ARCHITECT U.S. Assay Menu

160 Assays Available | **10 Assays in Development**

See subsequent pages for intended use and important safety information

Abbott

Assays in Development*

- High Sensitive Troponin I
- Tg
- Rubella IgG
- Rubella IgM
- Toxo IgG
- Toxo IgM
- CMV IgG
- CMV IgM
- HSV -1
- HSV -2

** - Not available in US*

IMMUNOASSAY

Cancer
AFP
CA 125
CA 15-3
CA 19-9 XR
CEA
Free PSA
HE-4 / ROMA
Total PSA

Cardiac
BNP
CK-MB
Galectin-3
Myoglobin
Troponin-I

Fertility / Pregnancy
DHEA-S
Estradiol
FSH
hCG (Total ß-hCG)
LH
Progesterone
Prolactin
SHBG
Testosterone

Infectious Disease
Anti-HAV IgG
Anti-HAV IgM
Anti-HBc
Anti-HBc IgM
Anti-HBs
Anti-HCV
HBsAg
HBsAg Confirmatory
HIV Ag/Ab Combo
Syphilis

Metabolic
Active-B12 (HoloTC)
Anti-CCP
B12
C-Peptide
Cortisol
Ferritin
Folate
Hemoglobin A1c
Homocysteine
Insulin
Intact PTH
Procalcitonin
Vitamin D

Therapeutic Drug Monitoring
Carbamazepine
Digoxin
Gentamicin
Phenobarbital
Phenytoin
Theophylline
Valproic Acid
Vancomycin

Thyroid
Anti-Tg
Anti-TPO
Free T3
Free T4
T-Uptake
Total T3
Total T4
TSH

Transplant
Cyclosporine
Sirolimus
Tacrolimus

CLINICAL CHEMISTRY

Drugs of Abuse /Toxicology
6-Acetylmorphine
Acetaminophen
Amphetamine/Methamphetamine
Barbiturates
Benzodiazepines (Urine/Serum)
Buprenorphine
Oxycodone
Cannabinoids
Cocaine
Ecstasy
Ethanol
Fentanyl
Methadone
Methadone (EDDP)
Opiates
Phencyclidine (PCP)
Propoxyphene
Salicylate
Tramadol
Tricyclic Antidepressants

General Chemistry
Acid Phosphatase
Alanine Aminotransferase (ALT)
Activated ALT
Albumin BCG
Albumin BCP
Alkaline Phosphatase
Ammonia
Amylase
Aspartate Aminotransferase (AST)
Activated AST
Calcium
Carbon Dioxide (CO2)

General Chemistry (cont)
Cholesterol
Creatine Kinase (CK)
Creatinine (Enzymatic/JAFFE)
Direct Bilirubin
Direct LDL (D-LDL)
Gamma-Glutamyl Transferase (GGT)
Glucose
HDL, Ultra
ICT Cl
ICT K
ICT Na
Iron (S, P)
Lactate Dehydrogenase (LD)
Lactic Acid
Lipase
Magnesium (Arsenazo)
Magnesium (Enzymatic)
Phosphorus
Total Bilirubin
Total Protein
Triglycerides
UIBC
Urea Nitrogen
Uric Acid, Next Generation
Urine/CSF Protein

Metabolic
Ferritin
Hemoglobin A1c
Hemoglobin A1c (Whole Blood)

Proteins
Alpha-1 Antitrypsin
Alpha-1 Glycoprotein

Proteins (cont)
Apolipoprotein A1
Apolipoprotein B
ASO
Beta2 Microglobulin
C-Reactive Protein
C-Reactive Protein (HS)
Ceruloplasmin
Complement C3
Complement C4
Free Light Chain: Kappa
Free Light Chain: Lambda
Haptoglobin
Immunoglobulin A (IgA)
Immunoglobulin E (IgE)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Lp(a)
Microalbumin (u)
Prealbumin
Rheumatoid Factor (RF)
Transferrin

Therapeutic Drug Monitoring
Amikacin
Carbamazepine
Digoxin
Gentamicin
Lithium
Phenobarbital
Phenytoin
Quinidine
Theophylline
Tobramycin
Valproic Acid
Vancomycin

CHOOSE TRANSFORMATION™

ADD-00060754

- Assay menu subject to platform

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ARCHITECT U.S. Assay Menu

INTENDED USE AND IMPORTANT SAFETY INFORMATION
•For *In Vitro* Diagnostic Use Only
•CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory.
•For complete assay information, see the assay specific package insert.

ARCHITECT AFP

Intended Use: The ARCHITECT AFP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of alpha-fetoprotein (AFP) in:
1. Human serum or plasma to aid in monitoring disease progression during the course of disease and treatment of patients with nonseminomatous testicular cancer.
2. Human serum, plasma and amniotic fluid at 15 to 21 weeks gestation to aid in the detection of fetal open neural tube defects (NTD). Test results when used in conjunction with ultrasonography or amniography are a safe and effective aid in the detection of fetal open NTD.
Important Safety Information: The concentration of alpha-fetoprotein (AFP) in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the AFP assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining AFP levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST:
1. For Cancer Management - Confirm baseline values for patients being serially monitored.
2. For Prenatal Testing - Establish a range of expected values for the new assay based on serum or plasma and amniotic fluid from pregnant women with confirmed gestational age.

United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

ARCHITECT Free PSA

Intended Use: The ARCHITECT Free PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free prostate specific antigen (PSA) in human serum. The ARCHITECT Free PSA assay is intended to be used in conjunction with the ARCHITECT Total PSA assay in men aged 50 years or older with total PSA values between 4 and 10 ng/mL and DRE non-suspicious for cancer to determine the % free PSA value. The ARCHITECT % free PSA value can be used as an aid in discriminating between prostate cancer and benign disease.
Important Safety Information: The concentration of free PSA in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the free PSA assay used. Values obtained with different assay methods cannot be used interchangeably. United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ARCHITECT Total PSA

Intended Use: The ARCHITECT Total PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of total PSA (both free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum:
- 1. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostatic biopsy is required for diagnosis of cancer.
- 2. As an adjunctive test to aid in the management of prostate cancer patients.

Important Safety Information: The concentration of total PSA in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the total PSA assay used. Values obtained with different assay methods, including Abbott PSA assays, cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining total PSA levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored. United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ARCHITECT Anti-HBc

Intended Use: The ARCHITECT CORE assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG and IgM antibodies to hepatitis B core antigen (anti HBc) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, sodium heparin) and neonatal serum. It is intended as an aid in the diagnosis of acute, chronic, or resolved hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

WARNING: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT CORE for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when the ARCHITECT CORE assay is used in conjunction with other manufacturers' assays for specific hepatitis markers. Users are responsible for establishing their own performance characteristics. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. Users are responsible for establishing their own assay performance characteristics in these populations.

Important Safety Information: Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

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ARCHITECT U.S. Assay Menu

INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

ARCHITECT Anti-HBc

Intended Use: The ARCHITECT CORE assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG and IgM antibodies to hepatitis B core antigen (anti HBc) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, sodium heparin) and neonatal serum. It is intended as an aid in the diagnosis of acute, chronic, or resolved hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

WARNING: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT CORE for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when the ARCHITECT CORE assay is used in conjunction with other manufacturers' assays for specific hepatitis markers. Users are responsible for establishing their own performance characteristics. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. Users are responsible for establishing their own assay performance characteristics in these populations.

Important Safety Information: Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

ARCHITECT HBsAg Qualitative

Intended Use: The ARCHITECT HBsAg Qualitative assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric serum and plasma and neonate serum. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. Not intended for use in screening blood, plasma, or tissue donors.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ARCHITECT HBsAg Qualitative Confirmatory

Intended Use: The ARCHITECT HBsAg Qualitative Confirmatory assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human adult and pediatric serum and plasma and neonate serum by means of specific antibody neutralization. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. Not intended for use in screening blood, plasma, or tissue donors.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ARCHTECT Anti-HBs (AUSAB)

Intended Use: The ARCHITECT AUSAB assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of antibody to hepatitis B surface antigen (anti-HBs) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. It is intended for quantitative measurement of antibody response following hepatitis B virus (HBV) vaccination, determination of HBV immune status, and for the laboratory diagnosis of HBV disease associated with HBV infection when used in conjunction with other laboratory results and clinical information.

WARNING: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT AUSAB for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

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ARCHITECT U.S. Assay Menu

INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

ARCHITECT Anti-HCV

Intended Use: The ARCHITECT Anti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies to hepatitis C virus (anti-HCV) in human adult serum and plasma (potassium EDTA, lithium heparin, and sodium heparin). Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection.

WARNING: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT Anti-HCV for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established for newborns, infants, children, or populations of immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ARCHITECT Anti-HBc IgM

Intended Use: The ARCHITECT CORE-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human adult and pediatric serum or plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HBc is indicated as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information.

WARNING: Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT CORE-M for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when the ARCHITECT CORE-M assay is used in conjunction with other manufacturers' assays for specific hepatitis markers. Users are responsible for establishing their own performance characteristics. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

ARCITECT HIV Ag/Ab Combo

Intended Use: The ARCHITECT HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV 1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin). The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1/HIV-2 infection in pediatric subjects (i.e., children as young as two years of age) and in pregnant women.

An ARCHITECT HIV Ag/Ab Combo reactive result does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody.

The ARCHITECT HIV Ag/Ab Combo assay is not intended for use in screening blood or plasma donors. The effectiveness of ARCHITECT HIV Ag/Ab Combo for use in screening blood or plasma donors has not been established. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical.

Important Safety Information: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

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