January 27, 2026

Beckman Coulter, Inc.
Loretta Lydon O'toole
Staff Regulatory Affairs Specialist
1000 Lake Hazeltine Dr.
Chaska, Minnesota 55318

Re: K251995
Trade/Device Name: Access anti-HAV IgM
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Assays
Regulatory Class: Class II
Product Code: LOL
Dated: December 29, 2025
Received: December 29, 2025

Dear Loretta Lydon O'toole:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251995

Device Name
Access anti-HAV IgM

Indications for Use *(Describe)*
The Access anti-HAV IgM assay is a paramagnetic particle, chemiluminescent immunoassay for the in vitro qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) 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, and tripotassium (K3) EDTA] using the DxI 9000 Access Immunoassay Analyzer. The Access anti-HAV IgM assay results may be used as an aid in the laboratory diagnosis of acute or recent hepatitis A virus (HAV) infection in individuals with signs and symptoms of hepatitis A virus, when used in conjunction with other serological and clinical information.

This assay is not intended for use for screening donors of blood or blood products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K251995 **Date Prepared:** January 23, 2026

Submitter Name and Address:
Beckman Coulter, Inc
1000 Lake Hazeltine Drive
Chaska, MN 55318

Primary Contact:
Loretta Lydon O'Toole
Staff Regulatory Affairs Specialist
Email : lotoole@beckman.com

Device Trade Name: Access anti-HAV IgM
Common Name: Hepatitis A virus (HAV) serological assays
Classification Regulation: 21 CFR 866.3310
Class: 2
Classification Product Code: LOL

Predicate Device
Device Name: Abbott ARCHITECT HAVAB-M
510(k) Numbers: K063329

Purpose for Submission: New device market clearance of Access anti-HAV IgM assay for use on the DxI 9000 Immunoassay Analyzer

Device Description

The Access anti-HAV IgM assay requires Access anti-HAV IgM (reagent packs), Access anti-HAV IgM Calibrator (C1), and Access anti-HAV IgM QC (QC1-QC2). The Access anti-HAV IgM assay is a two-step sandwich immunoassay. Paramagnetic particles coated with anti-human IgM monoclonal antibody and prediluted sample are added to a reaction vessel. After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. HAV antigen and anti-HAV monoclonal antibody alkaline phosphatase conjugate are added. HAV antigen complexed to the conjugate binds to the IgM antibodies captured on the particles. A second separation and wash step removes unbound conjugate.

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 cut-off 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-HAV IgM immunoassay. In addition, they are an integral part of good laboratory practices. When performing assays with Access reagents for anti-HAV IgM, 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-HAV IgM reagents are provided in liquid ready-to-use format designed for optimal performance on the Beckman Coulter DxI 9000 Access Immunoassay Analyzer only. Each reagent kit contains two reagent packs. The Access anti-HAV IgM Calibrator kit contains one vial, and the Access anti-HAV IgM QC kit contains three vials each of anti-HAV IgM positive control and anti-HAV IgM negative control. Other items needed to run the assay include Lumi-Phos PRO (chemiluminescent substrate) and UniCel DxI Wash Buffer II.

Intended Use

The Access anti-HAV IgM assay is a paramagnetic particle, chemiluminescent immunoassay for the *in vitro* qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K_2) EDTA, and tripotassium (K_3) EDTA using the DxI 9000 Access Immunoassay Analyzer. The Access anti-HAV IgM assay results may be used as an aid in the laboratory diagnosis of acute or recent hepatitis A virus (HAV) infection in individuals with signs and symptoms of hepatitis A virus, when used in conjunction with other serological and clinical information.

This assay is not intended for use for screening donors of blood or blood products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).

Substantial Equivalence Information

The Access anti-HAV IgM and Abbott ARCHITECT HAVAB-M 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-HAV IgM	Primary Predicate (K063329) ARCHITECT HAVAB-M	Comment
Reagent Intended Use and Clinical Indications	The Access anti-HAV IgM assay is a paramagnetic particle, chemiluminescent immunoassay for the *in vitro* qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K_2) EDTA, and tripotassium (K_3) EDTA using the DxI 9000 Access Immunoassay Analyzer. The Access anti-HAV IgM assay results may be used as an aid in the laboratory diagnosis of acute or recent hepatitis A virus (HAV) infection in individuals with signs and symptoms of hepatitis A virus, when used in conjunction with other serological and clinical information. This assay is not intended for use for screening donors of blood or blood products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).	The ARCHITECT HAVAB-M assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, and sodium heparin) and neonatal serum. A test for IgM anti-HAV is indicated for testing of specimens from individuals who have signs and symptoms consistent with acute hepatitis. Test results are used in conjunction with other laboratory results and clinical information as an aid in the diagnosis of acute or recent hepatitis A viral infection. Not intended for use in screening blood, plasma, or tissue donors. The effectiveness of ARCHITECT HAVAB-M for use in screening blood, plasma, or tissue donors has not been established. The assay is intended for use on the ARCHITECT i System.	Similar
Calibrator and QC Intended Use	Calibrator: The Access anti-HAV IgM Calibrator is intended to calibrate the Access anti-HAV IgM assay for the *in vitro* qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) in human serum and plasma). The Access anti-HAV IgM Calibrator is for use on the DxI 9000 Access Immunoassay Analyzer. QC: The Access anti-HAV IgM QC is intended to monitor system performance of the Access anti-HAV IgM assay. The Access anti-HAV IgM QC is for use on the DxI 9000 Access Immunoassay Analyzer.	Calibrator: The ARCHITECT HAVAB-M Calibrator is used to calibrate the ARCHITECT i System when the system is used for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) using the ARCHITECT HAVAB-M Reagent Kit. The performance of the ARCHITECT HAVAB-M Calibrator has not been established with any other IgM anti-HAV assays. QC: The ARCHITECT HAVAB-M Controls are used for monitoring the performance of the ARCHITECT i System when used for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) using the ARCHITECT HAVAB-M Reagent Kit. The performance of the ARCHITECT HAVAB-M Controls has not been established with any other IgM anti-HAV.	Similar

Features / Characteristics	Candidate Device Access anti-HAV IgM	Primary Predicate (K063329) ARCHITECT HAVAB-M	Comment
Operating Principle	Two-step, sandwich	Two-step, sandwich	Same
Analyte Measured	anti-HAV IgM	anti-HAV IgM	Same
Assay Type	Qualitative	Qualitative	Same
Detection Method	Automated, Chemiluminescence	Automated, Chemiluminescence	Same
Reagent, Calibrator, and QC format	Liquid, ready to use	Liquid, ready to use	Same
Calibrator(s)	1-level (positive) C1	1 level (positive) Calibrator 1	Same
Control(s)	2-levels 1 Negative, 1 Positive	2-levels 1 Negative, 1 Positive	Same
Sample Type	Serum and Plasma	Serum and Plasma	Same
Compatible Anticoagulants	Serum, Serum separator tube, Plasma [Lithium Heparin, Lithium Heparin separator tube, dipotassium (K_2) EDTA, and tripotassium (K_3) EDTA]	Human adult and pediatric serum and plasma (dipotassium EDTA, lithium heparin, sodium heparin) and neonatal serum	Different
Sample Volume	10 µL	70 µL	Different
Instrumentation	DxI 9000 Access Immunoassay Analyzer	ARCHITECT i System	Different
Final Test Result Reporting	≥ 1.00 S/CO Reactive < 1.00 S/CO Nonreactive	<0.80 S/CO Nonreactive 0.80 to <1.21 S/CO Grayzone ≥ 1.21 S/CO Reactive	Similar
Traceability/ Standardization	Calibrator: The value assigned was established using representative samples from the lot of calibrator and are specific to the assay methodologies of the Access reagents. QC: The analyte in the Access anti-HAV IgM QC is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.	Calibrator: Calibrator 1 is referenced against an Abbott Internal Reference Standard. This internal reference standard is manufactured by dilution of IgM anti-HAV reactive human plasma with IgM anti-HAV nonreactive human plasma. QC: The ranges for the controls are not lot specific and represent the total range of values which may be generated throughput the life of the product.	Similar
Time to Result	~29 minutes	29 minutes	Same
Reagent Storage and Stability - Unopened	Unopened at 2 to 10°C up to stated expiration date	Unopened at 2 to 8°C up to stated expiration date	Similar
Reagent Stability - After Opening	56 days	30 days	Different
Calibration Frequency	56 days	Once the calibration is accepted and stored, all subsequent samples may be tested without further calibration unless: • A reagent kit with a new lot number is used • Controls are out of range	Different

Standard/Guidance Document Referenced (if applicable):

1. Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays, Feb. 9, 2006
2. CLSI EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures*; 2014 (Reaffirmed September 2019)
3. CLSI EP07-A3, *Interference Testing in Clinical Chemistry*; 2018
4. CLSI EP37, First edition, Supplemental Tables for Interference Testing in Clinical Chemistry
5. CLSI EP09c 3rd Edition*, Measurement Procedure Comparison and Bias Estimation Using Patient Samples*, 2018
6. CSI EP10-A3 AMD, *Preliminary Evaluation of Qualitative Clinical Laboratory Measured Procedures*; 2014
7. CLSI EP25-ED2, *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents*; 2023
8. CLSI GP44-A4, *Procedures for Handling and Processing of Blood Specimens for Common Laboratory Tests*; 2010

Summary of Studies

Clinical Performance

Expected Results

The prospective study population was 61.08% White, 36.94% Black or African American, 0.53% Asian, 0.40% American Indian or Alaska Native, and 1.06% other. 45.91% of the prospective study population was of Hispanic ethnicity. 50.66% of the patients were female, 49.21% were male, and 0.13% were unknown. Patients in the prospective population were from the following states: Arizona (8, 1.06%), California (103, 13.59%), Florida (205, 27.04%), Idaho (72, 9.50%), North Carolina (13, 1.72%), Texas (295, 38.92%), and Virginia (62, 8.18%). Each sample was tested at one of three clinical sites located in Eden Prairie, MN; Minneapolis, MN; or Louisville, KY; using the Access anti-HAV IgM assay and commercially available anti-HAV IgM assays.

Distribution of Access anti-HAV Reactive and Nonreactive Results Among the Prospective Cohort by Age Group and Sex

Access anti-HAV IgM							
Age Group (years)	Sex	Reactive		Nonreactive		Total	
		N	%	N	%	N	%
2-12	Female	1	0.13	20	2.37	21	2.77
	Male	0	0.00	18	3.43	18	2.37
13-18	Female	0	0.00	26	4.62	26	3.43
	Male	0	0.00	35	0.66	35	4.62
19-21	Female	0	0.00	5	0.40	5	0.66
	Male	0	0.00	3	7.26	3	0.40
22-29	Female	0	0.00	55	4.49	55	7.26
	Male	0	0.00	34	9.63	34	4.49
30-39	Female	0	0.00	73	10.16	73	9.63
	Male	0	0.00	77	11.48	77	10.16
40-49	Female	0	0.00	87	10.95	87	11.48
	Male	1	0.13	83	9.37	84	11.08
50-59	Female	0	0.00	71	8.97	71	9.37
	Male	0	0.00	68	0.13	68	8.97
	Not Provided	0	0.00	1	4.62	1	0.13
60-69	Female	0	0.00	35	5.80	35	4.62
	Male	0	0.00	44	1.32	44	5.80
70-79	Female	0	0.00	10	1.32	10	1.32
	Male	0	0.00	10	0.13	10	1.32
80-89	Female	0	0.00	1	99.74	1	0.13
Total		**2**	**0.26**	**756**	**2.37**	**758**	**100.00**

Method Comparison

A multi-center study was conducted using the DxI 9000 Access Immunoassay Analyzer to evaluate the ability of the Access anti-HAV IgM assay to detect the presence of IgM antibodies to HAV in serum specimens from the intended use population. The study population included 855 specimens, consisting of 758 collected prospectively and 97 collected retrospectively. In the prospective cohort, 263 were from patients classified with signs and symptoms of hepatitis A and 495 were from patients classified as increased risk for hepatitis A due to lifestyle, behavior, occupation, or known exposure events. In addition, 97 retrospective specimens were collected from the acute HAV population (known anti-HAV IgM positive). The table below summarizes the number of specimens in each population.

Cohort	Sub-category	Adult	Pediatric
Prospective (n = 758)	Signs & Symptoms HAV (n=263)	262	1
	Increased Risk of HAV Infection (n=495)	388	107
Retrospective (n = 97)	Acute HAV Infection (n=97)	87	10
Total (n=855)		**737**	**118**

Positive percent agreement and negative percent agreement between the Access anti-HAV IgM assay and the CRM status in the overall population is summarized below.

Cohort	PPA		NPA	
	% (n/N)	95% CI	% (n/N)	95% CI
Signs/Symptoms HAV	N/A (0/0)	N/A	100.0 (263/263)	(98.6-100.0)
Increased Risk of HAV Infection	N/A (0/0)	N/A	99.6 (493/495)	(98.5-99.9)
Acute HAV Infection	100.0 (88/88)	(95.8-100.0)	66.7 (6/9)	(35.4-87.9)
Total	**100.0 (88/88)**	**(95.8-100.0)**	**99.3 (762/767)**	**(98.5-99.7)**

Comparison of Results for Pediatric Population
Access anti-HAV IgM assay verses the CRM status.

Age Range (years)	anti-HAV IgM CRM				Total
	Reactive		Nonreactive		
	Access anti-HAV IgM				
	Reactive	Nonreactive	Reactive	Nonreactive	
2-12	0	0	1	38	39
13-18	2	0	0	61	63
19-21	8	0	0	8	16
Total	**10**	**0**	**1**	**107**	**118**

Positive percent agreement and negative percent agreement between the Access anti-HAV IgM assay and the CRM status in pediatric samples is summarized below.

Pediatric Cohort	PPA		NPA	
Age Range (years)	**% (n/N)**	**95% CI**	**% (n/N)**	**95% CI**
2-12	N/A (0/0)	N/A	97.4 (38/39)	(86.8-99.5)
13-18	100.0 (2/2)	(34.2-100.0)	100.0 (61/61)	(94.1-100.0)
19-21	100.0 (8/8)	(67.6-100.0)	100.0 (8/8)	(67.6-100.0)
Total	**100.0 (10/10)**	**(72.2-100.0)**	**99.1 (107/108)**	**(94.9-99.8)**

In addition, the Access anti-HAV IgM assay was evaluated using 46 retrospective native pediatric samples, ranging in age from 11 to 21 years, that were confirmed to be anti-HAV IgM reactive based on vendor certificate of analysis. These samples were tested with both the Access anti-HAV IgM assay and

an FDA-approved anti-HAV IgM comparator assay. All 46 samples yielded reactive results with both assays, demonstrating 100% concordance in this pediatric population.

Seroconversion

Four commercially available patient seroconversion panels were tested using the Access anti-HAV IgM assay and a commercially available anti-HAV IgM reference assay to determine the seroconversion sensitivity of the assay. Equivalent detection with no difference in bleed number was observed in three of the four panels and earlier detection by the Access anti-HAV IgM assay was observed in one panel. The results are summarized in the table below.

Panel ID	First anti-HAV IgM positive result from initial draw date		Access anti-HAV IgM vs Reference Assay
	Access anti-HAV IgM (days)	Reference Assay (days)	Difference in bleed number for the first reactive bleed*
0615-0026	14	14	0
HAV002SCP	109	109	0
HAV003SCP	58	66	-1
SCP-HAV-002	8	8	0

*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-HAV IgM assay.

Imprecision

The imprecision of the Access anti-HAV IgM assay was evaluated in a study based on CLSI EP05-A3 guideline. The study design included two test runs per day over 20 test days. An eight-member panel of serum (S1-S4) and plasma (P1-P4) patient samples and the two Access anti-HAV IgM QC were assayed in each run (in triplicate). Each sample was tested using two lots of Access anti-HAV IgM reagent and two lots of calibrator on one DxI 9000 Access Immunoassay Analyzer. The results presented below are representative of product performance.

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory		Calibrator Lot-to-Lot		Reagent Lot-to-Lot		Overall	
Sample	N	Mean (S/CO)	SD (S/CO)	%CV	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	480	0.02	0.00	2.2	0.00	2.3	0.00	0.4	0.00	3.2	0.00	3.4	0.00	10.8	0.00	11.8
QC2	480	2.79	0.07	2.6	0.07	2.5	0.11	4.1	0.15	5.4	0.10	3.4	0.04	1.4	0.18	6.6
S1	480	0.02	0.00	1.9	0.00	1.7	0.00	0.6	0.00	2.6	0.00	3.5	0.00	6.1	0.00	7.5
S2	480	0.68	0.01	1.8	0.03	3.8	0.00	0.0	0.03	4.2	0.02	3.5	0.06	8.4	0.07	10.0
S3	480	2.91	0.06	2.0	0.10	3.6	0.00	0.0	0.12	4.1	0.10	3.5	0.24	8.2	0.29	9.8
S4	480	5.41	0.11	2.0	0.18	3.4	0.00	0.0	0.21	3.9	0.19	3.5	0.44	8.2	0.53	9.7
P1	480	0.02	0.00	1.9	0.00	2.5	0.00	1.5	0.00	3.4	0.00	3.6	0.01	28.9	0.01	29.4
P2	480	0.69	0.01	1.8	0.03	4.0	0.03	5.1	0.05	6.7	0.02	3.4	0.05	6.9	0.07	10.2
P3	480	2.03	0.03	1.7	0.09	4.6	0.11	5.2	0.15	7.2	0.07	3.4	0.18	8.8	0.24	11.8
P4	480	15.15	0.32	2.1	0.69	4.6	0.87	5.8	1.16	**7.7**	0.50	3.3	0.99	6.5	1.60	10.6

Reproducibility

A 5-day reproducibility study was performed on the DxI 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 sites, using one lot of Access anti-HAV IgM reagent, on three instruments. Each panel member was assayed in replicates of three at two separate times per day. The results are summarized in the following table.

			Between-Run		Between-Day		Between-Site		Repeatability (Within-Run)		Reproducibility	
Sample	**N**	**Mean (S/CO)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
S1	90	0.03	0.00	0.0	0.00	4.1	0.00	16.0	0.00	8.2	0.01	18.4
S2	90	0.66	0.01	1.6	0.02	2.6	0.03	5.1	0.02	3.3	0.05	6.8
S3	90	2.01	0.01	0.6	0.04	2.0	0.10	5.2	0.09	4.4	0.14	7.1
S4	90	5.49	0.21	3.7	0.00	0.0	0.26	4.7	0.14	2.5	0.36	6.5
P1	90	0.02	0.00	4.8	0.00	0.0	0.00	2.0	0.00	7.3	0.00	9.0
P2	90	0.70	0.01	1.8	0.01	1.1	0.06	9.0	0.02	2.5	0.07	9.5
P3	90	1.99	0.05	2.3	0.04	2.1	0.11	5.7	0.04	1.9	0.13	6.7
P4	90	15.38	0.26	1.7	0.11	0.7	1.29	8.4	0.28	1.8	1.35	8.8

Interfering Substances

The Access anti-HAV IgM assay was evaluated for interference consistent with CLSI EP07 ED3 guideline. Testing was performed using one negative sample and two reactive (one low positive and one moderate positive) samples at the concentrations indicated. Of the compounds tested, none were found to cause interference using the highest test concentrations indicated in the following table.

Potential Interferent	Highest Concentration Added
Hemoglobin	1,000 mg/dL
Total Protein	15 g/dL
Bilirubin unconjugated	43 mg/dL
Bilirubin conjugated	43 mg/dL
Biotin	3,510 ng/mL
Triglycerides (Intralipid)	2,000 mg/dL (37 mmol/L)
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

Cross Reactivity

Cross-reactivity was evaluated by testing samples for potentially cross-reacting conditions. No cross-reactivity was observed. 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)	14	0	14
Cytomegalovirus (CMV)	12	0	12
Herpes simplex virus (HSV 1/2)	11	0	11
Human immunodeficiency virus (HIV)	20	0	20
Hepatitis A virus (HAV) IgG	17	0	17
Hepatitis B virus (HBV)	10	0	10
Hepatitis C virus (HCV)	14	0	14
Varicella Zoster Virus (VZV)	10	0	10
Influenza Vaccine	10	0	10
Alcoholic Liver Disease (ALD)	10	0	10
Primary Biliary Cirrhosis (PBC)	14	0	14
Rubella	11	0	11
Measles	10	0	10
Mumps	10	0	10
Syphilis	17	0	17
HAMA	20	0	20
Anti-nuclear antibody (ANA)	22	0	22
Rheumatoid Factor (RF)	14	0	14
Systemic lupus erythematosus (SLE)	20	0	20
Multiple Myeloma	13	0	13
Pregnancy multipara	10	0	10
Pregnancy first trimester	21	0	21
Pregnancy second trimester	13	0	13
Pregnancy third trimester	10	0	10
Toxoplasmosis	15	0	15

Matrix Equivalence

A matrix equivalence study was performed using a protocol based on CLSI EP09c, 3rd Edition. Matched donor sets consisting of six specimen types each were used for the evaluation. Serum (without gel) served as the reference sample type. The Access anti-HAV IgM assay detects HAV IgM antibodies in the following matrices.

Sample Type
Serum without Gel (Reference)
Serum with Gel
Plasma Lithium Heparin without Gel
Plasma Lithium Heparin with Gel
K_2 EDTA
K_3 EDTA

The specifications were met for all anti-coagulants, demonstrating that serum with and without gel, plasma (lithium heparin with and without gel, K_2 EDTA, and K_3 EDTA) are acceptable sample types for use with Access anti-HAV IgM assay.

Sample Stability

Sample Handling Stability

Sample handling and freeze/thaw stability was established the for the Access anti-HAV IgM assay on the DxI 9000 Access Immunoassay Analyzer. The study verified the following sample handling claims:

- 72 hours at 20-25°C
- 7 days at 2-8°C

If testing will not be completed within the timelines stated above, samples should be frozen at -20°C or colder. Do not thaw more than 5 times. All pre-defined acceptance criteria were met.

Fresh vs Frozen Sample Stability

The equivalency between fresh samples (never frozen, after storage at 2-8°C), and frozen samples after storage at ≤ -18°C for at least 16 hours with the Access anti-HAV IgM assay on the DxI 9000 Access Immunoassay Analyzer. The study was based on CLSI GP44-A4 guideline.

Passing-Bablok regression analysis was applied to evaluate the frozen sample results against the fresh sample results for all samples combined and for the reactive samples separately.

Fresh and frozen samples demonstrated equivalency using the Access anti-HAV IgM assay.

Fresh vs Frozen Samples Regression Analysis Results

N	All Samples Combined Slope Result	N	Reactive Samples Slope Result
51	1.01	41	1.02

Reagent Stability

Access anti-HAV IgM shelf-life dating was established based on real time stability (RTS) studies for the Access anti-HAV IgM reagent pack and Access anti-HAV IgM QC. The studies were performed to verify the stability 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 and QC.

Intra-Assay Carryover

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

Hook Effect

A hook study was performed to evaluate whether high levels of analyte in patient specimens result in a hook effect that changes the reported results of the Access anti-HAV IgM assay on the DxI 9000 Access Immunoassay Analyzer. The study was performed using a ten-dilution series originating from four anti-HAV IgM positive samples (three plasma and one serum). No hook effect (no change in result interpretation) is 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-HAV IgM assay for use on the DxI 9000 Access Immunoassay Analyzer is as safe, as effective, and performs as well as the predicate device.