

CLIA Waived Tests

The specified tests that are listed in the regulation are:

1. Dipstick or Tablet reagent urinalysis (non automated) for the following:
 - Bilirubin
 - Glucose
 - Hemoglobin
 - Ketone
 - Leukocytes
 - Nitrite
 - pH
 - Protein
 - Specific gravity
 - Urobilinogen
2. Fecal occult blood
3. Ovulation tests - visual color comparison tests for luteinizing hormone
4. Urine pregnancy tests - visual color comparison tests
5. Erythrocyte sedimentation rate-non-automated
6. Hemoglobin-copper sulfate - non-automated
7. Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
8. Spun microhematocrit
9. (added 1/19/93) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

As of 6/6/06 the following is a listing of analytes for which waived methods are available:

ALANINE AMINOTRANSFERASE (ALT) (SGPT)
ALBUMIN, URINARY
ALCOHOL, SALIVA
AMINES
AMPHETAMINES
ASPARTATE AMINOTRANSFERASE (AST) (SGOT)
B-TYPE NATRIURETIC PEPTIDE (BNP)
BARBITURATES
BENZODIAZEPINES
BLADDER TUMOR ASSOCIATED ANTIGEN
CANNABINOIDS (THC)
CATALASE, URINE
CHOLESTEROL
COCAINE METABOLITES
COLLAGEN TYPE I CROSSLINK, N-TELOPEPTIDES (NTX)
CREATININE
ERYTHROCYTE SEDIMENTATION RATE, NONAUTOMATED WAIVED
ESTRONE-3 GLUCURONIDE
ETHANOL (ALCOHOL)
FECAL OCCULT BLOOD
FERN TEST, SALIVA
FOLLICLE STIMULATING HORMONE (FSH)

FRUCTOSAMINE
GASTRIC OCCULT BLOOD
GASTRIC PH
GLUCOSE
GLUCOSE MONITORING DEVICES (FDA CLEARED/HOME USE)
GLUCOSE, FLUID (APPROVED BY FDA FOR PRESCRIPTION HOME USE)
GLYCATED HEMOGLOBIN, TOTAL
GLYCOSYLATED HEMOGLOBIN (HGB A1C)
HCG, URINE
HDL CHOLESTEROL
HELICOBACTER PYLORI
HELICOBACTER PYLORI ANTIBODIES
HEMATOCRIT
HEMOGLOBIN
HEMOGLOBIN BY COPPER SULFATE, NONAUTOMATED
HGB, SINGLE ANALYTE INST. W/SELF-CONT...
HIV-1 AND HIV-2 ANTIBODIES
HIV-1 ANTIBODY
INFECTIOUS MONONUCLEOSIS ANTIBODIES (MONO)
INFLUENZA A
INFLUENZA A/B
INFLUENZA B
KETONE, BLOOD
KETONE, URINE
LACTIC ACID (LACTATE)
LDL CHOLESTEROL
LITHIUM
LUTEINIZING HORMONE (LH)
LYME DISEASE ANTIBODIES (BORRELIA BURGDORFERI ABS)
METHADONE
METHAMPHETAMINE/AMPHETAMINE
METHAMPHETAMINES
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
MICROALBUMIN
MORPHINE
NICOTINE AND/OR METABOLITES
OPIATES
OVULATION TEST (LH) BY VISUAL COLOR COMPARISON
OXYCODONE
PH
PHENCYCLIDINE (PCP)
PLATELET AGGREGATION
PROPOXYPHENE
PROTHROMBIN TIME (PT)
RESPIRATORY SYNCYTIAL VIRUS
SEMEN
SPUN MICROHEMATOCRIT
STREPTOCOCCUS, GROUP A
THYROID STIMULATING HORMONE (TSH)
TRICHOMONAS
TRICYCLIC ANTIDEPRESSANTS
TRIGLYCERIDE
URINE DIPSTICK OR TABLET ANALYTES, NONAUTOMATED
URINE HCG BY VISUAL COLOR COMPARISON TESTS
URINE QUALITATIVE DIPSTICK ASCORBIC ACID
URINE QUALITATIVE DIPSTICK BILIRUBIN
URINE QUALITATIVE DIPSTICK BLOOD
URINE QUALITATIVE DIPSTICK CHEMISTRIES
URINE QUALITATIVE DIPSTICK CREATININE
URINE QUALITATIVE DIPSTICK GLUCOSE
URINE QUALITATIVE DIPSTICK KETONE
URINE QUALITATIVE DIPSTICK LEUKOCYTES

URINE QUALITATIVE DIPSTICK NITRITE
URINE QUALITATIVE DIPSTICK PH
URINE QUALITATIVE DIPSTICK PROTEIN
URINE QUALITATIVE DIPSTICK SPECIFIC GRAVITY
URINE QUALITATIVE DIPSTICK UROBILINOGEN
VAGINAL PH