510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number
K251995

B Applicant
Beckman Coulter, Inc.

C Proprietary and Established Names
Access anti-HAV IgM

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LOL	Class II	21 CFR 866.3310 - Hepatitis A Virus (HAV) Serological Assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:
Clearance of new device: Access anti-HAV IgM

B Measurand:
Anti-HAV IgM

C Type of Test:
Qualitative serology test

III Intended Use/Indications for Use:

A Intended Use(s):
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).

B Indication(s) for Use:
N/A

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:
The Access anti-HAV IgM assay is for use on the Dxl 9000 Access Immunoassay Analyzer only.

IV Device/System Characteristics:

A Device Description:
The Access anti-HAV IgM assay is a paramagnetic particle, chemiluminescent immunoassay.

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 Calibrator is used to establish calibration (determine the cutoff value) for the Access anti-HAV IgM assay. By comparing the light intensity generated by a sample to the cutoff value, the presence or absence of hepatitis A virus IgM antibodies in the sample is determined. 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.

The Access anti-HAV IgM reagents are provided in a liquid ready-to-use format designed for optimal performance on the DxI 9000 Immunoassay analyzer. Each reagent kit contains two reagent packs. The Access anti-HAV IgM Calibrator and Access anti-HAV IgM QC are packaged and sold separately. The calibrator kit contains one (positive level) vial, and the QC kit contains 2 levels (negative and positive) three vials per level.

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 using the DxI 9000 Access Immunoassay Analyzer.

The Access anti-HAV IgM QC is intended for monitoring 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.

Other items required to run the assay using the DxI 9000 Immunoassay analyzer include Lumi-Phos PRO substrate and UniCel DxI Wash Buffer II.

B Principle of Operation:

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.

Access anti-HAV IgM Results Interpretation

Test results are determined automatically by the system software. Results (Signal/Cutoff (S/CO)) are reported to be "reactive" or "nonreactive" as a function of their relationship with the "cutoff" (signal "less than the cutoff" or "greater than or equal to" the cutoff value). Test results can be reviewed using the appropriate screen.

Table 4. Access anti-HAV IgM Results Interpretation

Result (S/CO)	Interpretation	Reporting Instructions
< 1.00	Nonreactive	Report result as nonreactive for anti-HAV IgM antibodies
≥ 1.00	Reactive	Report result as reactive for anti-HAV IgM antibodies

C Instrument Description Information:

1. Instrument Name:

   DxI 9000 Access Immunoassay Analyzer

2. Specimen Identification:
   Specimen identification can be done by a bar code or by manual entry. Bar code labels are read by the analyzer or when ordered by the LIS or middleware. Orders that are entered manually include the rack ID and position, and bar code labels are not necessary for specimen identification.

3. Specimen Sampling and Handling:
   No specific requirements for specimen handling for the analyzer is needed. Each specific reagent IFU contains specimen handling instructions.

4. Calibration:
   Assay calibration can be performed when prompted by the DxI 9000 analyzer or when requested by the operator. Assay calibration data are automatically evaluated by the system, using acceptance criteria defined by the assay protocol file. A current (or active) assay calibration is required for each assay that is to be performed. For the Access anti-HAV IgM assay, calibration is required **every 56 days** or when:
   - The active calibration has expired.

- A new reagent pack lot number is used.
- Indicated by quality control data.
- A major system component has been repaired or replaced.

5. Quality Control:
   Quality control samples are tested to ensure the validity of the calibration curve and patient sample results generated. Control samples should be processed as recommended in the product labeling.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Abbott ARCHITECT HAVAB-M

B Predicate 510(k) Number(s):
K063329

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251995	K063329
Device Trade Name	Access anti-HAV IgM	Abbott ARCHITECT HAVAB-M
General Device Characteristic Similarities		
Intended Use/Indications For 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 (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	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.

	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).	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.
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. 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.
Operating Principle	Two-step, sandwich	Two-step, sandwich
Analyte Measured	anti-HAV IgM	anti-HAV IgM
Assay Type	Qualitative	Qualitative
Detection Method	Automated,	Automated,

	Chemiluminescence	Chemiluminescence
Sample Type	Serum and Plasma	Serum and Plasma
Time to Result	~29 minutes	29 minutes
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
General Device Characteristic Differences		
Compatible Anticoagulants	Serum, Serum separator tube, Plasma [Lithium Heparin, Lithium Heparin separator tube, dipotassium (K2) EDTA, tripotassium (K3) EDTA].	Serum and plasma (dipotassium EDTA, lithium heparin, sodium heparin)
Sample Volume	10 µL	70 µL
Instrumentation	DxI 9000 Access Immunoassay Analyzer	ARCHITECT i System
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
Reagent Stability - After Opening	56 days at 2-10ºC	30 days
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

VI Standards/Guidance Documents Referenced:

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays.

The following Standards were used for general use:

- CLSI GP44-A4 "Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition"
- CLSI EP05-A3 "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition"
- CLSI EP07-3rd Ed "Interference Testing in Clinical Chemistry - 3rd Edition"
- CLSI EP10-A3 AMD "Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition"
- CLSI EP25-2nd Ed "EP25 - Evaluation of Stability of In Vitro Medical Laboratory Test Reagents - 2nd Edition"

- CLSI EP09c 3rd Ed "Measurement Procedure Comparison and Bias Estimation Using Patient Samples - 3rd Edition"
- CLSI EP37 "Supplemental Tables for Interference Testing in Clinical Chemistry"
- CLSI EP12-A2 "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline-Second Edition"
- CLSI EP24-42 "Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - Second Edition"
- ISO 15223-1 4th Ed 2021-07 "Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements"
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION "Medical devices - Part 1: Application of usability engineering to medical devices"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   a) Precision:
   The precision study was performed at one site using four reagent pack lots and four calibrator lots on one DXI 9000 Analyzer. Four reagent-calibrator combinations were evaluated for each specimen. Four serum and plasma specimens were tested in triplicate over 20 consecutive days with 2 runs per day, producing 480 measurements per specimen. Results are summarized in table 1.

Table 1: Within-laboratory precision study results for the Access anti-HAV IgM assay

			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

b) Reproducibility:

Reproducibility was evaluated using the Access anti-HAV IgM assay on the DxI 9000 Access Immunoassay Analyzer at three testing sites. Serum and plasma specimens were tested in triplicate with two runs per day for five days, which generated 30 measurements per specimen per site. Results are summarized in table 2.

Table 2: Reproducibility study results for the Access anti-HAV IgM assay

			Between-Run		Between-Day		Between-Site		Repeatability (Within-Run)		Reproducibility	
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**
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

2. Linearity:

N/A

3. Analytical Specificity/Interference:

a) Cross-reactivity

Potential cross-reactivity in the Access anti-HAV IgM assay was evaluated using serum or plasma samples with antibodies to different infectious agents and related diseases. The anti-HAV IgM negative status of each specimen was verified using commercially available anti-HAV IgM assay. Confirmation of presence of cross-reactant in sample was obtained either from the certificate of analysis (CoA) or characterized on an FDA approved/cleared method. The cross reactants, number of samples tested, and results are summarized in table 3.

Table 3. Cross-reactivity study results for the Access anti-HAV IgM assay

Category	Number of Samples Tested	Number of Reactive Samples by the Access anti-HAV IgM	Number of Non-Reactive Samples by the Access anti-HAV IgM
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

b) Endogenous and exogenous interference

Potential interference of endogenous and exogenous substances with the Access anti-HAV IgM assay was evaluated using three serum samples: negative, low positive and moderate positive anti-HAV IgM. Each sample was spiked individually with each of the potential interfering substances. Test samples with potential interferents were compared to control samples without potential interferents. Of the compounds tested, none were found to cause interference using the highest test concentrations indicated in table 4.

Table 4. Interference study results for the Access anti-IgM assay

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

c) Class specificity

Five (5) anti-HAV IgG and anti-HAV IgM known positive samples (double positive samples) were evaluated to demonstrate that IgG does not generate false results on the Access anti-HAV IgM assay. Anti-HAV status was confirmed using FDA cleared assays. The final IgM results were evaluated before and after IgG depletion and no changes were observed in anti-HAV IgM results.

d) Hook Effect

Four samples (three plasma and one serum) with high anti-HAV IgM concentrations were serially diluted in anti-HAV IgM negative matrix to cover the range from negative to high positive S/CO values and tested in three replicates each with three reagent lots on up to three instruments. No hook effect was observed for this assay.

4. Assay Reportable Range:
   N/A

5. Stability (Controls, Calibrators, QC, and samples):
   a) Stability studies supported the following stability claims (Table 5).

Table 5. Stability claims for the Access anti-HAV IgM assay

Study	Storage temperature	Supported claim
QC Shelf-life	2-10ºC	90 days
QC Open vial	2-10ºC	62 days
Reagent Shelf-life	2-10ºC	219 days
Reagent Open vial	2-10ºC	56 days
Calibrator Shelf-life	2-10ºC	88 days
Calibrator Open vial	2-10ºC	30 days
Calibration curve	n/a	56 days
Sample stability	20-25ºC 2-10ºC Freeze/Thaw cycles	72 hours 7 days N=5

b) Fresh/Frozen samples

The equivalency of fresh (never frozen) and frozen samples was demonstrated using a total of 51 samples including negative, low positive, and moderate positive samples. One aliquot of each sample was stored at 2-8°C and the other one was stored frozen at ≤ -18°C. The frozen aliquots were thawed and tested in parallel with the refrigerated samples. Fresh and frozen samples demonstrated equivalent results using the Access anti-HAV IgM assay.

6. Detection Limit:
   N/A

7. Analytical Sensitivity:
   a) Seroconversion

Seroconversion sensitivity of the Access anti-HAV IgM assay was evaluated in comparison to a comparator anti-HAV assay using four commercially available seroconversion panels. For each panel, the number of days to the first reactive result was the same between the comparator and the candidate assay. The results are summarized in table 6.

Table 6. Seroconversion sensitivity results for the Access anti-HAV IgM assay

Panel ID	First anti-HAV positive result from initial draw date		Access anti-HAV IgM vs comparator assay
	Access anti-HAV IgM (days)	Comparator 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

8. Assay Cut-Off:
   The Access anti-HAV IgM assay cut-off was determined by testing 268 specimens (54 positive and 214 negative) using two reagent lots. Specimen status was determined by testing on three FDA cleared assays. The Access anti-HAV IgM assay has a cut-off of 1.0 S/CO.

9. Accuracy (Instrument):
   N/A

10. Carry-Over:
    Sample-to-sample and sample-to-reagent pack carryover on the Access anti-HAV assay was evaluated in multiple runs alternating high positive and negative samples. No intra-assay carryover was observed.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   The assay performance was evaluated using a total of 855 patient specimens, 758 prospectively and 97 retrospectively collected from cohorts summarized in table 7. Three FDA cleared assays were used as comparator assays to determine the final anti-HAV IgM status of samples. Specimens were tested at three sites by the Access anti-HAV IgM and at one of the sites on the comparator devices. The agreement results for all cohorts and performance for adult and pediatric populations separately are summarized in table 8.

Table 7. Number of specimens and test agreements for all cohorts between the Access anti-HAV IgM and comparator assays

Cohort/Patient Category	anti-HAV IgM status by comparator assays				Total
	Nonreactive		Reactive		
	Access anti-HAV IgM				
	Nonreactive	Reactive	Nonreactive	Reactive	

Adult at-risk for HAV infection (prospective)	387	1	0	0	388
Adult with signs and symptoms (prospective)	262	0	0	0	262
Pediatric at-risk/with signs and symptoms (prospective)	107	1	0	0	108
Adult acute HAV (retrospective)	6	3	0	78	87
Pediatric acute HAV (retrospective)	0	0	0	10	10
Total	**762**	**5**	**0**	**88**	**855**

Table 8. Access anti-HAV IgM clinical performance

Cohort/Patient Category	NPA		PPA	
	% (n/N)	95% CI	% (n/N)	95% CI
Adult at-risk for HAV infection (prospective)	99.74 (387/388)	98.5-99.9	N/A (0/0)	N/A
Adult with signs and symptoms (prospective)	100.0 (262/262)	98.5-100.0	N/A (0/0)	N/A
Pediatric (ages 2 to 21) at-risk/with signs and symptoms (prospective)	99.1 (107/108)	94.9-99.8	N/A (0/0)	N/A
Adult acute HAV (retrospective)	66.7 (6/9)	35.4-87.9	100.0 (78/78)	95.3-100.0
Pediatric acute HAV (retrospective)	N/A (0/0)	N/A	100.0 (10/10)	72.2-100.0
Overall	**99.3 (762/767)**	**98.5-99.7**	**100.0 (88/88)**	**95.8-100.0**

Supplemental retrospective pediatric study:
Additional anti-HAV IgM positive samples from a pediatric population (ages 11 to 21) were obtained from three commercial vendors. The anti-HAV IgM reactive status was based on the vendor certificates of analysis and confirmed by testing with an FDA cleared assay. Positive percent agreement (PPA) between the Access anti-HAV IgM assay and a comparator assay was 100.0 (46/46), 95% CI 92.2 – 100.0.

2. Matrix Comparison:
To verify equivalent performance between different blood matrices, 65 native matched specimens consisting of six specimen types each were analyzed: twenty-five negative (neat) and forty anti-HAV IgM positive contrived samples. Results demonstrated that serum with gel and plasma samples (lithium heparin with and without gel, K2 EDTA, and K3 EDTA)

present equivalent performance when compared to serum without gel (reference matrix) and are acceptable sample types for use with the Access anti-HAV IgM assay.

C Clinical Studies:

1. Clinical Sensitivity:
   N/A

2. Clinical Specificity:
   N/A

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   N/A

D Clinical Cut-Off:
N/A

E Expected Values/Reference Range:
N/A

VIII Proposed Labeling:
The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.