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

I Background Information:

A 510(k) Number

K243846

B Applicant

Beckman Coulter Inc.

C Proprietary and Established Names

Access anti-HAV

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

Clearance for marketing of Access anti-HAV Assay, Access anti-HAV QC and Access Anti-HAV Calibrator.

B Measurand:

Total (IgG and IgM) antibodies to Hepatitis A Virus.

C Type of Test:

Chemiluminescent immunoassay (CLIA).

III Intended Use/Indications for Use:

A Intended Use(s):

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

The Access anti-HAV assay is indicated as an aid in the diagnosis of current or past HAV infection in persons with risk factors and/or signs or symptoms of hepatitis A, when used in conjunction with other serological and clinical information. The assay may also be used in the identification of HAV susceptible individuals and to determine the presence of an antibody response to HAV in vaccine recipients.

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:

Same as intended use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use with the DxI 9000 Analyzer from Beckman Coulter, Inc.

IV Device/System Characteristics:

A Device Description:

The Access anti-HAV assay is a two-step competitive immunoassay for the qualitative detection of total antibodies (anti-HAV IgG and IgM) to hepatitis A virus (HAV) using the DxI 9000 Access Immunoassay. It requires Access anti-HAV (reagent packs), Access anti-HAV Calibrator (C1), and Access anti-HAV QC (QC1-QC2). All reagents are provided in a liquid ready-to-use format. Each reagent kit contains two reagent packs. Calibrator contains one positive sample. 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. The calibration acceptance criteria are automatically applied to the data and acceptance or rejection of data occurs without operator intervention. A current (or active) assay calibration is required for each assay that is to be performed.

QC kit contains 2 levels, positive and negative, three vials per level. The final QC value assignment is embedded in the barcode on the Access anti-HAV QC card provided with the QC kit. The analyte in the Access anti-HAV QC is traceable to the manufacturer's working

calibrators. Traceability process is standardized to the Second International Reference Standard for Anti-Hepatitis A Immunoglobulin, Human (NIBSC: 97/646). Traceability process is based on EN ISO 17511.

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:

Paramagnetic particles coated with hepatitis A virus antigen and sample are added to a reaction vessel. Anti-HAV antibodies in the patient sample bind to the coated antigen. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. A monoclonal anti-HAV antibody alkaline phosphatase conjugate is added to the reaction vessel and the conjugate competes with the bound patient antibodies to affix the HAV antigen coated on the particles. After a second incubation and a wash step, the chemiluminescent substrate is 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. The qualitative assessment is automatically determined from a stored calibration. Results (Signal/Cutoff (S/CO)) are reported to be "reactive" or "nonreactive" as a function of their relationship with the "cutoff". When signal less than the cutoff the result is reported as "reactive", when signal is greater than or equal to the cutoff the result is reported as "nonreactive". Test results can be reviewed using the appropriate screen.

Results interpretation:

Test results are determined automatically by the system software as follows.
≥ 1.00 S/CO Non-reactive
< 1.00 S/CO Reactive

C Instrument Description Information:

1. Instrument Name:

   DxI 9000 Immunoassay Analyzer

2. Specimen Identification:

   Total (IgG and IgM) antibodies to Hepatitis A Virus in human serum and plasma

3. Specimen Sampling and Handling:

   Collection tubes include serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, sodium citrate, acid-citrate-dextrose (ACD), and citrate phosphate-dextrose (CPD)]

4. Calibration:

   Access anti-HAV Calibrator consists of 1 level (positive) provided as liquid ready-to-use

5. Quality Control:

Access anti-HAV QC kit contains positive control and negative control as liquid ready-to-use

V Substantial Equivalence Information:

A Predicate Device Name(s):
Elecsys Anti-HAV II

B Predicate 510(k) Number(s):
K190428

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243846 Candidate	K190428 Predicate
Device Trade Name	Access anti-HAV	Elecsys Anti-HAV II
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Access anti-HAV assay is a paramagnetic particle, chemiluminescent immunoassay for the in vitro qualitative detection of total antibodies (anti-HAV IgG and IgM) to hepatitis A virus (HAV) in human pediatric (2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, sodium citrate, acid-citrate-dextrose (ACD), and citrate phosphate-dextrose (CPD)] using the DxI 9000 Access Immunoassay Analyzer. The Access anti-HAV assay is indicated as an aid in the diagnosis of current or past HAV infection in persons with risk factors and/or signs or symptoms of hepatitis A, when used in conjunction with other serological and clinical information. The assay may also be used in the identification of HAV susceptible individuals and to determine the presence of an antibody response to HAV in vaccine recipients. This assay is not intended for use for screening donors of blood or blood	Immunoassay for the in vitro qualitative detection of total antibodies (IgG and IgM) to hepatitis A virus (HAV) in human pediatric (ages 2 through 21 years) and adult serum and plasma (Li heparin, potassium EDTA, Na citrate, Na heparin). The assay, in conjunction with other serological and clinical information, is indicated as an aid in the clinical laboratory diagnosis of acute or past hepatitis A virus infection in persons with signs or symptoms of hepatitis and in persons at increased risk for hepatitis A infection, or as an aid to identify HAV susceptible individuals and to determine the presence of an antibody response to HAV in vaccine recipients. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas e immunoassay analyzers. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. This

	products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).	assay has not been FDA cleared or approved for the screening of blood or plasma donors.
Principle	Competitive CLIA	Competitive eCLIA (electro CLIA)
Analyte	aHAV IgM and IgG	aHAV IgM and IgG
Assay Type	Qualitative	Qualitative
Controls	2 levels, 1 Positive, 1 Negative	2 levels, 1 Positive, 1 Negative
Result interpretation	≥ 1.00 S/CO Non-reactive < 1.00 S/CO Reactive	COI > 1.0 Non-reactive COI ≤ 1.0 Reactive
Reference standard (NIBSC code: 97/646)	Second International Standard for Anti-Hepatitis A, Immunoglobulin, Human, NIBSC code: 97/646	Second International Standard for Anti-Hepatitis A, Immunoglobulin, Human, NIBSC code: 97/646
General Device Characteristic Differences		
Instruments	DxI 9000	Cobas e 601
Calibration Method	1-point (positive), sold separately	2-point (positive and negative), packed in kit
Matrices (compatible anticoagulants)	Serum, Serum separator tube, Plasma (Lithium Heparin, Lithium Heparin separator tube Sodium Citrate, Acid Citrate Dextrose (ACD), Citrate Phosphate Dextrose (CPD))	Human serum, plasma (Li-Heparin, potassium EDTA, Na-Citrate, Na-Heparin)
Units	S/CO	COI (cutoff indices)
Volume of specimen needed	55 uL	20 uL
Time to result	41 min	18 min
Reagent On-board stability	21 days	8 weeks
Calibration frequency	28 days	8 weeks

VI Standards/Guidance Documents Referenced:

1. Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays; 2006.

2. CLSI EP05-A3 (R2019): Evaluation of Precision of Quantitative Measurement Procedures; 2019.

3. CLSI EP07-A3: Interference Testing in Clinical Chemistry; 2018.

4. CLSI EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples, Third Edition; 2018.

4. CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition; 2008.

5. CLSI EP24-A2: Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline – Second Edition; 2011.

6. CLSI EP25: Evaluation of Stability of *In Vitro* Medical Laboratory Reagents – Second Edition; 2023.

7. CLSI EP37: Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition; 2018.

8. CLSI EP41, Collection of Diagnostic Venous Blood Specimens – Seventh Edition; 2017.

9. GP44-A4 (Formerly H18-A4): Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline-Fourth Edition; 2014.

10. ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements – Fourth Edition; 2021.

11. ISO 17511: *In vitro* diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators trueness control materials and human samples – second edition; 2020.

12. IEC 62304: Medical device software - Software life cycle processes – Edition 1.1; 2015.

13. IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices Edition 1; 2015.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A. Precision.

Within-laboratory precision of the Access anti-HAV assay was evaluated at one internal site on one Dxl 9000 Analyzer. Four serum and four plasma specimens (2 reactive and 2 non-reactive for each matrix) were tested in 3 replicates per run, 2 runs per day, for 20 days, using 2 reagent pack lots and 2 calibrator lots. The precision study results are summarized in table 1.

Table 1: Within-laboratory precision study results

			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	1.87	0.04	2.3	0.08	4.0	0.04	2.2	0.10	5.1	0.08	4.4	0.03	1.6	0.13	7.0
QC2	480	0.37	0.01	2.5	0.02	4.7	0.01	2.0	0.02	5.7	0.02	4.4	0.00	0.0	0.03	7.2
P1	480	1.73	0.04	2.4	0.07	4.2	0.03	1.6	0.09	5.1	0.08	4.4	0.04	2.2	0.12	7.1
P2	480	0.67	0.01	2.1	0.02	3.0	0.02	2.8	0.03	4.7	0.03	4.4	0.02	2.3	0.05	6.9
P3	480	0.01	0.00	9.1	0.00	5.5	0.00	0.0	0.00	10.7	0.00	4.4	0.00	12.7	0.00	17.2
P4	480	1.29	0.03	2.3	0.04	2.8	0.03	2.6	0.06	4.5	0.06	4.4	0.05	3.8	0.10	7.4
S1	480	0.85	0.02	2.3	0.03	3.7	0.02	2.5	0.04	5.0	0.04	4.4	0.01	1.2	0.06	6.8
S2	480	1.19	0.03	2.4	0.05	4.4	0.02	1.8	0.06	5.3	0.05	4.4	0.03	2.9	0.09	7.5
S3	480	0.21	0.01	3.2	0.01	4.5	0.00	1.2	0.01	5.6	0.01	4.4	0.00	1.7	0.02	7.3
S4	480	1.55	0.04	2.3	0.06	3.9	0.03	2.2	0.08	5.0	0.07	4.4	0.05	3.4	0.12	7.5

B. Reproducibility.

A 5-day reproducibility study was performed at 3 testing sites (1 instrument per site). Four serum and four plasma specimens (2 reactive and 2 non-reactive for each matrix) were tested using one lot of Access anti-HAV reagent pack, Access anti-HAV Calibrator, and Access anti-HAV QC. Samples were tested in 3 replicates per run, 2 runs per day, for 5 days. The reproducibility study results are summarized in table 2.

Table 2. Reproducibility study results

			Between-Site		Between-Day		Between-Run		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	1.51	0.08	5.3	0.01	0.6	0.00	0.0	0.07	4.9	0.11	7.2
S2	90	1.05	0.05	4.7	0.03	2.7	0.01	0.7	0.03	3.0	0.07	6.2
S3	90	0.44	0.02	3.6	0.01	1.6	0.01	1.6	0.02	3.6	0.02	5.6
S4	90	0.15	0.01	7.3	0.00	1.6	0.00	1.5	0.01	5.8	0.01	9.6
P1	90	1.56	0.09	5.9	0.00	0.0	0.04	2.3	0.07	4.7	0.12	7.8
P2	90	1.10	0.06	5.8	0.01	1.0	0.01	1.1	0.04	4.1	0.08	7.2
P3	90	0.66	0.03	4.0	0.01	1.2	0.01	1.3	0.02	3.1	0.04	5.4
P4	90	0.00	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A	0.00	N/A

2. Linearity:

N/A.

3. Analytical Specificity/Interference:

A. Cross-reactivity.

Potential cross-reactivity in the Access anti-HAV assay was evaluated using specimens with viral antibodies and from patients with related conditions. The anti-HAV total status of each specimen was verified using commercially available comparator anti-HAV Total assay. One out of twelve anti-HSV-1 IgG specimens was positive by Access anti-HAV but negative by the comparator assay. All other specimens were negative for anti-HAV by both assays. The cross-reactants, numbers of samples, and study results are summarized in table 3.

Table 3. Cross-reactivity of Access anti-HAV assay

Category	Number of Samples Tested	Number of Reactive Samples by Access anti-HAV	Number of Non-Reactive Samples by Access anti-HAV
Viral Infections			
Cytomegalovirus (CMV)	10	0	10
Epstein-Barr Virus (EBV)	10	0	10
Herpes Simplex Virus-1 (HSV-1)	12	1	11
Herpes Simplex Virus-2 (HSV-2)	10	0	10
Toxoplasmosis	12	0	12
Viral Related Diseases			
Hepatitis B Virus (HBV)	10	0	10
Human Immunodeficiency Virus (HIV)	15	0	15
Hepatitis C Virus (HCV)	10	0	10
Varicella Zoster Virus (VZV)	10	0	10
Rubella	12	0	12
Measles	11	0	11
Mumps	10	0	10
Other Related Diseases			
Alcoholic Liver Disease (ALD)	10	0	10
Primary Biliary Cirrhosis (PBC)	10	0	10
Auto-Immune Diseases (Heterophile)			
Human Anti-Mouse Antibody (HAMA)	11	0	11
Anti-Nuclear Antibody (ANA)	10	0	10
Rheumatoid Factor (RF)	13	0	13
Systemic Lupus Erythematosus (SLE)	13	0	13
Multiple Myeloma	10	0	10

Pregnant Women			
Pregnancy Multipara	10	0	10
Pregnancy First Trimester (T1)	10	0	10
Pregnancy Second Trimester (T2)	10	0	10
Pregnancy Third Trimester (T3)	10	0	10

B. Interference.

Potential interference of endogenous and exogenous substances was evaluated using three serum samples: negative for anti-HAV (≥1.25 S/CO), high negative (~1.1-1.3 S/CO) and low positive (~0.65-0.95 S/CO). Each sample was spiked with each of the potential interfering substances, tested in 5 replicates, and compared to controls (sample without 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

Potential interferent	**Concentration tested**
Hemoglobin	1.0 g/dL
Total Protein	15 g/dL
Bilirubin Conjugated	43 mg/dL
Bilirubin Unconjugated	43 mg/dL
Triglycerides Intralipids	3,854 mg/dL (37 mmol/l)
Aspirin (acetylsalicylic acid)	3.00 mg/dL (167 µmol/L)
Salicylic acid	2.86 mg/dL (207 µmol/L)
Acetaminophen (paracetamol)	15.6 mg/dL (1030 µmol/L)
Ibuprofen	21.9 mg/dL (1060 µmol/L)
Atorvastatin	0.075 mg/dL (1.34 µmol/L)
Lisinopril	0.0246 mg/dL (0.607 µmol/L)
Levothyroxine	0.0429 mg/dL (0.552 µmol/L)
Metformin	1.20 mg/dL (92.9 µmol/L)
Amlodipine	0.0075 mg/dL (0.183 µmol/L)
Omeprazole	0.84 mg/dL (24.3 µmol/L)
Sertraline	0.0927 mg/dL (3.03 µmol/L)

C. Hook effect.

To evaluate whether high levels of analyte in patient specimens cause hook effect, three specimens with S/CO below 0.1 were serially diluted to cover the assay range of S/CO values, and tested each with three reagent lots, in three replicates, on three instruments. No hook effect was observed for this assay.

4. Assay Reportable Range:
   N/A (qualitative assay).

5. Stability (Controls, Calibrators, or Methods):

   A. Stability (Controls, Reagent, Calibrator, Calibration Curve, Sample Handling).
   Stability studies supported the following stability claims.

Study	Storage temperature	Supported claim
QC Shelf-life	2-10ºC	270 days
QC Open vial	2-10ºC	90 days
Reagent Shelf-life	2-10ºC	180 days
Reagent Open vial	2-10ºC	21 days
Calibrator Shelf-life	2-10ºC	180 days
Calibrator Open vial	2-10ºC	125 days
Calibration curve		28 days
Sample stability	25ºC 2-10ºC Freeze/Thaw cycles	72 hours 7 days N=5

   B) Fresh/frozen sample stability.

The equivalency of fresh and frozen samples was demonstrated using 56 serum 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. 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.

6. Detection Limit:
   (N/A)

7. Analytical Sensitivity:

   A. Analytical sensitivity at cut-off.

   The assay cut-off was evaluated using 118 positive and 65 negative patient specimens from individuals at risk for HAV infection and with signs and symptoms of HAV infection. The cut-off was set at 1.0 S/CO.
   The concentration of the Second International Standard for Anti-Hepatitis A, Immunoglobulin (NIBSC Code: 97/64) at the assay cut-off was evaluated using serial dilutions of the international standard prepared in serum and plasma samples. Samples were tested with the Access anti-HAV assay for seven days, two runs per day using 3 lots of calibrator and 3 lots of reagents. Regression analysis demonstrated the concentration at the assay cutoff (1.00 S/CO) was 18.0 mIU/mL.

   B. Seroconversion.

Seroconversion sensitivity of the Access anti-HAV was evaluated in comparison to a commercially available anti-HAV assay using four seroconversion panels obtained from commercial vendors. 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 5.

Table 5. Seroconversion sensitivity results

	First anti-HAV positive result from initial draw date		Access anti-HAV vs reference assay
Panel ID	Access anti-HAV (days)	Reference assay (days)	Difference in bleed number for the first reactive bleed
0615-0026	10	10	0
HAV002SCP	109	109	0
HAV003SCP	56	56	0
SCP-HAV-002	5	5	0

8. Within-assay carryover.

To evaluate within-assay carryover, alternating high positive and negative samples were tested in multiple runs using the Access anti-HAV assay. None of the results from negative sample obtained after testing a positive sample became positive.

B Comparison Studies.

1. Method Comparison.

The assay performance was evaluated using a total of 860 patient specimens from cohorts summarized in table 6. Composite Reference Method (CRM) was used to determine the comparator anti-HAV status. Serum samples were tested at three sites by the Access anti-HAV 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 tables 6-8.

Table 6. Access anti-HAV test agreements with CRM for all cohorts.

Cohort/Patient Category	Reference anti-HAV CRM				Total
	Nonreactive		Reactive		
	Access anti-HAV				
	Nonreactive	Reactive	Nonreactive	Reactive	
Adult at-risk for HAV infection (prospective)	165	2	2	219	388
Adult with signs and symptoms (prospective)	95	1	5	163	264
Acute adult (retrospective)	0	0	0	90	90
Pediatric	17	0	0	101	118
Total	**277**	**3**	**7**	**573**	**860**

Table 7. Anti-HAV performance for adult population.

Patient Category	NPA		PPA	
	% (n/N)	95% CI	% (n/N)	95% CI
Adult at-risk for HAV infection	98.8 (165/167)	95.7-99.7	99.1 (219/221)	96.8-99.8
Adult with signs and symptoms	99.0 (95/96)	94.3-99.8	97.0 (163/168)	93.2-98.7
Acute	N/A	N/A	100.0 (90/90)	95.9-100.0
Overall	98.9 (260/263)	96.7-99.6	98.5 (472/479)	97.0-99.3

Table 8. Anti-HAV performance for pediatric population.

Patient Category	NPA		PPA	
	% (n/N)	95% CI	% (n/N)	95% CI
Pediatric at-risk/with signs and symptoms (prospective)	100.0 (17/17)	81.6-100.0	100.0 (91/91)	95.9-100.0
Acute pediatric (retrospective)	N/A	N/A	100.0 (10/10)	72.2-100.0
Overall	**100.0 (17/17)**	**81.6-100.0**	**100 (101/101)**	**96.3-100.0**

Vaccine Study

A cohort of specimens collected pre- and post-HAV vaccination was evaluated using CRM and Access anti-HAV assay. Three HAV vaccines currently licensed in the U.S. were used in the study. Post-vaccination specimens were collected four to ten weeks after the complete vaccination was administered according to vaccine dosing instructions. The combined agreement results are summarized in table 9.

Table 9. Access anti-HAV test agreements with CRM for the vaccination cohort.

Vaccine		anti-HAV CRM				Total
		Reactive		Nonreactive		
		Access anti-HAV				
		Reactive	Nonreactive	Reactive	Nonreactive	
HAVRIX	Pre-vaccination	0	0	0	22	22
	Post-vaccination	22	0	0	0	22
TWINRIX	Pre-vaccination	0	0	0	21	21
	Post-vaccination	21	0	0	0	21
VAQTA	Pre-vaccination	0	0	0	16	16
	Post-vaccination	16	0	0	0	16

2. Matrix Comparison:

To verify equivalent performance between different matrices, 65 native specimens were analyzed, 25 of which were negative and 40—positive, with S/CO values distributed along the measuring range. Each specimen was collected in all 7 types of tubes listed in the intended use and compared with serum without gel (reference matrix). Results are summarized in table 9.

Table 9. Matrix comparison study results.

	Sample type vs Reference (Serum no gel)		
	Slope	**95% Interval Slope**	**Correlation coefficient (r)**
Serum gel	1.00	0.99 - 1.01	1.00
Li Heparin	1.01	0.99 - 1.04	1.00
Li Heparin + gel	1.02	1.00 - 1.03	1.00
Na Citrate	1.01	0.99 - 1.03	1.00
ACD	1.01	0.99 - 1.03	1.00
CPD	1.01	0.99 - 1.03	1.00

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

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.