatech Diagnostics Uriscreeen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
	2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories	
	3. Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System	Nova Biomedical Corp.	

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82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW,	1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood
82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	
82040QW, 82150QW, 82247QW,	1. Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood
82977QW, 84075QW, 84155QW, 84450QW, 84460QW	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	
82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}	Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82043QW	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW	1. Beckman Coulter ICON Microalb	Beckman Coulter, Inc.	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
	2. Boehringer Mannheim Chemstrip Micral	Boehringer Mannheim	
	3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test	Diagnostic Chemicals Limited	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82044QW(cont.)	- Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick) - Genzyme Daignostics OSOM ImmunoDip Urinary Albumin Test - Roche Diagnostics Chemstrip Mical (urine dipstick)	Diagnostic Chemicals Limited (USA) Genzyme Diagnostics Roche Diagnostics Corporation	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	- Alere Toxicology services, iScreen Saliva Alcohol Test Strip - Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip - American Screening Corporation, Reveal Saliva Alcohol Test Strip - Acon Laboratories Inc. Mission Saliva Alcohol Test Strip - Chematics Inc. Alco-Screen Saliva Alcohol Test - Chematics Inc. Alco-Screen 02 Saliva Alcohol Test - CLIAwaived Inc. Rapid Saliva Alcohol Test - Germaine Laboratories AimStrip Alcohol Saliva - Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip - OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test - OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	Acon Laboratories, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. Chematics, Inc. Chematics, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. Acon Laboratories, Inc. OraSure Technologies, Inc. OraSure Technologies, Inc.	Quantitative determination of alcohol (ethanol) in saliva

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82055QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	12. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test	STC Technologies Inc.	Quantitative determination of alcohol (ethanol) in saliva
	13. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	STC Technologies Inc.	
	14. Teco Diagnostics Saliva Alcohol Test	Teco Diagnostics	
82120QW, 83986QW	1. Limus Concepts FemExam TestCard (from vaginal swab)	Limus Concepts, Inc.	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkey SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82271QW	1. Aerscher Hemaprompt FG 2. SmithKline Gastrocult	Aerscher Diagnostics SmithKline	Rapid screening test to detect the presence of gastric occult blood
82271QW, 83986QW	Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates
82274QW G0328QW	1. American IVD Biotechnology Services Inc. FOB/CRC Advanced+ 2. Beckman Coulter Hemocult ICT (K961062) & (K080812) 3. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test 4. BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)	Ind Diagnostic Inc. Beckman Coulter, Inc. Alfa Scientific Designs, Inc. Ind Diagnostic Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay

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82274QW G0328QW(cont.)			
5.	BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (iFOBT)	Teco Diagnostics	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
6.	BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc	
7.	Care Diagnostics Clarity iFOB Test	Care Diagnostics, Inc.	
8.	Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	Wampole Laboratories	
9.	Clearview Ultra FOB Test	RAC Medical Group, Inc.	
10.	Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT)	Immunostics, Inc.	
11.	Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	
12.	Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
13.	Enterix Insure II Fecal Immunochemical Test	Enterix, Inc.	
14.	Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	
15.	Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test	New Bay Bioresearch Co. Ltd.	
16.	Henry Schein One Step+ iFOBT	Immunostics, Inc.	
17.	Hemosure One-Step Fecal Occult Blood Test	Hemosure, Inc.	
18.	immoCare Fecal Occult Blood Test	Care Diagnostic, Inc.	
19.	Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	Immunostics, In	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW G0328QW(cont.)	20. InSure Quik Fecal Immunochemical Test (F.I.T.)	Enterix, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	21. Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test	New Bay Research Co. Ltd.	
	22. Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	
	23. Medline iFOB One-Step Immunological Fecal Occult Blood Test	Ind Diagnostics Inc.	
	24. OC-Light iFOB Test	Polymedco, Inc	
	25. OSOM iFOB Test OSOM iFOBT Control Kit	Sekisui Diagnostics, Inc	
	26. OccuTech Fecal Occult Blood Rapid Test	YD Diagnostics Corp.	
	27. Polymedco Poly Stat OC-light FOB Test	Polymedco, Inc.	
	28. Teco Rapid Fecal Occult Blood (FOB) Card Test	Teco Diagnostics	
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyre 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc.	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and urea nitrogen (BUN) in whole blood
82435QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyre 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc	Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood

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82465QW (Contact your Medicare carrier for claims instructions.) 83718QW	1. Advanced Care	Johnson & Johnson	Cholesterol monitoring
	2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol	Boehringer Mannheim	
	3. ChemTrak AccuMeter	ChemTrak	
	4. ENA.C.T Total Cholesterol Test	ActiMed Laboratories, Inc.	
	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	
	6. Lifestream Technologies Cholesterol Monitor	Lifestream Technologies, Inc.	
	7. Lifestream Technologies Personal Cholesterol Monitor	Lifestream Technologies, Inc.	
	8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	
	9. PTS Bioscanner Test Strips Cholesterol	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.) 83718QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 82962	1. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	Measures total cholesterol and monitors blood glucose levels
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	2. Roche Diagnostics AccuChek Instant Plus Dual Testing System 1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
83718QW, 82947QW, 82950QW, 82951QW, 82952QW	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW	1. Cholestech LDX 2. Infopia USA LipidPro lipid profile and glucose measuring system	Cholestech Corp. Infopia CO., Ltd.	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	Wako APOLOWAKO Analyzer (Whole Blood)	Wako Chemicals USA, Inc.	Measures total cholesterol, hemoglobin A1c, glucose, and triglycerides in whole blood
82465QW(Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW 82523QW	Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)}	Abaxis, Inc.	Measures cholesterol, HDL cholesterol, glucose, alanine aminotransferase, aspartate aminotransferase, and triglycerides in whole blood
82565QW	Ostex International Osteomark NTX Point of Care Prescription Home Use Abbott i-STAT Crea Cartridge {Whole Blood}	Ostex International Inc. i-Stat Corporation	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine Quantitative measurement of creatinine in whole blood
82565QW, 84520QW	Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of creatinine and urea nitrogen in whole blood
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, aspartate aminotransferase, creatinine, gamma glutamyltransferase, glucose and urea nitrogen in whole blood
2.	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	Cleaplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)	Unipath Limited	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception
82947QW, 82950QW, 82951QW, 82952QW	1. HemoCue B-Glucose Photometer 2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer 3. Abbott i-STAT G Cartridge {Whole Blood}	HemoCue, Inc. HemoCue, Inc. i-Stat Corporation	Measures glucose levels in whole blood
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW	Abbott i-STAT EC4+ Cartridge {Whole Blood}	i-Stat Corporation	Measures glucose, potassium, sodium, and hematocrit in whole blood
82985QW	LXN Fructosamine Test System	LXN Corporation	Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)
82962, 82465QW(Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	1. LXN Duet Glucose Control Monitoring System 2. LXN IN CHARGE Diabetes Control System	LXN Corporation LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83001QW	1. Acon Laboratories, Inc. FSH Menopause Predictor Test 2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use} 3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use} 4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test 5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device 6. Genosis Fertell Female Fertility Test 7. Genua Menopause Monitor Test 8. Synova Healthcare MenocheckPro (Professional Use)	ACON Laboratories, Inc. ACON Laboratories, Inc. ACON Laboratories, Inc. Applied Biotech, Inc. ACON Laboratories, Inc. Genosis, Inc. Genua 1944 Inc Applied Biotech, Inc.	Detects follicle stimulating hormone in urine
83036QW	1. Axis-Shield Afinion AS100 Analyzer 2. Bayer AICNow+ Professional Use 3. Siemens Medical Diagnostics DCA Vantage Analyzer 4. Siemens DCA 2000 Analyzer 5. Siemens DCA 2000+ Analyzer	Axis-Shield Poc As Bayer Healthcare, LLC Siemens Healthcare Diagnostics, Inc. Siemens Healthcare Diagnostics, Inc. Siemens Healthcare Diagnostics, Inc	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
83037QW	1. Bayer AICNow+ {For professional use} 2. Bayer A1C Now SelfCheck 2. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bayer Corp. Bayer Healthcare, LLC. Bio-Rad Laboratories	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83037QW(cont.)	3. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
	4. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	
83605QW 83655QW	KDK Corporation Lactate Pro System ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	KDK Corporation ESA Biosciences, Inc.	Quantitative measurement of lactate in whole blood Quantitative measurement of blood lead in whole blood
83718QW	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood
83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW	Polymer Technology Systems CardioCheck PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips)	Polymer Technology Systems, Inc.	Measures HDL cholesterol, triglycerides, and glucose in whole blood
83721QW	Polymer Technology Systems Cardiocheck PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood
83861QW	TearLab Corporation TearLab Osmolarity System	TearLab Corporation	Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.
83880QW	1. Biosite Triage Meter {Whole Blood} 2. Biosite Triage Meter Plus {Whole Blood}	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
83986QW	All qualitative color comparison pH testing - body fluids (other than blood)	Various	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates
83986QW	1. Dale Medical Products, Inc. RightLevel pH 2. Dale Medical Products, Inc. RightSpot pH	EZ-NG, LLC. EZ-NG, LLC.	Gastric pH detection (acid-base balance)

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83986QW	1. FemTek pHEM-ALERT® 2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test 3. Common Sense Ltd. VA-Sense Kit 4. Common Sense Ltd. VS-Sense Test {qualitative} 5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test	FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Common Sense, Ltd Lil' Drug Store Products Inc.	Vaginal pH detection (acid-base balance)
84295QW, 84132QW, 85014QW	Abbott i-STAT E3+ Cartridge {Whole Blood}	i-Stat Corporation	Measures potassium, sodium, and hematocrit in whole blood
84443QW	1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood} 2. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette* 3. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette 4. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood} 5. ThyroTec, Inc. ThyroTest Whole Blood TSH Test 6. Jant Pharmacal Accutest TSH {Whole Blood} 7. Qualigen, Inc. FastChek TSH {Whole blood}	Screening Devices Canada Inc. Screening Devices Canada Inc. Screening Devices Canada Inc. Screening Devices Canada Inc. ThyroTes, Inc. Screening Devices Canada Inc. Screening Devices Canada Inc. Atkay, Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
84450QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer{whole blood}	Atkay, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
85610QW(cont.) (Contact your Medicare carrier for claims instructions.)	5. Coag-Sense Prothrombin Time (PT/INR) Monitoring system (Professional use)	CoaguSense, Inc.	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	6. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)	CoaguSense, Inc.	
	7. HemoSense INRatio System	HemoSense, Inc.	
	8. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	9. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	10. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	11. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.	
	12. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	
	13. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	14. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	
	15. Roche Diagnostics CoaguChek XS	Roche Diagnostics	
	16. Roche Diagnostics CoaguChek XS Plus System	Roche Diagnostics	
86629QW	1. Bion Diagnostic Sciences BTA stat Test (for home use)	Bion Diagnostic Sciences, Inc.	Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients
	2. LifeSign Status BTA	Polymedco, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW	1. Aceava Mono II {Whole Blood}	Biosite Inc.	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
	2. Aceava Mono Cassette {For whole Blood}	Princeton BioMeditech Corp.	
	3. Acon Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	4. Acon Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	5. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	6. BioStar Aceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	7. Cardinal Health SP Brand Rapid Test Mono {Whole Blood}	Cardinal Health	
	8. Clearview MONO Whole Blood, K042272/A013	Inverness Medical Professional Diagnostics	
	9. Clearview MONO Whole Blood, K042272/A016	Imovacon, Inc.	
	10. Clearview Mono-plus II	Applied Biotech, Inc.	
	11. Consult Diagnostics Mononucleosis Cassette {Whole Blood}	Princeton BioMeditech Corp.	
	12. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	13. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	14. Henry Schein OneStep Pro+ Mono {Whole Blood}*	Princeton BioMeditech Corp.	
	15. Icon Mono	Beckman Coulter, Inc.	
	16. Immuno Detector Mono {Whole Blood}	Princeton BioMeditech Corp.	
	17. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW (cont.)			
18.	Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
19.	Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
20.	Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
21.	LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
22.	LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
23.	McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
24.	Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
25.	PerMaxim RediScreen Mononucleosis {Whole Blood}	ACON Laboratories, Inc.	
26.	Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
27.	Poly Stat Mono Test {Whole Blood}	Innovacon, Inc.	
28.	ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only)	Biosite Inc.	
29.	Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	
30.	Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation	
31.	RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
32.	Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW (cont.)	33. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
86318QW	34. Signify Mono Cassette {Whole Blood}	Imovacon, Inc.	Immunassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	35. Signify Mono Whole Blood	Inverness Medical Professional Diagnostics	
	36. Stanbio Rely Mono Rapid Test {Whole Blood}	Imovacon, Inc.	
	37. Wampole Mono-Plus WB	Wampole Laboratories	
	38. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	39. Wyntek Signify Mono Test	Wyntek Diagnostics, Inc.	
	1. Abbott FlexPak HP Test for whole blood	SmithKline Diagnostics, Inc.	
	2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood}	Imovacon, Inc.	
	3. Abbott TestPack Plus H. pylori (for whole blood)	Abbott Laboratories	
	4. Acon® H. pylori Test Device	ACON Laboratories, Inc.	
	5. Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test	Alfa Scientific Designs, Inc.	
	6. Applied Biotech SureStep H. pylori WB Test (whole blood)	Applied Biotech, Inc.	
	7. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood	Beckman Coulter, Inc.	
	8. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)	Cortecs Diagnostics Limited	
	9. Cardinal Health SP Brand Rapid Test H. pylori (K990892)	Applied Biotech Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86318QW (cont.)			
	10. Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood} (K024350/A15)	Innovacon, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	11. Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood}	Princeton BioMeditech Corp.	
	12. EarlyDetect H. Pylori Whole Blood Rapid Test	Alpha Scientific Designs, Inc.	
	13. Fisher Healthcare Sure-Vue H. pylori Test {Whole Blood}	Innovacon, Inc.	
	14. Germaine Laboratories, Aimstep H. pylori {whole blood}	ACON Laboratories, Inc.	
	15. Henry Schein One Step+ H. Pylori Rapid Test Device (Whole Blood)	Innovacon, Inc.	
	16. Immunostics Detector H. Pylori WB (H. pyloi Antibody Test) {Whole Blood}	Princeton BioMeditech Corp.	
	17. Instant Technologies iScreen H.pylori Rapid Test Device	ACON Laboratories, Inc.	
	18. Inverness Medical Clearview H. pylori Test {whole blood}	Innovacon, Inc.	
	19. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	
	20. Inverness Medical Signify H. Pylori Whole Blood	Innovacon, Inc.	
	21. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	22. McKesson H. pylori Test (Whole Blood)	Alere	
	23. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	
	24. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86318QW (cont.)	25. Polymedco Poly Stat H. Pylori Test (Whole Blood) 26. Pro-Advantage by NDC H. pylori Device (Whole Blood) 27. QuickVue One-Step H. Pylori Test for Whole Blood 28. Quidel QuickVue One-Step H.pylori II Test. 29. Remel RIM® A.R.C. H.pylori Test 30. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood 31. Stanbio Rely H. pylon Rapid Test (Whole Blood) (Finger-stick only) 32. Trinity Uni-Gold™ H.pylori 33. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Innovacon, Inc. Innovacon, Inc. Quidel Corporation Quidel Corporation Remel SmithKline Diagnostics, Inc. Alere Trinity Biotech Applied Biotech, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
86386QW	1. Alere NMP22 BladderChek Test (Prescription Home Use) and (Professional Use) 2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Alere Matritech, Inc.	Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients
86618QW	Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay	Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood
86701QW	1. biol,ytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood} 2. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test	Biol,ytical Laboratories, Inc. OraSure Technologies, Inc	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86701QW(cont.)	3. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood 4. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)	OraSure Technologies, Inc. Trinity Biotech	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
G0433QW	1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood} 2. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid} 3. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	OraSure Technologies, Inc. OraSure Technologies, Inc. Chembio Diagnostic Systems, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood , venipuncture whole blood and/or oral fluid specimens
866803QW	OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference Panel	OraSure Technologies Inc.	Qualitative immunoassay to detect antibodies to hepatitis C virus in fingerstick whole blood and venipuncture whole blood specimens
87077QW	1. Ballard Medical Products CLOrtest 2. Dela West CLOrtest 3. GI Supply HP-FAST 4. GI Supply, Div. Chek-Med Systems HP One 5. Medical Instruments Corporation Pronto Dry H. pylori 6. Serim Pyloritek Test Kit	Ballard Medical Products Dela West Tri-Med Specialties Mycoscience Labs, Inc. GI Supply Medical Instruments Corporation Serim	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
87210QW	1. Stesans Maybe?Mon Mini Ovulation Microscope 2. O2 Unlimited Donna Ovulation Tester	LEC Associates O2 Unlimited Corp.	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87449QW	Zymetx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B
87804QW	- Alere Influenza A & B Test (For use with nasal Swabs only.) - Alere BinaxNow Influenza A & B Card {Nasopharyngeal (NP) Swab and Nasal Wash/Aspirate Specimens} - BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader} - BinaxNow Influenza A & B Test, K092223 - BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049 - BinaxNOW Influenza A & B Test {Nasopharyngeal (NP) Swab and Nasal Wash/Aspirate Specimens}, K053126 - BinaxNOW Influenza A & B Test {Nasopharyngeal (NP) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)} - Henry Schein OneStep+ Influenza A&B Test - Quidel Quickvue Influenza A+B Test	Alere Scarborough, Inc. Alere Scarborough, Inc. Becton, Dickinson and Company Binax, Inc Binax, Inc. Binax, Inc. Binax, Inc. Alere Scarborough, Inc. Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87804QW (cont.)	10. Sofia Analyzer and Influenza A+B FLA (for user with nasal swabs and nasopharyngeal swabs)	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
87804QW	1. BinaX Now® Flu A Test	BinaX, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza A Test Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza A Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza A Test	SA Scientific, Inc.	
87804QW	1. BinaX Now® Flu B Test	BinaX, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza B Test Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza B Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	
87807QW	1. Alere BinaXNOW RSV Card	Alere Scarborough, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. BinaX NOW RSV Test (K021687)	BinaX, Inc.	
	3. BinaX NOW RSV Test (K032166/A005)	BinaX, Inc.	
	4. Fisher Scientific Sure-Vue RSV Test	SA Scientific, Inc.	
	5. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	6. Quidel Quick Vue RSV Test	Quidel Corporation	
	7. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87808QW	1. Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs
	2. Sekisui Diagnostics, LLC OSOM Trichomonas Rapid Test	Genzyme Corp.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87809QW	1. Rapid Pathogen Screening RPS Adeno Detector 2. AdenoPlus (human eye fluid)	Rapid Pathogen Screening Rapid Pathogen Screening, Inc.	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid
87880QW	1. Abbott Signify Strep A Test (from throat swab only) 2. Abbott Laboratories Signify Strep A Dipstick 3. Acon® Strep A Rapid Strip Test 4. Acon® Strep A Twist Rapid Test 5. Applied Biotech SureStep Strep A (II) (direct from throat swab) 6. Beckman Coulter ICON DS Strep A Test 7. Beckman Coulter ICON SC Strep A Test 8. Beckman Coulter Primary Care Diagnostics ICON DS Strep A 9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test 10. Becton Dickinson BD Chek Group A Strep A Test 11. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab) 12. Binax NOW Strep A Test 13. BioStar Aceeava Strep A Test (direct specimen only) 14. Biotechnostix Rapid Response Strep A Rapid Test Device	Wyntek Diagnostics, Inc. Innovacon, Inc. ACON Laboratories, Inc. ACON Laboratories, Inc. Applied Biotech, Inc. Princeton BioMeditech Corp. ACON Laboratories, Inc. ACON Laboratories, Inc. Beckman Coulter, Inc. Imnovacon, Inc. Applied Biotech, Inc. Binax, Inc. Wyntek Diagnostics, Inc. Acon Laboratories Co.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)			
	15. Biotechnosix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	16. BTNX Rapid Response Strep A Rapid Test Strips	Sa Scientific, Inc.	
	17. BTNX, Inc. Strep A Rapid Test	Sa Scientific, Inc.	
	18. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	Applied Biotech Inc.	
	19. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon, Inc.	
	20. CLIA waived inc Rapid Strep A Test	Sa Scientific, Inc.	
	21. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	22. DE Healthcare Products TruView Strep A Cassette Test	ACON Laboratories, Inc.	
	23. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	
	24. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	25. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	26. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	27. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	28. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	29. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)			
	30. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	31. Henry Schein Inc, One Step+ Strep A Dipstick Test	Henry Schein	
	32. Henry Schein OneStep Pro+ Strep A Cassette*	Princeton Biomeditech Corp.	
	33. Immunostics Detector Strep A Direct	ACON Laboratories, Inc.	
	34. Immunostics Immuno/Strep A Detector	ACON Laboratories, Inc.	
	35. Instant Technologies iStrep Strep A	ACON Laboratories, Inc.	
	36. Inverness Medical BioStar Acecava Strep A Test	Innovacon, Inc.	
	37. Inverness Medical BioStar Acecava Strep A Twist	Innovacon, Inc.	
	38. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)	Innovacon, Inc.	
	39. Jant Pharmacial AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	40. Jant Pharmacial Accustrip Strep A Value+ Test Strip	Innovacon, Inc.	
	41. Jant Pharmacial Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	42. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	43. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	44. LifeSign LLC Status Strep A	Princeton BioMeditech	
	45. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)			
	46. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	47. McKesson Strep A Test – Dipstick	Alere San Diego, Inc.	
	48. McKesson Strep A Test – Twist	Alere San Diego, Inc.	
	49. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	50. Mooremedical Strep A Rapid Test – Dipstick	Alere San Diego, Inc.	
	51. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon, Inc.	
	52. PSS Consult Diagnostics Strep A Dipstick	Innovacon, Inc.	
	53. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon, Inc.	
	54. PSS World Medical Select Diagnostics Strep A Twist	Innovacon, Inc.	
	55. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	56. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc.	
	57. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	58. QuickVue® Dipstick Strep A	Quidel Corporation	
	59. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	60. Quidel QuickVue In-Line Strep A {direct from throat swab} (K934484/A013)	Quidel Corporation	
	61. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	62. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	63. Sekisui Diagnostics LLC, OSOM Strep A Test(direct from throat swab} 64. Sekisui Diagnostics LLC, OSOM Ultra Strep A Test 65. SmithKline ICON Fx Strep A Test (from throat swab only) 66. Stanbio Laboratory E-Z Well Strep A Rapid Device Test 67. Stanbio QuStick Strep A 68. Wyntek Diagnostics OSOM Strep A Test 69. Wyntek OSOM® Ultra Strep A Test	Sekisui Diagnostics LLC Sekisui Diagnostics LLC Binax, Inc. Acon Laboratories Co. Stanbio Laboratory Wyntek Diagnostics, Inc. Wyntek Diagnostics, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
87905QW	1. Gryphus Diagnostics BVBlue 2. Genzyme Diagnostics OSOM BVBlue Test	Gryphus Diagnostics, LLC Gryphus Diagnostics, LLC	Enzyme activity test for the detection of staildase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool} 1. Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility	Meridian Bioscience, Inc. Embryotech Laboratories, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens Screening test to measure sperm concentration
89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	2. SpermCheck Vasectomy Fertell Male Fertility Test	Princeton BioMeditech Corp. Genosis Ltd.	Detects sperm in semen following a vasectomy Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml
89321QW			