Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

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

I Background Information:

A 510(k) Number

K190428

B Applicant

Roche Diagnostics

C Proprietary and Established Names

Elecsys Anti-HAV II

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
QCH	Class II	21 CFR 866.3920 - Assayed quality control material for clinical microbiology assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Total antibodies (IgG and IgM) to hepatitis A virus (HAV)

C Type of Test:

Qualitative immunoassay using electrochemiluminescence technology

III Intended Use/Indications for Use:

A Intended Use(s):

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 assay has not been FDA cleared or approved for the screening of blood or plasma donors.

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:

cobas e 601 analyzer

IV Device/System Characteristics:

A Device Description:

Elecsys Anti-HAV II is a second-generation competitive immunoassay by Roche Diagnostics for the in vitro qualitative detection of total antibodies (IgG and IgM) to the hepatitis A virus (HAV) in human pediatric and adult serum and plasma. It is intended for use on the cobas e 601 immunoassay analyzer and utilizes the electrochemiluminescence immunoassay "ECLIA" technology.
Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration. Results are expressed as cutoff indices (COIs).

The Elecsys Anti-HAV II is intended to be used with the following calibrators and controls:

- AHAV 2 Cal1 and AHAV 2 Cal2, included in the reagent RackPack
- PreciControl Anti-HAV II, sold separately

B Principle of Operation:

The Elecsys Anti-HAV II assay is a qualitative, serological, competitive immunoassay:

- 1st incubation: 20 µL of sample; the sample anti-HAV binds the added HAV antigen
- 2nd incubation: After addition of biotinylated antibodies and ruthenium complex*-labeled antibodies specific for HAV antigen, together with streptavidin-coated microparticles, the still-free binding sites on the HAV antigens become occupied. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell M. Application of a voltage to the electrode induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

*Tris(2,2'-bipyridyl) ruthenium(II)-complex (Ru(bpy))

Interpretation of the results

Numeric result	Result message	Interpretation / further steps
COI*) > 1.0	Non-reactive	Negative for HAV-specific antibodies
COI ≤ 1.0	Reactive	Positive for HAV-specific antibodies

* COI = cutoff index

The cutoff of the Elecsys Anti-HAV II assay was established with internal studies, and validation of the cutoff was performed by external clinical studies. The cutoff of COI = 1.0 corresponds to ≤ 25.4 IU/L, as established with the 2nd International Standard for Anti-Hepatitis A, Immunoglobulin, Human, NIBSC code: 97/646.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:
   cobas e 601

2. Specimen Identification:
   Automated barcode scanning onboard the cobas e 601

3. Specimen Sampling and Handling:
   Automated using the cobas e 601

4. Calibration:
   Calibration is performed using the calibrators provided with the Elecsys Anti-HAV II:
   AHAV 2 Cal1, negative calibrator
   AHAV 2 Cal2, positive calibrator

5. Quality Control:
   PreciControl Anti-HAV II is used for quality control.

V Substantial Equivalence Information:

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

B Predicate 510(k) Number(s):
K100903

C Comparison with Predicate(s):

	Device K190428	Predicate K100903
Device Trade Name	Elecsys Anti-HAV II	Elecsys Anti-HAV
General Device Characteristic Similarities		
Intended Use/Indications For Use	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	Immunoassay for the in vitro qualitative detection of total antibodies (IgM and IgG) to hepatitis A virus in human serum and plasma (K2-EDTA). The assay is intended for use as an aid in the laboratory diagnosis of past or acute/recent hepatitis A infection. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with hepatitis A virus in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis A infection, or used as an aid to determine the presence of antibody response to HAV in vaccine recipients. The electrochemiluminescence

	Device K190428	Predicate K100903
	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 assay has not been FDA cleared or approved for the screening of blood or plasma donors.	immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.
Assay Method	Same as predicate	Competition principle binding protein
Detection Method	Same as predicate	Electrochemiluminescence
Applications/Test Time	Same as predicate	18 minutes
Calibration Method	Same as predicate	2-point calibration
Calibration Interval	Same as predicate	Calibration must be performed once per reagent lot using fresh reagent (i.e., not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • after 1 month (28 days) when using the same reagent lot • after 7 days (when using the same reagent kit stored on the analyzer) • as required: e.g., quality control findings outside the defined limits
Traceability/ Standardization	Same as predicate	Second International Standard for Anti Hepatitis A, Immunoglobulin, Human, NIBSC code: 97/646
General Device Characteristic Differences		
Instrument Platform	cobas e 601	Elecsys 2010, cobas e 411, cobas e 601, cobas e 602, and MODULAR ANALYTICS E170

	Device K190428	Predicate K100903
Reagent R2	• Application of a different biotinylated monoclonal anti-HAV antibody (mouse) • Change in the ruthenium label complex and increased concentration for the ruthenium labeled monoclonal antibody	• Biotinylated monoclonal anti-HAV antibody (mouse) • Ruthenium labeled monoclonal anti-HAV antibody (mouse)
Reagents R1 and R2	TRIS buffer based	HEPES buffer based
Sample Type	Human serum, plasma (K_2-EDTA, K3-EDTA, Na-Citrate, Na-Heparin)	Human serum, plasma (K_2-EDTA)
Calibrator	AHAV 2 Cal1 and AHAV2 Cal2 (packed in kit – ready to use)	Anti-HAV Cal1 and Cal2 (packed in kit – lyophilized)
Sample Volume	20 µL	50 µL
Controls	PreciControl Anti-HAV II	PreciControl Anti-HAV
Interpretation of Results	COI > 1.0 Non-reactive COI ≤ 1.0 Reactive	≥ 22.0 IU/L Reactive 18.0 ≤ IU/L< 22.0 Equivocal <18.0 IU/L Negative

VI Standards/Guidance Documents Referenced:

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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

A panel comprised of five human serum pools and controls was tested with the Elecsys Anti-HAV II assay. Two aliquots of each panel member were tested in each of two runs per day for 21 days (n = 84). Calibration was performed on day 1 and day 17. The study was performed on one cobas e 601 Immunoassay Analyzer using one lot of reagents.

		Repeatability		Within-Laboratory Precision	
Sample	**Mean (COI)**	**SD[a)] (COI)**	**CV (%)**	**SD (COI)**	**CV (%)**
HSP 1 [b)]	1.42	0.016	1.1	0.028	2.0
HSP2	1.15	0.012	1.1	0.022	1.9

		Repeatability		Within-Laboratory Precision	
Sample	**Mean (COI)**	**SD[a] (COI)**	**CV (%)**	**SD (COI)**	**CV (%)**
HSP3	0.955	0.009	0.9	0.022	2.3
HSP4	0.665	0.009	1.3	0.020	2.9
HSP5	0.006	0.0002	3.0	0.0002	3.3
PC AHAV II 1[c]	1.30	0.015	1.1	0.024	1.8
PC AHAV II 2	0.339	0.005	1.5	0.009	2.7

a) SD = standard deviation
b) HSP = human serum pool
c) PC = PreciControl

2. Reproducibility

A reproducibility study was performed at three sites using three cobas e 601 analyzers and one reagent lot. A panel consisting of four human serum pools and the PreciControls was tested in three replicates per run, two runs per day for five days (n = 90). The combined precision data for the three testing sites is shown in the following table.

Precision on the cobas e 601 analyzer					
		Repeatability		**Between-run**	
Sample	Mean COI	SD	CV %	SD	CV %
HSP1	0.813	0.010	1.3	0.016	1.9
HSP2	0.904	0.012	1.3	0.016	1.8
HSP3	1.01	0.018	1.7	0.013	1.3
HSP4	0.449	0.005	1.1	0.011	2.5
PC A-HAV II 1	1.30	0.018	1.4	0.009	0.7
PC A-HAV II 2	0.376	0.006	1.6	0.013	3.3

Precision on the cobas e 601 analyzer							
		Between- day		**Between- site**		**Reproducibility**	
Sample	Mean COI	SD	CV %	SD	CV %	SD	CV %
HSP1	0.813	0.000	0.0	0.011	1.3	0.022	2.7
HSP2	0.904	0.000	0.0	0.014	1.5	0.024	2.7
HSP3	1.01	0.004	0.4	0.016	1.6	0.027	2.7
HSP4	0.449	0.000	0.0	0.007	1.5	0.014	3.1
PC A-HAV II 1	1.30	0.010	0.7	0.018	1.4	0.029	2.2

Precision on the cobas e 601 analyzer							
		Between- day		Between- site		Reproducibility	
Sample	Mean COI	SD	CV %	SD	CV %	SD	CV %
PC A-HAV II 2	0.376	0.000	0.0	0.003	0.9	0.014	3.8

3. Linearity:

   Not applicable.

4. Analytical Specificity/Interference:

   a) Cross-reactivity
   The effect of potentially cross-reacting antibodies present in anti-HAV negative serum or plasma samples was evaluated. A panel of samples negative for anti-HAV and positive for the conditions / analytes listed below was tested with the Elecsys Anti-HAV II and the comparator Elecsys Anti-HAV assays on the cobas e 601 analyzer. The panel was comprised of ten positive samples for each condition / analyte. Each sample was non-reactive for anti-HAV with both the Elecsys Anti-HAV II and the comparator Elecsys Anti-HAV assays, indicating no cross-reactivity of the Elecsys Anti-HAV II assay with antibodies to other infectious agents.

   - Acute Hepatitis B infection
   - Acute Hepatitis C infection
   - HIV infection
   - EBV infection
   - Anti-CMV antibodies
   - Anti-HSV antibodies
   - *Toxoplasma gondii* infection
   - *Treponema pallidum* infection
   - Anti-Mumps/Rubeola antibodies
   - Anti-Rubella antibodies
   - Anti-Parvovirus B19 antibodies
   - Anti-nuclear antibodies (ANA)

   b) Interference
   Endogenous substances

   The impact of potentially interfering endogenous substances was evaluated by testing four human serum samples on the cobas e 601 analyzer:

   - Negative sample
   - High negative sample
   - Low positive sample
   - Positive sample

   One aliquot of each serum sample was spiked with the endogenous substance and another aliquot was spiked with the same volume of the matrix used to prepare the stock

interfering substance. The aliquot containing the endogenous substance was then diluted into the unspiked aliquot in 10% increments. The recovery for each spiked sample was calculated by comparison to the reference (unspiked) sample.

The substances shown in the following table were evaluated and no interference was observed up to the listed concentration.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 1129 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.621 mmol/L or ≤ 1000 mg/dL
Intralipid	≤ 2000 mg/dL
Rheumatoid factor	≤ 1400 IU/mL
IgG	≤ 7.0 g/dL
IgA	≤ 1.6 g/dL
IgM	≤ 1.0 g/dL
Serum albumin	≤ 7.0 g/dL

Biotin:
Five human serum samples were spiked with a range of biotin concentrations and tested with the Elecsys Anti-HAV II on the cobas e 601 analyzer. The results are shown in the following tables.

% Bias for samples containing various concentrations of biotin up to 1200 ng/mL								
Sample	COI with no biotin added	Biotin concentration (ng/mL)						
		20	40	60	80	100	120	140
negative 1	1.37	0.18	-2.7	-3.8	-7.3	-11	-14	-17
negative 2	1.17	0.92	-0.60	-4.8	-6.2	-9.9	-14	-17 (FP)*
high-negative	1.06	0.58	-1.3	-4.2	-6.6 (FP)	-10 (FP)	-14 (FP)	-18 (FP)
low-positive	0.861	0.65	-3.7	-3.9	-9.3	-11	-16	-19
positive	0.540	-2.2	-7.9	-12	-15	-19	-24	-28

* FP = false positive due to biotin interference

% Bias for samples containing various concentrations of biotin up to 1200 ng/mL							
Sample	COI with no biotin added	Biotin concentration (ng/mL)					
		160	180	200	300	600	1200
negative 1	1.37	-19	-23	-27	-37* (FP)	-65 (FP)	-77 (FP)
negative 2	1.17	-20 (FP)	-24 (FP)	-27 (FP)	-39 (FP)	-68 (FP)	-79 (FP)
high-negative	1.06	-21 (FP)	-24 (FP)	-26 (FP)	-46 (FP)	-71 (FP)	-80 (FP)
low-positive	0.861	-23	-27	-29	-44	-71	-82
positive	0.540	-30	-36	-39	-52	-77	-86

* FP = false positive result due to biotin interference

Negative specimens with biotin concentrations up to 100 ng/mL demonstrated ≤ 11 % negative bias in COI values. Biotin concentrations greater than 100 ng/mL lead to higher negative bias and in consequence can lead to false positive Elecsys Anti HAV II results. Pharmacokinetic studies have shown that serum concentrations of biotin can reach up to 355 ng/mL within the first hour after ingestion for subjects consuming supplements of 20 mg biotin per day[1] and up to 1160 ng/mL in plasma for subjects consuming a single dose of 300 mg biotin.[2]

5. Assay Reportable Range:

Not applicable.

6. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:
This method has been standardized against WHO Standards NIBSC (National Institute for Biological Standards and Control) code: 97/646.

Specimen Stability:
Six of each human serum, K2-EDTA, Li-Heparin, and Na-Citrate plasma samples and seven K3-EDTA and Na-Heparin plasma samples were aliquoted and measured fresh (reference value) and after storage. Samples were tested in triplicate at the designated time points. Results support the stability of specimens stored under the following conditions:

- 2-8°C for 14 days
- 20-25°C for 6 days
- -15 to -25°C for 3 months
- 5 freeze / thaw cycles

7. Assay Cut-Off:

The 2nd International Standard for Anti-Hepatitis A, Immunoglobulin, Human, NIBSC code: 97/646 was serially diluted to target concentrations ranging from 0 to 500 IU/L in 10 samples prepared from pooled Anti-HAV negative serum. The samples were tested in 2 replicates per run in 2 runs. The study was performed using three reagent and three calibrator lots. The concentration at the cutoff COI = 1 was determined to be ≤ 25.4 IU/L.

[1] Grimsey P, Frey N, Bendig G, et al. Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. International Journal of Pharmacokinetics 2017 Sept 14;2(4):247-256.
[2] Piketty ML, Prie D, Sedel F, et al. High-dose biotin therapy leading to false biochemical endocrine profiles: validation of a simple method to overcome biotin interference. Clin Chem Lab Med. 2017 May 1;55(6):817-825.

B Comparison Studies:

1. Matrix Comparison:

The recovery of analyte values in the presence of anticoagulants with the Elecsys Anti-HAV II assay was determined by comparing values obtained from samples drawn into matched serum and plasma collection tubes from 60 subjects. The samples were spiked with anti-HAV positive sera from individual donors to obtain a range of anti-HAV concentrations and were tested on the cobas e 601. The difference in COI value of each plasma sample compared to the matched serum sample was calculated. The following table summarizes the results:

	K_2-EDTA	**K_3-EDTA**	**Na-Heparin**	**Li-Heparin**	**Na-Citrate**
COI range observed	0.007 - 1.37	0.008 - 1.38	0.007 - 1.39	0.007 - 1.41	0.007 - 1.37
Maximum % change for COI > 1.0	+8.7%	+9.7%	+6.8%	+6.8%	+4.7%
Maximum difference for COI ≤ 1.0	+0.155	+0.188	+0.125	+0.132	+0.097

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):

Method comparison
Samples from 961 subjects were tested with the Elecsys Anti-HAV II and the comparator Elecsys Anti-HAV assays at three sites using the cobas e 601. Prospective, retrospective, and remnant specimens were included. Results are shown in the following tables.

	Elecsys Anti-HAV assay results (all sites combined)			
Elecsys Anti-HAV II results	**Reactive ≥ 22 IU/L**	**Border 18.0 ≤ IU/L < 22.0**	**Non-reactive < 18.0 IU/L**	**Total**
Reactive COI ≤ 1.0	501	6	16	523
Non-reactive COI >1.0	0	1	437	438

	Elecsys Anti-HAV assay results (all sites combined)			
Elecsys Anti-HAV II results	**Reactive ≥ 22 IU/L**	**Border 18.0 ≤ IU/L < 22.0**	**Non-reactive < 18.0 IU/L**	**Total**
Total	501	7	453	961

	Absolute	Relative %	95 % CI
PPA	501/502	99.80	98.90; 99.99
NPA	437/459	95.21	92.83; 96.97

Of 502 subjects reactive by the comparator assay, 501 were also positive by the Elecsys Anti-HAV II assay for a positive percent agreement (PPA) of 99.8%. Of 453 subjects non-reactive by the comparator assay, 437 were also non-reactive by the Elecsys Anti-HAV II assay for a negative percent agreement (NPA) of 95.2%. A total of 23 subjects were discordant between the Elecsys Anti-HAV II assay and the comparator assay. Specimens with results in the borderline range of (18.0 ≤ IU/L < 22.0) for the comparator Elecsys Anti-HAV assay were counted as discordant when calculating agreements with the Elecsys Anti-HAV II assay. The lower bound of the confidence interval for the PPA was 98.90% and the lower limit of the confidence interval for NPA was 92.83%.

The study included samples from the following patient cohorts: routine HAV testing, hospitalized, increased risk, symptomatic, characterized acute HAV infected, and pediatric.

Positive percent agreement and negative percent agreement with their respective 95th percentile confidence interval (CI) for each cohort are summarized in the following table.

Summary of the percent agreements for various specimen cohorts: Elecsys Anti-HAV II* assay versus the predicate (Elecsys Anti-HAV assay)†				
	PPA		**NPA**	
Cohort	**PPA (x/n)**	**95 % CI**	**NPA (x/n)**	**95 % CI**
Routine HAV testing	100 (91/91)	(96.03, 100)	94.50 (103/109)	(88.40, 97.95)
Hospitalized	98.21 (55/56)	(90.45, 99.95)	97.22 (140/144)	(93.04, 99.24)
Increased risk for hepatitis	100 (119/119)	(96.95, 100)	94.25 (82/87)	(87.10, 98.11)
Symptomatic	100 (129/129)	(97.18, 100)	96.70 (88/91)	(90.67, 99.31)
Characterized acute HAV	100 (65/65)	(94.48, 100)	100 (10/10)	(69.15, 100)
Pediatric	100 (42/42)	(91.59, 100)	77.78 (14/18)	(52.36, 93.59)
Overall	99.80 (501/502)	(98.90, 99.99)	95.21 (437/459)	(92.83, 96.97)

* Cutoff of 1.0 COI used for Elecsys Anti-HAV II assay

† Specimens with results in the borderline range of (18.0 ≤ IU/L < 22.0) for Elecsys Anti-HAV assay were counted as discordant with the Elecsys Anti-HAV II assay

The lower bound of the 95% confidence intervals for PPA ranged from 90.45% in the hospitalized cohort to 97.18% in the symptomatic cohort. The lower bound of the ≥ 95% confidence intervals for NPA ranged from 52.36% in the pediatric cohort to 93.04% in the hospitalized cohort. For the pediatric cohort, there were 18 specimens negative by the predicate Elecsys Anti-HAV assay, of which 14 (77.8%) were also negative with the Elecsys Anti-HAV II assay. Of the 4 discrepant results in the pediatric population, 2 were borderline by the predicate Elecsys Anti-HAV assay and were counted as discordant when calculating negative percent agreement. The lower bound of the 95% CI for the NPA in the pediatric population is influenced by the small number of specimens (n = 18).

Pre- and Post-HAV Vaccination

A cohort of specimens that were collected both pre- and post-HAV vaccination was evaluated by the Elecsys Anti-HAV II assay and the predicate Elecsys Anti-HAV assay. The post-vaccination specimen was obtained at least 4 weeks, but not more than 10 weeks, after the completion of the vaccine regimen. Three HAV vaccines, which are currently licensed in the U.S., were used. No discordant results between the Elecsys Anti-HAV II and the Elecsys Anti-HAV assay were observed. The combined results are summarized in the following table:

	HAVRIX	TWINRIX	VAQTA	All Vaccines
PPA	100.00 (15/15)	100.00 (19/19)	100.00 (15/15)	100.00 (49/49)
95% CI	(78.20, 100.00)	(82.35, 100.00)	(78.20, 100.00)	(92.75, 100.00)
NPA	100.00 (15/15)	100.00 (19/19)	100.00 (15/15)	100.00 (49/49)
95%CI	(78.20, 100.00)	(82.35, 100.00)	(78.20, 100.00)	(92.75, 100.00)

Seroconversion Panels

Four seroconversion panels were evaluated. Each panel consisted of multiple specimens collected from one subject over time. According to information provided by the panel vendor, the collection days spanned the point of seroconversion from a non-reactive anti-HAV status to a reactive status. The four panels were analyzed with the Elecsys Anti-HAV II and the predicate Elecsys Anti-HAV assays using the cobas e 601. Results for the Elecsys Anti-HAV II and Elecsys Anti-HAV assays were equivalent in all four panels.

	Bleed Day of Earliest Reactive Result (Draw #)	
Panel ID	**Elecsys Anti-HAV II**	**Comparator Elecsys Anti-HAV**
BX-HAV-001	1 (1)*	1 (1)*
BX-HAV-002	6 (2)	6 (2)
SC0026	10 (4)	10 (4)
SC903	38 (3)	38 (3)

*Non-reactive at bleed day 0 according to data supplied by the vendor of the panel

D Clinical Cut-Off:

Refer to the Assay Cut-off section above for additional details.

E Expected Values/Reference Range:

Prospectively collected serum specimens were tested with the Elecsys Anti-HAV II assay to evaluate the prevalence of HAV antibodies in a population of presumed healthy adults. Individuals were recruited at two sites, one in the Eastern United States (New York), representing a historically lower prevalence region, and one in the Western United States (Utah), representing a historically higher prevalence region. A total of 800 specimens, 400 from each collection site, were evaluated. Results showed reactive rates of 29.50% in the Eastern US vs. 53.75% in the Western US.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

IX Conclusion:

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