

Accuracy in Action: Advancing Infectious Disease Management with High Sensitivity and Specificity

Early detection is essential for clinicians to initiate timely treatment and provide lifesaving care—and accurate laboratory test results are vital to this process.



Beckman Coulter offers a comprehensive and expanding infectious disease portfolio to help you address challenges, enhance workflow, and achieve actionable results. By leveraging the capabilities of the Dxl 9000 Immunoassay Analyzer, our highly sensitive and state-of-the-art assays equip your lab to meet the continually growing demands to deliver improved care to your patients.

What sets our infectious disease assays apart:

- **Excellent performance for informed decisions:** Manage complex infectious disease cases with our Infectious Disease portfolio including our 4th generation HIV assay which allows for earlier diagnosis by simultaneously detecting and differentiating HIV-1 p24 antigen and HIV-1/HIV-2 antibodies.
- **Workflow efficiencies:** Ready-to-use reagents and Beckman Coulter's validated **HBsAg High Positive algorithm** streamline operations, eliminates repeat testing for samples ≥ 100.00 S/CO.
- **High-quality products:** Our products, clinically validated at external sites, are designed to meet regulatory testing requirements while consistently upholding the highest quality and compliance standards.
- **Disease monitoring and collaborative research:** Committed to continuous improvement, we will monitor and test new strains to ensure our assays remain accurate and effective.

Assay Characteristics

Assay*	Sample Type	Sample Pickup (μL)	Time to First Result (minutes)	Onboard Stability (days)	Result Interpretation
Access HIV Ag/Ab combo	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	60	~30	56	< 1.00 S/CO Nonreactive ≥ 1.00 S/CO Repeatedly Reactive (initially reactive samples retested in duplicate)
Access anti-HCV	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	3	~22	56	< 1.00 S/CO Non-reactive ≥ 1.00 S/CO Repeatedly Reactive (initially reactive samples retested in duplicate)
Access HBsAg	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	45	~29	56	< 1.00 S/CO Nonreactive ≥ 1.00 to < 100.00 S/CO – Repeatedly Reactive (initially reactive samples retested in duplicate) ≥ 100.00 S/CO Reactive – No retest or additional confirmatory testing required
Access HBsAg Confirmatory	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	90	~29	56	< 1.00 S/CO Nonreactive ≥ 1.00 S/CO + ≥ 40% NT Confirmed Positive ≥ 1.00 S/CO + < 40% NT Not Confirmed, Dilute sample and retest in HBsAg Confirmatory assay per IFU
Access anti-HBc Total	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	105	~36	56	< 1.00 S/CO: Repeatedly reactive (initially reactive samples retested in duplicate) ≥ 1.00 S/CO: Nonreactive
Access anti-HBc IgM	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	10	~29	56	< 1.00 S/CO Nonreactive ≥ 1.00 S/CO Reactive
Access anti-HBs	Serum, SST, Li Hep, Li Hep Separator Tube	45	~30	56	< 10.00 mIU/mL: Nonreactive ≥ 10.00 mIU/mL: Reactive
Access Syphilis	Serum, SST, Li Hep, Li Hep Separator Tube, K ₂ EDTA, K ₃ EDTA, Na Citrate, ACD, CPD	50	~22	56	< 1.00 S/CO Nonreactive for Treponemal Antibodies ≥ 1.00 S/CO Repeatedly Reactive for Treponemal Antibodies (initially reactive samples tested in duplicate)

Elevate your confidence and efficiency with exceptional sensitivity and specificity.

Clinical Sensitivity

Assay	Number tested	Sensitivity %
Access HIV Ag/Ab combo	665/665	100.0 (99.43–100.0)
Access anti-HCV	510/510	100.0 (99.3–100.0)
Access HBsAg	455/455	100.0 (99.19–100.0)
Access anti-HBc Total	449/450	99.78 (98.75–99.96)
Access anti-HBc IgM	220/220	100.0 (98.28–100.0)
Access anti-HBs	399/406	98.28 (96.48–99.16)
Access Syphilis	544/545	99.82 (98.98–100.0)

Clinical Specificity

Assay	Number tested	Specificity %
Access HIV Ag/Ab combo	8,107/8,114	99.91 (99.82–99.96)
Access anti-HCV	7,319/7,349	99.6 (99.4–99.7)
Access HBsAg	7,064/7,070	99.92 (99.82–99.97)
Access anti-HBc Total	6,229/6,256	99.57 (99.37–99.7)
Access anti-HBc IgM	1,398/1,398	100.0 (99.73–100.0)
Access anti-HBs	917/926	99.03 (98.16–99.49)
Access Syphilis	5,874/5,881	99.88 (99.75–99.95)

Populations Evaluated: Blood donors, hospitalized patients, and patients infected with viral hepatitis, HIV, or syphilis.

Ordering Information

Access HIV Ag/Ab Combo

Access HIV Ag/Ab combo (2 packs, 100 tests/pack)	C39450
Access HIV Ag/Ab combo Calibrators (C1 for HIV-1 p24 antigen and C2 for HIV antibody, 1 vial each, 2.0 mL/vial)	C39451
Access HIV Ag/Ab combo QC (QC1–QC5, 1 vial each, 4.0 mL/vial) HIV Ag/Ab negative control, HIV-1 Ab, HIV-1 p24 Ag, HIV-2 Ab, and HIV-1 group O Ab positive)	C39452
Access HIV Ag/Ab combo QC II (QC1–QC3, 2 vials each, 4.0 mL/vial HIV Ag/Ab negative control, HIV-1 Ab, and HIV-1 p24 Ag positive)	C49254

Access anti-HCV

Access anti-HCV (2 packs, 100 tests/pack)	C39441
Access anti-HCV Calibrator C1 (1 vial/kit, 2.0 mL/vial)	C39442
Access anti-HCV QC (2 levels, 3 vials/level 4.0 mL/vial)	C39443

Access HBsAg and Access HBsAg Confirmatory

Access HBsAg (2 packs, 100 tests/pack)	C39422
Access HBsAg Calibrator (1 level, 1 vial, 2.0 mL/vial)	C39423
Access HBsAg QC (2 levels, 3 vials/level, 4.0 mL/vial, 2 QC cards)	C39424
Access HBsAg Confirmatory (2 packs, 50 tests/pack)	C39425

Access anti-HBc IgM

Access anti-HBc IgM (2 packs, 100 tests/pack)	C39428
Access anti-HBc IgM Calibrator (1 positive level for anti-HBc IgM, 2.0 mL/vial)	C39429
Access anti-HBc IgM QC QC1–QC2 (3 vials each of anti-HBc IgM positive control QC2 and anti-HBc IgM negative control QC1), 4.0 mL/vial	C39430

Access anti-HBc Total

Access anti-HBc Total (2 packs, 100 tests/pack)	C39432
Access anti-HBc Total Calibrator (1 positive level for anti-HBc antibody, 2.5 mL/vial)	C39433
Access anti-HBc Total QC QC1–QC2 (1 negative and 1 positive level), 3 vials each level, 4.0 mL/vial	C39434

Access anti-HBs

Access anti-HBs (2 packs, 100 tests/pack)	C39426
Access anti-HBs Calibrators (S0–S5 calibrators, 1 vial/level, 2 mL/vial)	C39427
Access anti-HBs QC QC1–QC2 (3 vials each of anti-HBs positive control and anti-HBs negative control) 4.0 mL/vial	C39431

Access Syphilis

Access Syphilis (2 packs, 100 tests/pack)	C80411
Access Syphilis Calibrators (C0–C1, 2.0 mL/vial, 1 vial each level)	C80412
Access Syphilis QC (QC1–QC2, 4.0 mL/vial, 3 vials each level)	C80413



*References: Access HIV Ag/Ab IFU C85578, Access anti-HCV IFU C77903, Access HBsAg IFU C84174, Access anti-HBc IgM IFU C96510, Access anti-HBc Total IFU C96517, Access anti-HBs IFU C88580, Access Syphilis IFU D05954

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