

Automated Solutions To Help Every Laboratory Improve Patient Care

Access® 2 Immunoassay System*

- Easy-to-use, bench-top analyzer offers high-performance in compact space
- Up to 100 tests per hour
- Refrigerated compartment enhances reagent stability
- Same expansive menu as larger platforms



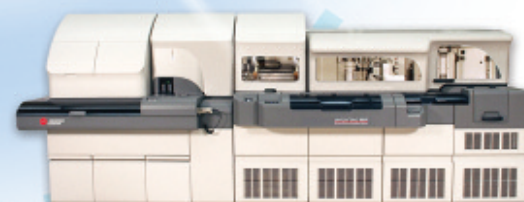
UniCel® Dxl 800 Access® Immunoassay System*

- Throughput up to 400 tests per hour
- 50 reagent packs on board at once allow you to configure menu to meet your testing needs
- Automation connection aligns with Clinical Laboratory Standards Institute guidelines



Broad and Expanding Menu

- Assays deliver clinically equivalent results on all analyzers
- Same reagent packs used on all analyzers simplifies inventory management
- Dedicated development of new and novel markers
- More than 55 Access assays available in the European Union



UniCel® DxC 880i Synchron® Access® Clinical System***

- Parallel processing of chemistry and immunoassay tests helps eliminate bottlenecks
- Integrated workcell for increased productivity
- Closed-tube sampling for both chemistry and immunoassay
- System throughput of up to 1440 chemistry and 400 immunoassay tests an hour***

* Check with your local sales representative for the availability of assays on each system.

** In development

*** Based on individual analyzer throughput.

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Managing Infectious Disease and Blood Virus Testing

Discover the Right Diagnostic Solutions with Beckman Coulter



The Access family of immunoassay systems from Beckman Coulter offers a broad menu of high-quality assays across a wide range of disease states. The Infectious Disease and Blood Virus (ID/BV) panels offer exceptional clinical performance, based on a history of research and innovation. Combined with simplified, automated instrument systems, including the high-throughput UniCel® Dxl 800, the UniCel® Dxl 600 for medium sized labs, the benchtop Access® 2 and the integrated workcell

Unicel® DxC 880i your laboratory has the versatility and comprehensive menu it needs.

Chemistry
Lab Automation
Information Systems
Immunodiagnosics
Centrifugation
Molecular Diagnostics
Disease Management
Hematology
Hemostasis
Flow Cytometry
Primary Care



Simplify • Automate • Innovate



Simplify • Automate • Innovate



Access® Blood Virus Assays

Hepatitis A: The pathology induced by the Hepatitis A virus (HAV) is characterized by a clinical picture from silent infection to acute hepatitis. HAV infection is diagnosed by detection of IgM and IgG directed against HAV in serum. Beckman Coulter offers these two serological markers to laboratories and clinicians to aid in the diagnosis of HAV.

HAV Ab

- Referenced against the WHO standard
- Quantitative assay for accurate determination of immune status
- Relative specificity: 99.8% (n=887)
- Relative sensitivity: 100% (n=433)

HAV IgM

- Early detection of rising IgM titer; high signal to cut-off ratio
- IgM immunocapture assay: helps reduce interference from rheumatoid factor
- Relative specificity: 99.9% (n= 1535)
- Relative sensitivity: 99.0% (n=210)

Hepatitis B: Hepatitis B virus (HBV) infection is recognized as a global health problem. The diagnosis of HBV is based on the presence of different serological markers expressed at known interval after exposure to the virus. Laboratories can take advantage of several different Beckman Coulter assays to aid in the diagnosis of HBV.

HBs Ag

- Analytical sensitivity: < 0.1 ng/mL SFTS^{*} Panel 2005
0.056 IU/mL WHO 00/588
0.020 PEI^{**} U/mL for “ad” subtype
0.024 PEI^{**} U/mL for “ay” subtype
- Genotype (A to G) recognition
- Detection of different HBsAg mutant forms (including G145R)
- Excellent Specific Margin (number of standard deviation between the mean of the negative population and the cut off)
- Relative specificity: 99.9% (n=5585)
- Relative sensitivity: 100% (n=410) with samples from subjects with acute or chronic hepatitis

HBs Ab

- Standardized to the WHO Reference Preparation W1042
- Analytical sensitivity:
1.87 mIU/mL for WHO
0.81 mIU/mL for SFTS panel
- Relative specificity: 98.1% (n=1831)
- Relative sensitivity: 98.4% (n=753)

HBc Ab

- Sensitivity PEI^{**}: <1 U/mL
- Relative sensitivity: 99.3 % (n=432)
- Relative specificity: 99.8% (n=5116)

HBc IgM

- IgM immunocapture assay: helps reduce interference from rheumatoid factor
- Relative specificity: 100% (n=1551)
- Relative sensitivity: 96.8% (n= 220)
- Relative sensitivity (chronic hepatitis follow up): 97.7% (n=130)

Hepatitis C and HIV: It is estimated that 170 million (WHO weekly report, 1999) and 40 million (UNAIDS report, 2005) people are infected by HCV or HIV, respectively. These viruses are a worldwide health problem. Thanks to a partnership with Bio-Rad, Beckman Coulter offers specific and sensitive assays to help laboratories and clinicians diagnose possible infections.

HCV Ab Plus^{***}

- Relative specificity: 99.8% (n= 5995 blood donors)
- Relative sensitivity: 100% with 511 well-documented positive samples

HIV 1/2 NEW^{***}

- Early detection of IgG-, IgM- and IgA-specific antibodies
- Relative specificity: 99.9% (n=5057 blood donors)
- Relative sensitivity: 100% with 765 well-documented positive samples (HIV-1 group M; HIV-1 group O; HIV-2)



Access® Infectious Disease Assays

Rubella: Rubella is a viral illness with worldwide distribution. The infection is usually benign or even unapparent in children and adults. Infections which occur in utero may result in serious birth defects. Beckman Coulter's Rubella IgG and IgM helps laboratories and clinicians assess immune status or detect seroconversion.

Rubella IgG

- Standardized against the WHO Reference Preparation, 2nd ISP
- Relative specificity: 99.4% versus HAI (Hemagglutination Inhibition test) and in pregnant/non-pregnant population
- Relative sensitivity: 98.3% versus HAI and in pregnant/non-pregnant population

Rubella IgM

- IgM immunocapture assay: helps reduce interference from rheumatoid factor
- Relative specificity: 99.8% (n=3383)
- Relative sensitivity: 100% (n=64) in an external study

Toxoplasma: Toxoplasmosis is a world health problem – at least 500 million people have antibodies against the *Toxoplasma gondii* parasite, even though the disease is often asymptomatic.¹ There is a risk of severe congenital abnormalities to a fetus if there is a primary infection of the mother just prior to or during pregnancy. Detection of Toxoplasma-specific IgG and IgM antibodies are used to determine the stage of the infection. Beckman Coulter assays aid in the diagnosis of toxoplasmosis.

Toxo IgG

- Standardized to the WHO 3rd International Standard (TOXM)
- Antigen highly enriched in membrane protein P30
- Relative specificity: 98.9% and 100% in hospitalized individuals (n=449) and pregnant women (n=196) population, respectively
- Relative sensitivity: 99.7% and 100% in hospitalized individuals (n=1333) and pregnant women (n=357) population, respectively

Toxo IgM II

- IgM immunocapture assay: helps reduce interference from rheumatoid factor
- Relative specificity: 99.9% (n=1035)
- Relative sensitivity: 98.3% (n=180)

References

1. Wendel S. Current concepts on the transmission of bacteria and parasites by blood components. Vox Sang 1994; 67: 161-74