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

I Background Information:

A 510(k) Number

K252424

B Applicant

Abbott Laboratories

C Proprietary and Established Names

Anti-HCV Next

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MZO	Class II	21 CFR 866.3169 - Hepatitis C Virus (HCV) Antibody Test	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:
Clearance for marketing of the Anti-HCV Next Reagent Kit, Anti-HCV Next Calibrator, and Anti-HCV Next Controls to be used on the Alinity i analyzer.

B Measurand:
Anti-HCV antibodies

C Type of Test:
Chemiluminescent microparticle immunoassay (CMIA)

III Intended Use/Indications for Use:

A Intended Use(s):

The Anti-HCV Next assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human adult serum (collected in serum and serum separator tubes) and plasma (collected in sodium heparin, lithium heparin, lithium heparin separator, sodium citrate, disodium EDTA, tripotassium EDTA, dipotassium EDTA, and dipotassium EDTA separator tubes) on the Alinity i system.

The Anti-HCV Next assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis, persons at risk for hepatitis C infection, and pregnant women. The test does not determine the state of infection or associated disease. Not cleared for use in screening blood, plasma, or tissue donors.

B Indication(s) for Use:

See Intended Use(s) above.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on the Alinity i system.

IV Device/System Characteristics:

A Device Description:

The Anti-HCV Next assay is an automated, combined one-step/two-step immunoassay for the qualitative detection of anti-HCV in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample, streptavidin-coated paramagnetic microparticles precomplexed with biotinylated HCV constructs, acridinium-labeled recombinant and peptide conjugates, and assay diluent are combined and incubated. The anti-HCV present in the sample binds to the HCV coated microparticles and to the acridinium-labeled conjugates, forming a sandwich. The mixture is washed. In a second step, additional acridinium-labeled HCV antigen conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of anti-HCV in the sample and the RLU detected by the system optics.

The presence or absence of anti-HCV in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration.

This product is composed of 4 components, which are packaged as a 2-cartridge reagent set. Both cartridges are required to perform the assay.

Volumes (mL) listed in the following table indicate the volume per cartridge set.

List Number (LN)	06T7921	06T7931
Tests per cartridge	100	500
Number of cartridges per kit	2	2
Tests per kit	200	1000
Microparticles	6.6 mL	27.0 mL
Conjugate 1	4.2 mL	13.8 mL
Assay Diluent	5.9 mL	14.0 mL
Conjugate 2	6.1 mL	26.5 mL

- **Microparticles**: Streptavidin-coated microparticles precomplexed with biotinylated HCV antigen (*E. coli*, recombinant) and biotinylated HCV Core synthetic peptide in pyrophosphate-buffered saline with surfactants. Minimum concentration: 0.05% solid Preservative: sodium azide.
- **Conjugate**: Acridinium-labeled HCV antigen (*E. coli*, recombinant) and acridinium-labeled HCV Core synthetic peptide conjugate in pyrophosphate-buffered saline. Minimum concentration: 10 ng/mL. Preservative: sodium azide.
- **Assay Diluent**: Pyrophosphate buffer with protein additives (bovine) and detergent. Preservatives: sodium azide and antimicrobial agents.
- **Conjugate 2**: Acridinium-labeled HCV antigen (*E. coli*, recombinant) conjugate in pyrophosphate-buffered saline. Minimum concentration: 0.01 ng/mL. Preservative: sodium azide.

Anti-HCV Next Calibrator and Anti-HCV Next Controls are sold separately.

Interpretation of Results

Initial Results

S/CO	Instrument Interpretation	Retest Procedure
0.00 - < 0.90	Nonreactive	No retest required.
0.90 - < 1.00	Grayzone	Retest in duplicate.
≥ 1.00	Reactive	No retest required.

Final Interpretation

Initial Result	Retest Result	Result	Interpretation
Nonreactive	No retest required.	Nonreactive	Anti-HCV not detected; does not exclude the possibility of exposure to HCV.
Grayzone	If 2 results are ≥ 1.00 S/CO	Reactive	Presumptive evidence of anti-HCV; follow

Initial Result	Retest Result	Result	Interpretation
			medical guidelines for recommendations for supplemental testing[12]
	If 2 or 3 results (including initial result) are < 1.00 S/CO	Nonreactive	Anti-HCV not detected; does not exclude the possibility of exposure to HCV.
Reactive	No retest required.	Reactive	Presumptive evidence of anti-HCV; follow medical guidelines for recommendations for supplemental testing[12].

B Instrument Description Information:

1. Instrument Name:
   Alinity i system

2. Specimen Identification:
   Specimens are automatically identified via a built-in barcode reader or can be manually scanned using the System Control Module.

3. Specimen Sampling and Handling:
   The samples may be loaded on the system in any order. The system pipettor robot dispenses and aspirates liquids, as appropriate for each reaction. Sample handling and reagent transport is performed by a handler robot. This automated system manages up to 150 samples simultaneously using a robotic handler to prevent contamination during continuous loading.

4. Calibration:
   The system uses RFID or 2D barcodes for calibration, which needs to be performed once every 30 days.

   The Anti-HCV Next Calibrator is provided at one level positive for HCV antibody. Calibration data is valid for up to 30 days.

   Calibrator 1: Contains recalcified, heat inactivated, human plasma reactive for anti-HCV. Preservatives: sodium azide and antimicrobial agents.

   The Anti-HCV Next Calibrator is manufactured and referenced to an internal reference standard. The S/CO is 5.56 $\pm$ 12.7%.

5. Quality Control:
   QC testing is recommended every 24 hours or upon reagent lot changes to ensure results stay within target ranges.

   Controls
   - **Negative Control:** Contains recalcified, human plasma. Target 0.02 S/CO (NA-0.5 S/CO)
   - **Positive Control:** Contains recalcified, heat-inactivated, human plasma reactive for anti-HCV. Target 3.6 S/CO (1.8-5.4 S/CO)

- Preservatives: sodium azide and antimicrobial agents.

The Alinity i Anti-HCV Next positive control is referenced to an internal reference standard.

V Substantial Equivalence Information:

A Predicate Device Name(s):
LIAISON XL MUREX HCV Ab; LIAISON XL MUREX Control HCV Ab

B Predicate 510(k) Number(s):
P190011

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252424	P190011
Device Trade Name	Anti-HCV Next	LIAISON XL MUREX HCV Ab
Regulation Number	21 CFR 866.3169	Same
Regulation Name	Hepatitis C Virus (HCV) Antibody Test	Same
Regulatory Class	Class II	Class III
Product Code	MZO	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Anti-HCV Next assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human adult serum (collected in serum and serum separator tubes) and plasma (collected in sodium heparin, lithium heparin, lithium heparin separator, sodium citrate, disodium EDTA, tripotassium EDTA, dipotassium EDTA, and dipotassium EDTA separator tubes) on the Alinity i system. The Anti-HCV Next assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of hepatitis C virus (HCV) infection in persons with signs and symptoms of hepatitis, persons at risk for HCV infection, and pregnant women. The test does not determine the state of infection or associated disease. Not cleared for use in screening	The LIAISON XL MUREX HCV Ab assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative determination of specific antibodies to hepatitis C virus (anti-HCV) in human adult and pediatric (2-21 years) serum and plasma (lithium and sodium heparin, sodium citrate and di-potassium EDTA) samples including separator tubes, on the LIAISON XL Analyzer. It is intended to be used as an aid in the diagnosis of HCV infection. The assay may also be used as an aid in the diagnosis of HCV infection in pediatric subjects and in pregnant women. The test does not determine the state of infection or associated disease. The assay is not intended for use in screening blood, plasma, or tissue donors.

	blood, plasma, or tissue donors.	
Analyte Measured	Hepatitis C Virus (HCV) Antibody	Same
General Device Characteristic Differences		
Test Principle	Chemiluminescent microparticle immunoassay (CMIA). Qualitative, 1-step/2-step	Chemiluminescent immunoassay (CLIA). Qualitative 2-step
Capture Antigens	Streptavidin-coated microparticles precomplexed with biotinylated NS3h antigen and Core Peptide	Magnetic particle coated with HCV core and NS4 recombinant antigens, streptavidin-coated magnetic microparticles and aqueous Biotinylated HCV Nonstructural protein 3 (NS3) recombinant antigen.
Components	Microparticles – Streptavidin-coated microparticles precomplexed with biotinylated HCV antigen (E coli, recombinant) and biotinylated HCV core synthetic peptide in pyrophosphate-buffered saline with surfactants. Minimum concentration: 0.05% solids. Preservative: sodium azide. Conjugate 1 – Acridinium-labeled HCV antigen (E coli, recombinant) and acridinium-labeled HCV core synthetic peptide conjugate in pyrophosphate-buffered saline. Minimum concentration: 10 ng/mL. Preservative: sodium azide. Conjugate 2 – Acridinium-labeled HCV antigen (E coli, recombinant) conjugate in pyrophosphate-buffered saline. Minimum concentration: 0.01 ng/mL. Preservative: sodium azide. Assay Diluent – Pyrophosphate buffer with protein additives (bovine) and detergent. Preservatives: sodium azide and antimicrobial agents.	Magnetic particles [SORB] - Magnetic particles coated with HCV core and NS4 recombinant antigens (produced in baculovirus and E. coli respectively), streptavidin-coated magnetic particles, BSA, PBS buffer, EDTA, preservatives. HCV NS3 Antigen [Ag] - Biotinylated HCV NS3 recombinant antigen (produced in E.coli), MES buffer, preservatives. Conjugate [CONJ] - Mouse monoclonal IgG to human IgG conjugated to an isoluminol derivative, fetal calf serum, phosphate buffer, 0.2% ProClin 300, preservatives, an inert red dye. Specimen diluent [DIL|SPE] - BSA, casein, non-specific recombinant protein (produced in E.coli), phosphate buffer, EDTA, preservatives, an inert blue dye.
Type of Specimen	Serum and Plasma	Serum and Plasma
Calibrator(s)	1 Calibrator	1Calibrator
Calibration Storage	Maximum of 30 days	Maximum of 8 weeks
Control(s)	2 Controls (1 Negative, 1 Positive) Negative Control (negative	Controls (1 Negative, 1 Positive) Negative Control (human

	recalcified human plasma) Positive Control (recalcified, heat-inactivated, human plasma reactive for anti-HCV)	serum/plasma non-reactive for HCV antigens and antibodies) Positive Control (inactivated human serum/plasma reactive for HCV antibodies)
Instrument Platform	Alinity i system	LIAISON XL Analyzer

VI Standards/Guidance Documents Referenced:

CLSI C24 4th Edition (Replaces C24-A3) Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions

CLSI EP05-A3 Third Edition (Reaffirmed: September 2019) Evaluation of Precision of Quantitative Measurement Procedures

CLSI EP07 3rd Edition Interference Testing in Clinical Chemistry

CLSI EP12 3rd Edition Evaluation of Qualitative Binary Output Examination Performance

CLSI EP17-A2 Second Edition Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures

CLSI EP25 2nd Edition Evaluation of Stability of In Vitro Medical Laboratory Test Reagents

CLSI EP35 1st Edition Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

CLSI EP37 1st Edition Supplemental Tables for Interference Testing in Clinical Chemistry

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Laboratory Precision (20-Day)

A study was performed based on guidance from CLSI EP05-A3. Testing was conducted using 3 lots of the Anti-HCV Next reagents, 3 lots of the Anti-HCV Next Calibrator, 3 lots of the Anti-HCV Next Controls, and 2 instruments. Two controls and 3 recalcified human plasma panels were tested in 2 replicates twice per day on 20 days on 3 reagent lot/calibrator lot combinations on 2 instruments, where a unique reagent lot and a unique calibrator lot are paired. The performance is shown in the following table.

Sample	n	Mean (S/CO)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory[a]		Between-Lot[b]		Between-Instrument		Overall Within-Laboratory[c]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	480	0.01	0.001	N/A	0.000	N/A	0.000	N/A	0.001	N/A	0.006	N/A	0.000	N/A	0.006	N/A
Positive Control	480	3.62	0.088	2.4	0.042	1.2	0.094	2.6	0.136	3.8	0.143	3.9	0.096	2.7	0.219	6.1
Panel 1	480	0.79	0.019	N/A	0.010	N/A	0.021	N/A	0.030	N/A	0.035	N/A	0.026	N/A	0.052	N/A
Panel 2	480	1.22	0.025	2.1	0.020	1.6	0.037	3.0	0.049	4.0	0.052	4.3	0.038	3.1	0.081	6.6
Panel 3	480	3.12	0.065	2.1	0.056	1.8	0.083	2.7	0.119	3.8	0.148	4.7	0.088	2.8	0.209	6.7

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Anti-HCV Next reagent lot and Anti-HCV Next calibrator lot are confounded, and the confounding effect is represented by between-lot.

[c] Includes repeatability (within-run), between-run, between-day, between-lot, and between-instrument variability.

System Reproducibility

A study was performed based on guidance from CLSI EP05-A3. Testing was conducted at each of 3 testing sites using 1 lot of the Anti-HCV Next reagents, 1 lot of the Anti-HCV Next Calibrator, 1 lot of the Anti-HCV Next Controls, and 1 instrument. Two controls and 3 recalcified human plasma panels were tested in 4 replicates at 2 separate times per day on 5 different days. The performance is shown in the following table.

Sample	n	Mean (S/CO)	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility[a]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	120	0.02	0.000	N/A	0.000	N/A	0.000	N/A	0.000	N/A	0.000	N/A
Positive Control	120	3.47	0.049	1.4	0.034	1.0	0.000	0.0	0.000	0.0	0.059	1.7
Panel 1	120	0.77	0.041	N/A	0.000	N/A	0.000	N/A	0.009	N/A	0.042	N/A
Panel 2	120	1.19	0.066	5.5	0.000	0.0	0.000	0.0	0.020	1.6	0.068	5.7
Panel 3	120	3.02	0.106	3.5	0.000	0.0	0.000	0.0	0.046	1.5	0.115	3.8

[a] Includes repeatability (within-run), between-run, between-day, and between-site variability.

2. Linearity:
N/A

3. Analytical Specificity/Interference:

a) Potentially Interfering Endogenous Substances and Potentially Interfering Drugs

Studies were performed based on guidance from CLSI EP07, 3rd ed. Each substance was evaluated at 2 levels of the analyte (approximately 0.80 S/CO and 1.20 S/CO).

The studies demonstrated that the Anti-HCV Next assay is not susceptible to interference at the following interferent levels.

Potentially Interfering Endogenous Substance	**Interferent Level**
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Hemoglobin	1000 mg/dL
Total Protein	15 g/dL
Triglycerides	1500 mg/dL

Potentially Interfering Drug	**Interferent Level**
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3.0 mg/dL
Amoxicillin	5.4 mg/dL
Ascorbic Acid	5.25 mg/dL
Biotin	4250 ng/mL
Glecaprevir + Pibrentasvir	1791 ng/mL + 330 ng/mL
Ibuprofen	21.9 mg/dL
Pegylated (PEG) Interferon-alpha2a	0.18 mg/L
Ribavirin	1200 mg/L

b) Cross-reactivity (other specimen conditions or disease states)

The Anti-HCV Next assay was evaluated for potential interference using specimens from individuals with other disease states or medical conditions unrelated to HCV infection. The results were compared to a commercially available anti-HCV assay and data are summarized in the following table.

		Commercially Available Assay			
		Reactive		**Nonreactive**	
		Anti-HCV Next		**Anti-HCV Next**	
Category	**n**	**Reactive**	**Nonreactive**	**Reactive**	**Nonreactive**
Alcoholic Liver Disease	17	0	0	0	17
Anti-Dengue Virus	12	0	0	1	11
Anti-Double-Stranded DNA (Anti-dsDNA)	20	9	0	1	10
Anti-Hepatitis E Virus (Anti-HEV)	12	0	0	0	12

Category	n	Commercially Available Assay			
		Reactive		Nonreactive	
		Anti-HCV Next		Anti-HCV Next	
		Reactive	Nonreactive	Reactive	Nonreactive
Anti-Herpes Simplex Virus (Anti-HSV) Type 1/2	12	0	0	0	12
Anti-Mitochondrial Antibodies (AMA)	2	0	0	0	2
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	12	0	0	0	12
Anti-Nuclear Antibodies (ANA)	12	0	0	0	12
Anti-Parvovirus B19	12	0	0	0	12
Anti-Rubella Virus	11	0	0	0	11
Anti-Varicella Zoster Virus	12	1	0	0	11
Autoimmune Hepatitis	20	1	0	0	19
Cytomegalovirus (CMV) (Acute or Chronic)	12	1	0	0	11
E Coli	10	0	0	0	10
Elevated Total Bilirubin	12	5	0	0	7
Elevated Total Protein	12	4	0	0	8
Epstein-Barr Virus (EBV) (Acute or Chronic)	12	0	0	0	12
Fatty Liver Disease	16	0	0	0	16
Hemodialysis Patients	12	1	0	0	11
Hepatitis A (Acute or Chronic)	12	0	0	0	12
Hepatitis A Virus (HAV) Vaccination	12	1	0	0	11
Hepatitis B (Acute or Chronic)	33	0	0	0	33
Hepatitis B Virus (HBV)	12	0	0	0	12
HBV Vaccination	22	10	0	1	11

Category	n	Commercially Available Assay			
		Reactive		Nonreactive	
		Anti-HCV Next		Anti-HCV Next	
		Reactive	Nonreactive	Reactive	Nonreactive
Hepatitis D (Acute or Chronic)	11	0	0	1	10
Human Anti-Mouse Antibodies (HAMA)	12	0	0	0	12
Human Immunodeficiency Virus (HIV)	12	0	0	0	12
Human T-Cell Lymphotropic Virus (HTLV)	12	0	0	0	12
Hyper IgG or IgM (Monoclonal)	10	0	0	0	10
Influenza Vaccine Recipients	12	1	0	0	11
Non-Alcoholic Steatohepatitis (NASH)	33	1	0	0	32
Non-Specific Heterophile Antibodies	11	0	0	0	11
Pregnant and Multiparous Females	24	0	0	0	24
Primary Biliary Cirrhosis	33	2	0	0	31
Rheumatoid Factor (RF)	22	4	0	0	18
SARS-CoV-2 Vaccinees (Recent)	12	0	0	0	12
Smooth Muscle Antibodies (SMA)	12	0	0	0	12
Systemic Lupus Erythematosus (SLE)	12	0	0	0	12
Toxic Hepatitis (Acute or Chronic)	22	7	0	1	14
Toxoplasmosis IgG Positive	12	2	0	0	10
Treponema Pallidum	12	0	0	0	12
Yeast Infection	10	3	0	0	7
Total	**615**	**53**	**0**	**5**	**557**

c) Hook Effect

A study was performed to assess the high dose hook effect. A high-level anti-HCV positive sample, reactive at 1:78,125 dilution, was still reactive when tested undiluted with the Anti-HCV Next assay. The undiluted high-level anti-HCV positive sample mean result was 39.98 S/CO. The Anti-HCV Next assay is not susceptible to false negative results due to a high-dose-hook effect.

4. Assay Reportable Range:
N/A

5. Stability, Expected Values (Controls, Calibrators, or Methods, and samples):

a) Reagent stability

Reagent Shelf-Life Stability:

The purpose of this study was to establish the expiration dating of the Anti-HCV Next Reagent Kit when stored at the recommended storage temperature (2 to 8°C).

Four reagent lots were evaluated (3 lots of the 100 kit size and 1 lot of the 500 kit size) at time 0 (baseline) and once a month after storage at 2 to 8°C over a 13-month period.

Regression analysis was performed to calculate the % shift of the S/CO value from each time point to the intercept (regressed baseline).

The data supports a reagent shelf-life stability claim of up to 12 months when stored unopened at the recommended storage condition (2 to 8ºC).

Calibrator and controls shelf-life stability:

The purpose of this study was to establish the expiration dating of the Anti-HCV Next calibrator and controls when stored at the recommended storage temperature (2 to 8°C).

The data supports a shelf-life stability claim of up to 18 months for the calibrators and controls when stored unopened at the recommended storage condition (2 to 8ºC).

Reagent Storage Stability-In Use

The purpose of this study was to determine the time period over which the Alinity i reagents can be kept in the refrigerator and alternately moved back and forth from the refrigerator to the analyzer, simulating customer use over time.

The data supports a reagent in-use stability claim of up to 12 months when stored at the recommended storage condition (2 to 8ºC).

Reagent Storage Stability-Inverted Reagent Storage (INV)

The purpose of this study was to demonstrate stability of the Anti-HCV Next Reagents when the reagent kit is stored in an inverted position. The data supports a reagent inverted stability claim of up to 12 months when stored at the recommended storage condition (2 to 8ºC).

b) Specimen Stability

The use of the Anti-HCV Next assay is supported for testing serum and plasma specimens that have been stored at the following conditions:

- -20°C or colder off the cells/clot/gel up to 3 months
- 2 to 8°C on and off the cells/clot/gel up to 7 days
- 15 to 30°C on and off the cells/clot/gel up to 3 days
- 6 Freeze/Thaw Cycles after storage at 2 to 8°C at -20°C or colder

6. Analytical Sensitivity:

Seroconversion Sensitivity

To determine the seroconversion sensitivity, 31 seroconversion panels obtained from commercial vendors were tested on the Alinity i system using the Anti-HCV Next assay. The panel results were compared to a commercially available anti-HCV assay. The Anti-HCV Next assay detected 6 panels as reactive ahead, 1 panel as reactive behind, and 24 panels equal to the commercially available anti-HCV assay. Ahead and behind were determined based on the first reactive result, followed by continuously reactive results (in subsequent donations bleeds, if applicable). Data are summarized in the following table.

	Days to First Continuously Reactive Result		
Panel ID	**Anti-HCV Next**	**Commercially Available Anti-HCV Assay**	**Difference in Days[a]**
6215	20	20	0
6221	0	0	0
6222	36	36	0
6224	7	7	0
6225	45	73	-28
6226	30	30	0
6227	74	74	0
6228	21	28	-7
6229	17	10	7
9041	62	62	0
9044	21	21	0
9045	32	32	0
9046	69	69	0
9047	28	28	0
9054	82	82	0

	Days to First Continuously Reactive Result		
Panel ID	**Anti-HCV Next**	**Commercially Available Anti-HCV Assay**	**Difference in Days[a]**
10000	53	53	0
10025	56	56	0
10026	77	80	-3
10043	50	ND[b]	N/A
10062	41	41	0
10071	75	77	-2
10165	24	24	0
PHV912	0	0	0
PHV915	0	0	0
PHV916	9	9	0
PHV917	85	85	0
PHV919	0	0	0
PHV924	59	59	0
PHV926	0	0	0
SCP-HCV-009	52	52	0
SCP-HCV-011	27	N/A[c]	N/A

N/A = Not Applicable

[a] Difference in days = Anti-HCV Next days to first reactive result – commercially available anti-HCV assay days to first reactive result.

[b] ND = No bleed of this panel was detected reactive by the commercially available anti-HCV assay.

[c] First reactive result for the commercially available anti-HCV assay was not continuously reactive on subsequent bleed.

The total number of seroconversion panel bleeds detected with the Anti-HCV Next assay on Alinity i was greater than or equal to the number of panels behind compared to the number detected with the commercially available anti-HCV assay.

7. Assay Cut-Off:

The cutoff level was set to 1.00 S/CO given by the Sample Relative Light Unit (RLU)/ cutoff RLU, where the cutoff RLU was set to be 0.18 x Calibrator 1 Mean RLU.

The cutoff verification by ROC analysis supports that the selected cutoff level (1.00 S/CO) is within the range to optimize specificity and sensitivity. The cutoff was validated by the clinical studies included in this submission.

8. Accuracy (Instrument):

   N/A

9. Carry-Over:

   A study was conducted to evaluate the Anti-HCV Next assay (for Alinity i instrument) for its susceptibility to within-assay sample carryover. Specifically, it tested whether samples with exceptionally high levels of anti-HCV antibodies would contaminate or affect the results of other samples. The carryover effect was determined by calculating the difference in the mean Signal to Cutoff (S/CO) values between protected and unprotected samples.

Anti-HCV Next for Alinity i Within-Assay Sample Carryover

Protected Sample			Unprotected Sample			Difference[a]		% Difference[b]	
N	Mean (S/CO)	SD	N	Mean (S/CO)	SD	Result (S/CO)	Two-Sided 95% CI	Result	Two-Sided 95% CI
12	0.79	0.014	12	0.77	0.025	-0.01	(-0.03, 0.01)	-1.4	(-3.6, 0.8)

[a] Difference = Unprotected sample mean (S/CO) - Protected sample mean (S/CO)

[b] %Difference = (Difference / Protected sample mean) x 100

The results indicate that there is no significant carryover effect within the assay.

10. Genotype Detection

    A total of 149 HCV specimens from genotypes 1 through 6 (including genotype 4 non-a subtype) were evaluated using the Anti-HCV Next assay on the Alinity i system.

    All specimens were reactive with the Anti-HCV Next assay.

Genotype	n
Genotype 1	59
Genotype 2	23
Genotype 3	25
Genotype 4	21
Genotype 4 non-a subtype	5
Genotype 5	8
Genotype 6	8

B Comparison Studies:

1. Method Comparison with Predicate Device:
   See Clinical Studies section.

2. Matrix Comparison:

The study's purpose was to evaluate the suitability of eleven different blood collection tube types against a control serum tube for use with the Abbott Alinity i Anti-HCV Next assay.

Matched donor sets consisting of the different tube types were obtained from 12 individual donors and individual positive samples were used to prepare low positive analyte level samples.

The analysis of 1,074 valid replicates demonstrated that for all evaluation tube types the mean percent difference for low-positive samples ranged from 0.1% to 2.0%, and the mean difference for negative samples was 0.00 S/CO.

The study demonstrated that the following blood collection tube types are acceptable for use with the Alinity i Anti-HCV Next assay:

- Serum
- Serum (Separator Tube)
- Dipotassium EDTA (including plasma separator tube)
- Tripotassium EDTA
- Lithium Heparin (including separator tube)
- Sodium Heparin
- Sodium Citrate
- Citrate Phosphate Dextrose (CPD)
- Citrate Phosphate Dextrose Adenine-1 (CPDA-1)
- Disodium EDTA

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):

   A clinical study was conducted to evaluate the performance of the Alinity i Anti-HCV Next assay. The study involved testing 3,732 prospectively collected specimens from various patient populations, including individuals at risk for HCV infection, those with signs and symptoms of hepatitis, and pregnant women.

   The performance of Anti-HCV Next was evaluated against a final HCV infection status that includes results from FDA approved anti-HCV assays and HCV RNA assay.

The Positive percent agreement (PPA) and Negative percent agreement (NPA) of Alinity i Anti-HCV Next assay are shown in the following table.

Specimen Category	Number Tested	HCV Status						PPA (%) (95% CI)	NPA (%) (95% CI)
		HCV Infected		Indeterminate		HCV Not Infected			
		R	NR	R	NR	R	NR		
Individuals at Risk for HCV Infection	1584	232	2	2	0	49	1299	99.15 (232/234) (96.94, 99.77)	96.22 (1299/1350) (95.07, 97.12)
Individuals with Signs and Symptoms of Hepatitis	1898	155	0	2	0	31	1710	100.00 (155/155) (97.58, 100.00)	98.11 (1710/1743) (97.35, 98.65)
Pregnant Females	250	11	0	0	0	8	231	100.00 (11/11) (74.12, 100.00)	96.65 (231/239) (93.54, 98.29)
Overall	**3732**	**398**	**2**	**4**	**0**	**88**	**3240**	**99.50 (398/400) (98.20, 99.86)**	**97.24 (3240/3332) (96.63, 97.74)**

R = Reactive; NR = Nonreactive; PPA= Positive Percent Agreement: NPA= Negative Percent Agreement: CI = Confidence Interval,

Overall Agreement:

Positive Percent Agreement (PPA): 99.50% (398/400)
Negative Percent Agreement (NPA): 97.24% (3,240/3,332)

D Clinical Cut-Off:

N/A

E Expected Values/Reference Range:

A. Expected Values

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.
It is recommended that each laboratory determines its own reference range based upon its particular locale and population characteristics.
Of the 3732 specimens tested in the Anti-HCV Next clinical study, 1898 (50.9%) were from individuals with signs and symptoms of hepatitis, 1584 (42.4%) were from individuals at risk for HCV infection, and 250 (6.7%) were from pregnant females. Testing of these specimens was performed at 3 clinical sites located in Charleston, SC; Temple, TX; and Baltimore, MD.

F Other Supportive Instrument Performance Characteristics Data:

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.