

The following is a list of analytes that have test systems categorized as “waived”. Under the current process, waiver may be granted to: 1) any test listed in the regulation; 2) any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met; and 3) test systems cleared by the FDA for home use.

Analytes with waived products are listed below. More information is available at the FDA web site:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>

Or use the Laboratory Compliance & Quality Assurance website

<http://oregon.gov/DHS/ph/lcqa/index.shtml> to reach the FDA (under Related Links) click on the ‘Verify Waived test/FDA’ link. At the FDA site, click on any analyte to see what test systems have been approved as waived.

**Analytes With Approved Waived Test Systems (updated 6/27/07)**

Analyte Name	CPT CODE
ADENOVIRUS	PENDING
AEROBIC/ANAEROBIC ORGANISMS-VAGINAL	PENDING
ALANINE AMINOTRANSFERASE (ALT) (SGPT)	84460QW
ALBUMIN	82044QW
ALBUMIN, URINARY	82044QW
ALCOHOL, SALIVA	82055QW
ALKALINE PHOSPHATASE (ALP)	PENDING
AMINES	82120QW
AMPHETAMINES	80101QW
AMYLASE	PENDING
ASPARTATE AMINOTRANSFERASE (AST) (SGOT)	84450QW
B-TYPE NATRIURETIC PEPTIDE (BNP)	83880QW
BARBITURATES	80101QW
BENZODIAZEPINES	80101QW
BILIRUBIN, TOTAL	PENDING
BLADDER TUMOR ASSOCIATED ANTIGEN	86294QW

<b>BLOOD LEAD</b>	<b>PENDING</b>
<b>CALCIUM, TOTAL</b>	<b>PENDING</b>
<b>CANNABINOIDS (THC)</b>	<b>80101QW</b>
<b>CATALASE, URINE</b>	<b>81007QW</b>
<b>CHOLESTEROL</b>	<b>82465QW</b>
<b>CHOLESTEROL + HDL</b>	<b>82465QW 83718QW</b>
<b>CHOLESTEROL + HDL + GLUCOSE</b>	<b>82465QW 83718QW 82947QW</b>
<b>COCAINE METABOLITES</b>	<b>80101QW</b>
<b>COLLAGEN TYPE 1 CROSSLINK, N-TELOPEPTIDES (NTX)</b>	<b>82523QW</b>
<b>CREATININE</b>	<b>82570QW</b>
<b>ECSTASY (METHYLENEDIOXYMETHAMPHETAMINE - MDMA)</b>	<b>80101QW</b>
<b>ERYTHROCYTE SEDIMENTATION RATE, NONAUTOMATED WAIVED</b>	<b>85651</b>
<b>ESTRONE-3 GLUCURONIDE</b>	<b>82679QW</b>
<b>ETHANOL (ALCOHOL)</b>	<b>82055QW</b>
<b>FECAL OCCULT BLOOD DIAGNOSTIC ENTERIX, IN SURE SCREENING 1 TO 3 SPECIMENS</b>	<b>82270 82274 G0107</b>
<b>FECAL OCCULT BLOOD EIA METHOD (need diagnostic code G0328QW)</b>	<b>82274QW</b>
<b>FERN TEST, SALIVA</b>	<b>87210QW</b>
<b>FOLLICLE STIMULATING HORMONE (FSH)</b>	<b>83001QW</b>
<b>FRUCTOSAMINE</b>	<b>82985QW</b>
<b>GAMMA GLUTAMYL TRANSFERASE (GGT)</b>	<b>PENDING</b>
<b>GASTRIC OCCULT BLOOD</b>	<b>82273QW</b>
<b>GASTRIC PH</b>	<b>83986QW</b>
<b>GLUCOSE</b>	<b>82947QW</b>
<b>GLUCOSE MONITORING DEVICES (FDA CLEARED/HOME USE)</b>	<b>82962</b>
<b>GLUCOSE, FLUID (FDA CLEARED/PRESCRIPTION HOME USE)</b>	<b>82962</b>
<b>GLUCOSE TOLERANCE TEST</b>	<b>Multiple codes</b>
<b>GLYCATED HEMOGLOBIN, TOTAL</b>	<b>83036QW</b>
<b>GLYCOSYLATED HEMOGLOBIN (HGB A1C)</b>	<b>83036QW</b>

HCG, URINE	81025
HDL CHOLESTEROL	83718QW
HELICOBACTER PYLORI	87077QW
HELICOBACTER PYLORI ANTIBODIES	86318QW
HEMATOCRIT	85014QW
HEMOGLOBIN	85018QW
HEMOGLOBIN BY COPPER SULFATE, NONAUTOMATED	83026
HGB, SINGLE ANALYTE INST. W/SELF-CONT	85018QW
HIV-1 AND HIV-2 ANTIBODIES	86703QW
HIV-1 ANTIBODIES	86701QW
HIV-1 ANTIBODY	86701QW
INFECTIOUS MONONUCLEOSIS ANTIBODIES (MONO)	86308QW
INFLUENZA A	Pending
INFLUENZA A/B ZymeTX Zstatflu <sup>(C)</sup> All others	87449QW 87804QW
INFLUENZA B	Pending
KETONE, BLOOD	82010QW
KETONE, URINE	81002
LACTIC ACID (LACTATE)	83605QW
LDL CHOLESTEROL	83721QW
LIPID PROFILE	80061QW
LIPID PROFILE + GLUCOSE	80061QW 82947QW
LITHIUM	80178QW
LUTEINIZING HORMONE (LH)	83002QW
LYME DISEASE ANTIBODIES (BORRELIA BURGDOFERI ABS)	86618QW
METHADONE	80101QW
METHAMPHETAMINE/AMPHETAMINE	80101QW
METHAMPHETAMINES	80101QW
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
MICROALBUMIN (see web site to determine the correct CPT code for your waived product)	82044QW 83518QW
MORPHINE	80101QW

<b>N-TELOPEPTIDES (NTX)</b>	<b>82523QW</b>
<b>NICOTINE AND/OR METABOLITES</b>	<b>80101QW</b>
<b>OPIATES</b>	<b>80101QW</b>
<b>OVULATION TEST (LH) BY VISUAL COLOR COMPARISON)</b>	<b>84830</b>
<b>OXYCODONE</b>	<b>80101QW</b>
<b>PH</b>	<b>83986QW</b>
<b>PHENCYCLIDINE (PCP)</b>	<b>80101QW</b>
<b>PLATELET AGGREGATION</b>	<b>85576QW</b>
<b>PROPOXYPHENE</b>	<b>PENDING</b>
<b>PROTEIN, TOTAL</b>	<b>PENDING</b>
<b>PROTHROMBIN TIME (PT)</b>	<b>85610QW</b>
<b>RESPIRATORY SYNCYTIAL VIRUS</b>	<b>87807QW</b>
<b>SEMEN</b>	<b>89300QW</b>
<b>SPUN MICROHEMATOCRIT</b>	<b>85013</b>
<b>STREPTOCOCCUS, GROUP A</b>	<b>87880QW</b>
<b>THYROID STIMULATING HORMONE (TSH)</b>	<b>84443QW</b>
<b>TRICHOMONAS</b>	<b>87899QW</b>
<b>TRICYCLIC ANTIDEPRESSANTS</b>	<b>80101QW</b>
<b>TRIGLYCERIDE</b>	<b>84478QW</b>
<b>UREA (BUN)</b>	<b>PENDING</b>
<b>URIC ACID</b>	<b>PENDING</b>
<b>URINARY PROTEIN, QUALITATIVE</b>	<b>81002</b>
<b>URINE DIPSTICK OR TABLET ANALYTES, NONAUTOMATED</b>	<b>81002</b>
<b>URINE HCG BY VISUAL COLOR COMPARISON TESTS</b>	<b>81025</b>
<b>URINE QUALITATIVE DIPSTICK ASCORBIC ACID</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK BILIRUBIN</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK BLOOD</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK CHEMISTRIES</b>	<b>81003</b>
<b>URINE QUALITATIVE DIPSTICK CREATININE</b>	<b>82570QW</b>
<b>URINE QUALITATIVE DIPSTICK GLUCOSE</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK hCG</b>	<b>84703QW</b>

<b>URINE QUALITATIVE DIPSTICK KETONE</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK LEUKOCYTES</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK NITRITE</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK PH</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK PROTEIN</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK SPECIFIC GRAVITY</b>	<b>81002</b>
<b>URINE QUALITATIVE DIPSTICK UROBILINOGEN</b>	<b>81002</b>
<b>URINE SEMI-QUANTITATIVE DIPSTICK MICROALBUMIN</b>	<b>82044QW</b>
<b>VAGINAL PH</b>	<b>83986QW</b>

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