



February 19, 2026

Beckman Coulter, Inc.
Fatima Pacheco
Staff Regulatory Affairs Specialist
1000 Hazeltine Dr.
Chaska, Minnesota 55318

Re: K253687
Trade/Device Name: Access anti-HBc Total
Regulation Number: 21 CFR 866.3173
Regulation Name: Hepatitis B virus antibody assays
Regulatory Class: Class II
Product Code: SEI
Dated: November 21, 2025
Received: November 21, 2025

Dear Fatima Pacheco:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253687

Device Name
Access anti-HBc Total

Indications for Use (Describe)

The Access anti-HBc Total assay is a paramagnetic particle, chemiluminescent immunoassay for the in vitro qualitative detection of total antibodies to hepatitis B virus core antigen (anti-HBc) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K2) EDTA, tripotassium (K3) EDTA, sodium citrate, acid citrate dextrose (ACD) and citrate phosphate dextrose (CPD)] using the DxI 9000 Access Immunoassay Analyzer.

The Access anti-HBc Total assay may be used as an aid in the laboratory diagnosis of acute, chronic or resolved hepatitis B virus (HBV) infection of individuals with signs and symptoms of hepatitis or at risk for hepatitis B virus infection, including pregnant women, when used in conjunction with other laboratory results and clinical information.

The Access anti-HBc Total assay is for use on the DxI 9000 Access Immunoassay Analyzer only.
This assay is not intended for the screening of blood, plasma, and cell or tissue donors.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K253687

Date Prepared: February 18, 2026

Submitter Name and Address:

Beckman Coulter, Inc
1000 Lake Hazeltine Drive
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Primary Contact:

Fatima Pacheco
Staff Regulatory Affairs
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Device Trade Name: Access anti-HBc Total

Common Name: Qualitative and Quantitative Hepatitis B virus antibody assays

Classification Regulation: 21 CFR 866.3173

Class: II

Classification Product Code: SEI

Predicate Device

Device Name: ARCHITECT CORE

510(k) Numbers: P080023

Purpose for Submission: New device market clearance of Access anti-HBc Total assay for use on the Dxl 9000 Immunoassay Analyzer

Device Description

The Access anti-HBc Total assay requires Access anti-HBc Total (reagent packs), Access anti-HBc Total Calibrator (C1), and Access anti-HBc Total QC (QC1-QC2). The Access anti-HBc Total assay is a two-step competitive immunoassay. Paramagnetic particles coated with HBc antigen and sample are added to a reaction vessel. Anti-HBc antibodies present in the patient sample bind to the antigen-coated particles during the incubation, after which the material bound to the solid phase are held in a magnetic field while unbound materials are washed away. Alkaline phosphatase coupled to HBc monoclonal antibodies is added and this conjugate competes with the patient antibodies bound to the HBc antigens coated on the particles.

After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. A chemiluminescent substrate is then added to the vessel and light generated by the reaction is measured with a luminometer. The light production is compared to the cutoff value defined during calibration of the instrument. The qualitative assessment is automatically determined from a stored calibration.

Quality control (QC) materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access anti-HBc Total immunoassay. In addition, they are an integral part of good laboratory practices. When performing assays with Access reagents for anti-HBc Total, include quality control materials to validate the integrity of the assay. The assayed values should fall within the acceptable range if the test system is working properly.

The Access anti-HBc Total reagents are provided in liquid ready-to-use format designed for optimal performance on the Beckman Coulter Dxl 9000 Access Immunoassay Analyzer only. Each reagent kit contains two reagent packs. The Access anti-HBc Total Calibrator kit contains one vial, and the Access anti-HBc Total QC kit contains three vials, each of anti-HBc total positive control and anti-HBc total negative control. Other items needed to run the assay include Lumi-Phos PRO (chemiluminescent substrate) and UniCel Dxl Wash Buffer II.

Intended Use

The Access anti-HBc Total assay is a paramagnetic particle, chemiluminescent immunoassay for the *in vitro* qualitative detection of total antibodies to hepatitis B virus core antigen (anti-HBc) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K₂) EDTA, tripotassium (K₃) EDTA, sodium citrate, acid citrate dextrose (ACD) and citrate phosphate dextrose (CPD)] using the Dxl 9000 Access Immunoassay Analyzer.

The Access anti-HBc Total assay may be used as an aid in the laboratory diagnosis of acute, chronic or resolved hepatitis B virus (HBV) infection of individuals with signs and symptoms of hepatitis or at risk for hepatitis B virus infection, including pregnant women, when used in conjunction with other laboratory results and clinical information.

The Access anti-HBc Total assay is for use on the Dxl 9000 Access Immunoassay Analyzer only.

This assay is not intended for the screening of blood, plasma, and cell or tissue donors.

Substantial Equivalence Information

The Access anti-HBc Total and ARCHITECT CORE reagents employ prepackaged reagents for use on automated test systems. A comparison of the key device features, including similarities and differences of these assays, is shown in the following table.

Comparison Table

Features / Characteristics	Candidate Device Access anti-HBc Total	Primary Predicate (P080023) ARCHITECT CORE	Comment
Reagent Intended Use and Clinical Indications	<p>The Access anti-HBc Total assay is a paramagnetic particle, chemiluminescent immunoassay for the <i>in vitro</i> qualitative detection of total antibodies to hepatitis B virus core antigen (anti-HBc) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K₂) EDTA, tripotassium (K₃) EDTA, sodium citrate, acid citrate dextrose (ACD) and citrate phosphate dextrose (CPD)] using the Dxl 9000 Access Immunoassay Analyzer.</p> <p>The Access anti-HBc Total assay may be used as an aid in the laboratory diagnosis of acute, chronic or resolved hepatitis B virus (HBV) infection of individuals with signs and symptoms of hepatitis or at risk for hepatitis B virus infection, including pregnant women, when used in conjunction with other laboratory results and clinical information. The Access anti-HBc Total assay is for use on the Dxl 9000 Access Immunoassay Analyzer only.</p> <p>This assay is not intended for the screening of blood, plasma, and cell or tissue donors.</p>	<p>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.</p>	Similar
Calibrator and QC Intended Use	<p><u>Calibrator:</u> The Access anti-HBc Total Calibrator is intended to calibrate the Access anti-HBc Total assay for the <i>in vitro</i> qualitative detection of hepatitis B virus core total antibodies (anti-HBc) in human serum and plasma using the Dxl 9000 Access Immunoassay Analyzer.</p> <p><u>QC:</u> The Access anti-HBc Total QC is intended for monitoring system performance of the Access anti-HBc Total assay. The Access anti-HBc Total QC is for use on the Dxl 9000 Access Immunoassay Analyzer.</p>	<p><u>Calibrator:</u> The ARCHITECT CORE Calibrator is used for the calibration of the ARCHITECT i System when the system is used for the qualitative detection of IgG and IgM antibodies to hepatitis B core antigen (anti-HBc) with the ARCHITECT CORE Reagent Kit. The performance of the ARCHITECT CORE Calibrator has not been established with any other anti-HBc assays.</p> <p><u>QC:</u> The ARCHITECT CORE Controls are used for monitoring the performance of the ARCHITECT i System when used for the qualitative detection of IgG and IgM antibodies to hepatitis B core antigen (anti-HBc) with the ARCHITECT CORE Reagent Kit. The performance of the ARCHITECT CORE Controls has not been established with any other anti-HBc assays.</p>	Similar
Operating Principle	Two-step competitive	Two-step immunoassay	Similar
Analyte Measured	anti-HBc	Same	Same
Assay Type	Qualitative	Same	Same
Detection Method	Automated, Chemiluminescence	Automated, CMIA	Similar

Features / Characteristics	Candidate Device Access anti-HBc Total	Primary Predicate (P080023) ARCHITECT CORE	Comment	
Reagent, Calibrator, and QC format	Liquid, ready to use	Same	Same	
Calibrator(s)	1-level C1 (positive)	2 levels Calibrator 1 (positive)	Same	
Control(s)	2-levels 1 Negative, 1 Positive	2-levels 1 Negative Control, 1 Positive Control	Same	
Sample Type	Serum and Plasma	Same	Same	
Compatible Anticoagulants	Serum, Serum separator tube, Plasma [Lithium Heparin, Lithium Heparin separator tube, Dipotassium EDTA, Tripotassium EDTA Sodium Citrate, Acid Citrate Dextrose (ACD) Citrate Phosphate Dextrose (CPD)]	Human serum, plasma (dipotassium EDTA, Lithium Heparin, Sodium Heparin)	Similar	
Sample Volume	105 µL	75 µL	Different	
Instrumentation	Dxl 9000 Access Immunoassay Analyzer	ARCHIECT i Systems	Different	
Test Result Reporting	≥ 1.00 S/CO Non-reactive < 1.00 S/CO Reactive	Initial Results		
		Initial Result (S/CO)	Interpretation	Retest Procedure
		< 0.80	Nonreactive	No retest required.
		0.80 to < 1.21	Grayzone	Retest same specimen in duplicate.
		> 1.21	Reactive	Retest same specimen in duplicate.
		Final Interpretation		
		Initial Interpretation	Results with Retest	Final Interpretation
		Nonreactive	No retest required	Nonreactive
		Grayzone	If 2 of 3 results are < 1.00 S/CO	Nonreactive
			If 2 of 3 results are ≥ 1.00 S/CO	Reactive
Reactive	If both retest results are < 1.00 S/CO	Nonreactive		
			Different	

Features / Characteristics	Candidate Device Access anti-HBc Total	Primary Predicate (P080023) ARCHITECT CORE		Comment
			If 2 of 3 of the results are ≥ 1.00 S/CO Reactive	
Traceability/ Standardization	Calibrator is traceable to the manufacturer's working calibrator.	ARCHITECT CORE Calibrator is standardized against the reference standard of the Paul Ehrlich Institute Germany.		Same
Time to Result	~ 36 minutes	~ 29 minutes		Different
Reagent Storage and Stability	Unopened at 2 to 10°C up to stated expiration date	Unopened at 2 to 8°C up to stated expiration date		Similar
Reagent In-use (On-board) Stability	45 days	30 days		Different
Calibration Frequency	56 days	30 days		Different

Summary of Studies

Clinical Performance

Expected Results

The US study population represented 58.8% White, 26.1% Black or African American, 4.2% Asian, 1.8% American Indian or Alaska Native, 0.2% Native Hawaiian or other Pacific Islander, and 8.9% from unknown/other or unwilling to answer. 33.2% of the prospective study population was of Hispanic ethnicity. The majority of patients were female (58.4% female and 41.6% male) from the following states: Arizona (585, 24.5%), California (118, 4.9%), Connecticut (125, 5.2%), Florida (304, 12.7%), Georgia (61, 2.6%), Idaho (71, 3.0%), Minnesota (68, 2.8%), North Carolina (1, 0.0%), New Jersey (91, 3.8%), New York (444, 18.6%), Ohio (8, 0.3%), Pennsylvania (58, 2.4%), South Carolina (33, 1.4%), Tennessee, (39, 1.6%), Texas (380, 15.9%), and Virginia (5, 0.2%). Each sample was tested at one of three clinical sites located in Minneapolis, MN; Louisville, KY; or Baltimore, MD using the Access anti-HBc Total assay and a commercially available anti-HBc Total assay.

The Access anti-HBc Total results for the study population for all clinical trial sites combined by age group and sex are summarized in the table below. Samples were considered reactive if S/CO was < 1.00 upon testing and non-reactive if S/CO was ≥ 1.00.

Distribution of Access anti-HBc Total Reactive and Nonreactive Results by Age Range and Sex

Access anti-HBc Total						
Age Range (years)	Sex	Reactive		Nonreactive		Total
		N	%	N	%	
2-12	Female	0	0	6	100	6
	Male	0	0	11	100	11
13-18	Female	1	2.9	33	97.1	34
	Male	0	0	24	100	24
19-21	Female	0	0	73	100	73
	Male	2	7.1	26	92.9	28
22-29	Female	6	2.0	296	98.0	302
	Male	4	3.6	106	96.4	110
30-39	Female	8	2.9	270	97.1	278
	Male	18	13.4	116	86.6	134
40-49	Female	21	10.8	173	89.2	194
	Male	42	25.8	121	74.2	163
50-59	Female	64	23.6	207	76.4	271
	Male	105	42.9	140	57.1	245
60-69	Female	47	27.6	123	72.4	170
	Male	90	45.7	107	54.3	197
70-79	Female	15	26.3	42	73.7	57
	Male	15	25.0	45	75.0	60
	Female	2	20.0	8	80.0	10

Access anti-HBc Total						
Age Range (years)	Sex	Reactive		Nonreactive		Total
		N	%	N	%	
80-89	Male	3	16.7	15	83.3	18
90+	Female	0	0	1	100	1
	Male	0	0	5	100	5
Total		443	18.5	1,948	81.5	2,391

Method Comparison

A multi-center study was conducted using the Dxl 9000 Access Immunoassay Analyzer to evaluate the ability of the Access anti-HBc Total assay to detect anti-HBc Total in serum specimens from the intended use population. The study population included 2,391 prospectively collected specimens. Of the 2,391 specimens collected, 2,065 were from non-pregnant adults classified as increased risk for hepatitis due to lifestyle, behavior, occupation, or known exposure events, or individuals with signs and symptoms of hepatitis. 171 prospective specimens were from the pregnant population with increased risk and/or showed signs and symptoms of hepatitis. Specimens from the pregnant population included 71 from the first trimester, 67 from the second trimester, and 33 from the third trimester. In addition, 155 were pediatric (2 – 21 years) specimens with increased risk and/or sign & symptoms. The table below summarizes the number of specimens in each population.

Cohort	Adult (Non-Pregnant)	Pregnant	Pediatric (Non-Pregnant)
	IR/S&S* (N)	IR/S&S (N)	IR/S&S (N)
Total (n=2,391)	2,065	171	155

*IR/S&S =Increased Risk and/or Signs & Symptoms

Comparison of Results HBV Classification Category

Access anti-HBc Total results for each HBV classification were compared with the final interpretation from the reference anti-HBc Total assay used for classification. The results for the intended use population are described in the table below.

Cohort	Reference anti-HBc Total				Total (N)
	Reactive		Nonreactive		
	Access anti-HBc Total				
	Nonreactive	Reactive	Nonreactive	Reactive	
	(N)	(N)	(N)	(N)	
Acute	0	1	2	0	3
Recovery	1	199	1	3	204
Chronic	3	93	0	0	96
Immune due to natural infection	3	121	0	0	124
Immune due to HBV Vaccination	0	0	834	11	845
Not Previously Infected	0	0	1,099	7	1,106
Not interpretable/ Unknown profile ^a	0	7	4	0	11
Missing Test Data ^b	0	1	1	0	2
Total	7	422	1,941	21	2,391

a Samples were classified as "Not Interpretable" if their HBV seroprofile was predefined in the study protocol, and "Unknown" if not predefined. For data presentation, these are grouped as "Not Interpretable/Unknown", due to both groups having atypical seropatterns not aligning with HBV classification criteria.

b Samples were classified as "Missing Test Data" if insufficient volume was available to determine the HBV classification.

Positive percent agreement and negative percent agreement between the Access anti-HBc Total assay and the reference assay final interpretation for the intended use population is summarized in the following table.

Total	PPA		NPA	
	% (n/N)	95% CI	% (n/N)	95% CI
2,391	98.4 (422/429)	96.67 - 99.21	98.9 (1,941/1,962)	98.37 - 99.30

Comparison of Results - Overall Signs and Symptoms Population

Access anti-HBc Total	Reference anti-HBc Total assay		Total (N)
	Nonreactive (N)	Reactive (N)	
Nonreactive	163	1	164
Reactive	3	54	57
Total	166	55	221

- % Positive Agreement = 98.2% (54/55), 95% Confidence Interval = 88.66% to 99.62%
- % Negative Agreement = 98.2% (163/166), 95% Confidence Interval = 94.82% to 99.38%

Comparison of Results - Overall Increased Risk Prospective Population

Access anti-HBc Total	Reference anti-HBc Total assay		Total (N)
	Reactive (N)	Nonreactive (N)	
Reactive	368	18	386
Nonreactive	6	1,778	1,784
Total	374	1,796	2,170

- % Positive Agreement = 98.4% (368/374), 95% Confidence Interval = 96.54% to 99.26%
- % Negative Agreement = 99.0% (1,778/1,796), 95% Confidence Interval = 98.42% to 99.37%

Comparison of Results for Pregnant Women by Trimester

171 serum samples were prospectively collected from a pregnant population with risk factors and/or signs and symptoms of hepatitis B. Samples were tested using the Access anti-HBc Total assay and the reference anti-HBc Total assay. The results of anti-HBc Total testing at all sites combined by age group is presented in the following table.

Age Group	Trimester	Reference anti-HBc Total assay	
		Reactive	Nonreactive
		Access anti-HBc Total	
		Reactive (N)	Nonreactive (N)
≤ 21 years	First	0	12
	Second	0	5

Age Group	Trimester	Reference anti-HBc Total assay	
		Reactive	Nonreactive
		Access anti-HBc Total	
		Reactive (N)	Nonreactive (N)
	Third	0	4
> 21 years	First	2	57
	Second	1	61
	Third	0	29
Total		3	168

The positive percent agreement and negative percent agreement between the Access anti-HBc Total assay and the reference anti-HBc Total assay for the pregnant women population is summarized in the following table. This population included 21 pregnant subjects of pediatric age range (18 – 21 years).

Trimester	Total	PPA		NPA	
		% (n/N)	95% CI	% (n/N)	95% CI
First	71	100.0 (2/2)	34.24 - 100.0	100.0 (69/69)	94.73 - 100.0
Second	67	100.0 (1/1)	20.65 - 100.0	100.0 (66/66)	94.50 - 100.0
Third	33	N/A	N/A	100.0 (33/33)	89.57 - 100.0
Overall	171	100.0 (3/3)	43.85 - 100.0	100.0 (168/168)	97.76 - 100.0

Comparison of Results for Pediatric Population

155 serum samples were prospectively collected from a pediatric (non-pregnant) population (2 – 21 years) with risk factors and/or signs and symptoms. Samples were tested using the Access anti-HBc Total assay and the reference anti-HBc Total assay. The results of anti-HBc Total testing are presented in the following table.

Access anti-HBc Total	Reference anti-HBc Total assay		Total (N)
	Reactive (N)	Nonreactive (N)	
Reactive	3	0	3
Nonreactive	0	152	152
Total	3	152	155

- % Positive Agreement = 100.0% (3/3), 95% Confidence Interval = 43.85% to 100.0%
- % Negative Agreement = 100.0% (152/152), 95% Confidence Interval = 97.54% to 100.0%

Seroconversion

Seven commercially available patient seroconversion panels were tested using the Access anti-HBc Total assay and a reference assay to determine the seroconversion sensitivity of the assay. Equivalent detection with no difference in bleed number was observed in 4 of the 7 panels and earlier detection by the Access anti-HBc Total assay was observed in 3 panels. The results are summarized in the table below.

Panel ID	First anti-HBc Total positive result from initial draw date		Access anti-HBc Total vs. Reference assay
	Access anti-HBc Total (days)	Reference assay (days)	Difference in bleed number from the first reactive bleed*
HBV-6281	41	41	0
HBV-9092	85	85	0
HBV-9093	49	49	0
HBV-9072	159	> 159**	≤ -1**
HBV-001	29	29	0
HBV-002	56	59	-1
HBV-004	65	71	-1

*The difference in bleed number is compared to the reference assay. For example, -1 indicates that the reference assay required 1 additional bleed before reactivity was determined compared to the Access anti-HBc Total assay.

**The panel never seroconverted from a nonreactive status to a reactive status with the reference anti-HBc Total assay.

Imprecision

The imprecision of the Access anti-HBc Total assay was evaluated in a study based on CLSI EP05-A3 guideline. The study design included two test runs per day over a minimum of 20 test days. A ten-member panel of serum (S1-S4) and plasma (P1-P4) patient samples and the two Access anti-HBc Total QC were assayed in each run in triplicate. Three lots each of Access anti-HBc Total reagent, two lots of Access anti-HBc Total Calibrator were tested on three Dxl 9000 Access Immunoassay Analyzers. The results are summarized in the following table.

Sample	N	Mean (S/CO)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Reagent Lot		Between-Instrument		Within Laboratory (overall)	
			SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV
QC1	2,160	6.24	0.170	2.7	0.225	3.6	0.099	1.6	0.156	2.5	0.093	1.5	0.350	5.6
QC2	2,160	0.31	0.015	N/A	0.018	N/A	0.000	N/A	0.009	N/A	0.010	N/A	0.027	N/A
S1	2,160	5.14	0.146	2.8	0.209	4.1	0.048	0.9	0.138	2.7	0.122	2.4	0.318	6.2
S2	2,160	1.20	0.046	3.9	0.060	5.0	0.020	1.7	0.032	2.7	0.016	1.4	0.087	7.2
S3	2,160	0.85	0.031	3.7	0.044	5.2	0.018	2.2	0.021	2.4	0.011	1.3	0.061	7.2
S4	2,160	0.10	0.005	N/A	0.004	N/A	0.003	N/A	0.003	N/A	0.002	N/A	0.008	N/A
P1	2,160	5.21	0.135	2.6	0.158	3.0	0.138	2.6	0.141	2.7	0.107	2.1	0.306	5.9
P2	2,160	1.16	0.051	4.4	0.050	4.3	0.049	4.2	0.033	2.8	0.015	1.3	0.094	8.1
P3	2,160	0.82	0.035	4.3	0.029	3.5	0.040	4.8	0.022	2.7	0.010	1.2	0.065	7.9
P4	2,160	0.09	0.005	N/A	0.003	N/A	0.004	N/A	0.003	N/A	0.002	N/A	0.008	N/A

Note: %CV are not meaningful when S/CO approaches zero. Results are noted as N/A.

Reproducibility

A 5-day reproducibility study was performed on the Dxl 9000 Access Immunoassay analyzer based on CLSI EP05-A3 guideline. An eight-member panel of patient samples, including serum and plasma samples, were assayed at three clinical sites, using one lot of Access anti-HBc Total reagent kit, on three

instruments (one instrument per site). Each panel member was assayed in replicates of three at two separate times per day. The results are summarized in the following table.

Sample	N	Mean (S/CO)	Repeatability Within Run		Between Run		Between Day		Between Site		Reproducibility	
			SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV	SD (S/CO)	%CV
S1	90	5.02	0.204	4.1	0.041	0.8	0.056	1.1	0.076	1.5	0.228	4.5
S2	90	1.20	0.059	4.9	0.005	0.4	0.030	2.5	0.043	3.6	0.079	6.6
S3	90	0.85	0.051	5.9	0.000	0.0	0.008	0.9	0.027	3.1	0.058	6.8
S4	90	0.10	0.007	N/A	0.001	N/A	0.001	N/A	0.006	N/A	0.010	N/A
P1	90	5.21	0.172	3.3	0.109	2.1	0.031	0.6	0.148	2.8	0.254	4.9
P2	90	1.15	0.065	5.6	0.056	4.9	0.000	0.0	0.062	5.4	0.105	9.2
P3	90	0.81	0.037	4.5	0.028	3.5	0.022	2.7	0.038	4.6	0.064	7.8
P4	90	0.09	0.007	N/A	0.003	N/A	0.001	N/A	0.005	N/A	0.009	N/A

Note: %CV are not meaningful when S/CO approached zero. Results are noted as N/A.

Interfering Substances

Testing was performed using two negative samples (one low negative and one high negative) and one reactive (one low positive) sample with substances at the concentrations indicated. Of the compounds tested, none were found to cause interference using the highest test concentrations indicated in the table below.

Potential Interferent	Highest Concentration Added
Hemoglobin	500 mg/dL
Total Protein	15 g/dL
Bilirubin conjugated	40 mg/dL
Bilirubin unconjugated	40 mg/dL
Triglycerides (Intralipid)	19.20 mmol/L (2,000 mg/dL)
Aspirin (acetylsalicylic acid)	167 µmol/L
Salicylic acid	207 µmol/L
Acetaminophen (paracetamol)	1,030 µmol/L
Ibuprofen	1,060 µmol/L
Atorvastatin	1.34 µmol/L
Lisinopril	0.607 µmol/L
Levothyroxine	0.552 µmol/L
Metformin	92.9 µmol/L
Amlodipine	0.183 µmol/L
Omeprazole	24.3 µmol/L
Sertraline	3.03 µmol/L
Cholesterol	400 mg/dL

The Access anti-HBc Total assay does not utilize biotin-streptavidin chemistry; as a result, it is not susceptible to biotin interference.

Cross Reactivity

A total of 280 samples were tested for anti-HBc Total cross-reactivity categories on both the Access anti-HBc Total assay and reference device. The Access anti-HBc Total assay results for cross-reactivity study demonstrate no cross reactivity on the Dxl 9000 Access Immunoassay. The results are summarized in the following table.

Category	Number of samples tested	Number of Reactive samples	Number of Nonreactive samples
Epstein-Barr virus (EBNA IgG or VCA IgG)	10	0	10
Cytomegalovirus (CMV)	10	0	10
Herpes simplex Virus-1 (HSV 1/2)	10	0	10
Human immunodeficiency virus (HIV)	10	0	10
Hepatitis A virus (HAV)	10	0	10
Hepatitis C virus (HCV)	10	0	10
Hepatitis E virus (HEV)	10	0	10
Alcoholic liver disease	10	0	10
Primary biliary cirrhosis	10	0	10
Flavivirus (Zika)	10	0	10
Flavivirus (Dengue)	10	0	10
Flavivirus (West Nile)	10	0	10
Influenza post-vaccination	10	0	10
HAMA	10	1	9
Anti-nuclear antibody (ANA)	10	0	10
Rheumatoid Factor	10	0	10
Systemic lupus erythematosus (SLE)	10	0	10
Multiple Myeloma	10	0	10
Pregnancy multipara	10	0	10
Pregnancy first trimester	10	0	10
Pregnancy second trimester	10	0	10
Pregnancy third trimester	10	0	10
Syphilis	10	0	10
Toxoplasmosis	10	0	10
Transplant recipient	10	0	10
Dialysis patients	10	0	10
Hemophiliac / Clotting factor	10	0	10
anti-E. coli (including E. coli urinary infection)	10	0	10
Rubella	10	0	10
Varicella Zoster Virus (VZV)	10	0	10
Measles	10	0	10
Mumps	10	0	10

Analytical Sensitivity

The Access anti-HBc Total assay was designed to have an analytical sensitivity of less than 1.40 IU/mL using the WHO 1st International Standard (IS) for Anti-HBc, NIBSC code: 95/522.

This study aimed at finding the minimum analyte level (IU/mL) that scientists were still able to detect the antibody in one sample. The analytical sensitivity was determined as the intersection point of fitted model and S/CO value being 1.00. The maximum overall analytical sensitivity results determined in this study are summarized in the following table.

Standard	Analytical Sensitivity
WHO 1 st International Standard NIBSC code: 95/522	0.69 IU/mL (95% CI: 0.69 - 0.69 IU/mL)

Matrix Equivalence

A matrix equivalence study was performed using a protocol based on CLSI EP09c, 3rd Edition. Matched donor sets consisting of nine specimen types each were used for the evaluation. Serum (without gel) served as the reference sample type. The results from the study demonstrate the equivalency between the reference sample type, serum (without gel) and the eight serum/plasma matrices evaluated. The results support use of human serum (without gel), serum separator tubes, or plasma (lithium heparin, lithium heparin with gel, dipotassium (K₂) EDTA, tripotassium (K₃) EDTA, sodium citrate, acid citrate dextrose (ACD), and citrate phosphate dextrose (CPD)) sample types.

Sample Stability

Sample Handling Stability

Sample handling and freeze/thaw stability was established for the Access anti-HBc Total assay on the Dxl 9000 Access Immunoassay Analyzer.

The study verified the following sample handling claims.

- Up to 72 hours when stored at 20-25°C
- Up to 7 days when stored at 2-8°C
- Up to 30 days, thaw samples no more than 4 times when stored at ≤ -20°C or colder.

Reagent Stability Studies

Access anti-HBc Total reagents shelf-life dating was established based on real time stability (RTS) studies for the Access anti-HBc Total reagent pack, Access anti-HBc Total Calibrator, and Access anti-HBc Total QC. The studies were performed to determine the shelf-life at the recommended storage condition (2-10°C), using a protocol based on CLSI EP25-ED2 guideline.

In-use studies were also performed using a protocol based on CLSI EP25-ED2 guideline. Each study included evaluation stability following simulated winter and summer transport stresses on the reagent packs, Calibrator, and QC.

Intra-Assay Carryover

Testing was conducted to assess the sample-to-sample and sample-to-reagent pack carryover on the Access anti-HBc Total assay. Test procedures were based on CSI EP10-A3 AMD guideline. No intra-assay carryover was observed with the Access anti-HBc Total assay tested on the Dxl 9000 Access Immunoassay Analyzer.

Hook Effect

A hook study was performed to evaluate if high levels of analyte in patient specimens result in a hook effect that changes the reported results of the Access anti-HBc Total assay on the Dxl 9000 Access Immunoassay Analyzer. The study was performed using a ten-dilution series originating from three anti-HBc Total positive samples. No hook effect (no change in result interpretation) was observed for this assay.

Substantial Equivalence Comparison Conclusion

The results of the non-clinical analytical and clinical performance studies demonstrate that the Beckman Coulter Access anti-HBc Total assay for use on the Dxl 9000 Access Immunoassay Analyzer is as safe, as effective, and performs as well as the predicate device.