

The following is a list of analytes that have test systems categorized as “waived”. Under the current process, waived status 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 test products are listed below. More information is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm> or use the Laboratory Compliance website [www.healthoregon.org/lcqa](http://www.healthoregon.org/lcqa) - look under ‘More Information’ located on the right side, then click ‘Verify Test Product is Waived (FDA)’ link. Once at the FDA site, click any analyte to see test systems approved as waived.

### **Analytes with Approved Waived Test Systems**

<b>Analyte Name</b>	<b>CPT CODE</b>
<b>ADENOVIRUS</b>	<b>87899QW</b>
<b>AEROBIC/ANAEROBIC ORGANISMS-VAGINAL</b>	<b>87999QW</b>
<b>ALANINE AMINOTRANSFERASE (ALT) (SGPT)</b>	<b>84460QW</b>
<b>ALBUMIN</b>	<b>82044QW</b>
<b>ALBUMIN, URINARY</b>	<b>82044QW</b>
<b>ALCOHOL, SALIVA</b>	<b>82055QW</b>
<b>ALKALINE PHOSPHATASE (ALP)</b>	<b>84075QW</b>
<b>AMINES</b>	<b>82120QW</b>
<b>AMPHETAMINES</b>	<b>80101QW</b>
<b>AMYLASE</b>	<b>82150QW</b>
<b>ASPARTATE AMINOTRANSFERASE (AST) (SGOT)</b>	<b>84450QW</b>
<b>B-TYPE NATRIURETIC PEPTIDE (BNP)</b>	<b>83880QW</b>
<b>BARBITURATES</b>	<b>80101QW</b>
<b>BENZODIAZEPINES</b>	<b>80101QW</b>
<b>BILIRUBIN, TOTAL</b>	<b>82247QW</b>
<b>BLADDER TUMOR ASSOCIATED ANTIGEN</b>	<b>86294QW</b>
<b>BLOOD LEAD</b>	<b>83655QW</b>

<b>BUPRENORPHINE</b>	<b>PENDING</b>
<b>CALCIUM, IONIZED</b>	<b>82310QW</b>
<b>CALCIUM, TOTAL</b>	<b>82310QW</b>
<b>CANNABINOIDS (THC)</b>	<b>80101QW</b>
<b>CARBON DIOXIDE, TOTAL (CO2)</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 G0328</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>82977QW</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>

GLYCATED HEMOGLOBIN, TOTAL	83036QW
GLYCOSYLATED HEMOGLOBIN (HGB A1C)	83036QW
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	87804QW
INFLUENZA A/B ZymeTX Zstatflu <sup>(C)</sup> All others	87449QW 87804QW
INFLUENZA B	87804QW
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)	80101QW

<b>MICROALBUMIN (see web site to determine the correct CPT code for your waived product)</b>	<b>82044QW 83518QW</b>
<b>MORPHINE</b>	<b>80101QW</b>
<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>PHOSPHORUS</b>	<b>PENDING</b>
<b>PLATELET AGGREGATION</b>	<b>85576QW</b>
<b>POTSSIUM</b>	<b>84132QW</b>
<b>PROPOXYPHENE</b>	<b>80101QW</b>
<b>PROTEIN, TOTAL</b>	<b>84157QW</b>
<b>PROTHROMBIN TIME (PT)</b>	<b>85610QW</b>
<b>RESPIRATORY SYNCYTIAL VIRUS</b>	<b>87807QW</b>
<b>SEMEN</b>	<b>89300QW</b>
<b>SODIUM</b>	<b>84295QW</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>84520QW</b>
<b>URIC ACID</b>	<b>84550QW</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>81003QW</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>

Waived Analytes and cpt.doc  
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