April 28, 2026

Abbott Laboratories
Linda Sohn
Senior Manager Regulatory Affairs
100 Abbott Park Rd. Cp1
Abbott Park, IL 60064

Re: K252424
Trade/Device Name: Anti-HCV Next
Regulation Number: 21 CFR 866.3169
Regulation Name: Hepatitis C Virus Antibody Tests
Regulatory Class: Class II
Product Code: MZO
Dated: March 30, 2026
Received: March 30, 2026

Dear Linda Sohn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

UWE SCHERF -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K252424

Device Name
Anti-HCV Next

Indications for Use *(Describe)*
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 blood, plasma, or tissue donors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. 510(k) Number

K252424

II. Applicant Name

Abbott Laboratories
Department C2D2
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Abbott Park, IL 60064

Primary contact person for all communications:

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Date summary prepared: April 21, 2026

III. Device Name

Anti-HCV Next (also referred to as AntiHCVNx)

Reagents

Trade Name: Anti-HCV Next Reagent Kit
Device Classification: Class II, Special Controls*
Classification Name: Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus
Governing Regulation: 21 CFR 866.3169*
Code: MZO

Calibrator

Trade Name: Anti-HCV Next Calibrator
Device Classification: Class II, Special Controls*
Classification Name: Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus
Governing Regulation: 21 CFR 866.3169*
Code: MZO

Controls

Trade Name: Anti-HCV Next Controls
Device Classification: Class II, Special Controls*
Classification Name: Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus
Governing Regulation: 21 CFR 866.3169*
Code: MZO

IV. Predicate Device

Liaison XL Murex HCV Ab (P190011)

* FDA issued Final Order 86 FR 66173 to reclassify certain HCV Antibody qualitative assay devices from Class III to Class II with special controls. The final order renamed the assays to Hepatitis C Virus Antibody Tests and established a regulation number 21CFR § 866.3169.

V. Description of Device

Reagents

The kit configuration of the Anti-HCV Next Reagent Kit is described below.

List Number (LN)	**06T7921**	**06T7931**
Tests per cartridge	100	500
Number of cartridge sets 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 (*Escherichia coli* [*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.
- **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.

Calibrators

The Anti-HCV Next Calibrator is described below.

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

Calibrator	Quantity	Color
Calibrator 1	1 x 3.0 mL	Green[a]

[a] Dye: Green (Acid Yellow No. 23 and Acid Blue No. 9)

The Anti-HCV Next Calibrator is standardized against internal reference material.

Controls

The Anti-HCV Next Controls are described below.

- The **Negative Control** contains recalcified, human plasma.
- The **Positive Control** contains recalcified, heat-inactivated, human plasma reactive for anti-HCV.
- Preservatives: sodium azide and antimicrobial agents.

The ranges may be used for individual replicate control specifications on the Alinity i system.

Control	Quantity	Color	Range (S/CO)
Negative Control	3 x 3.0 mL	Natural	0.00 – 0.50
Positive Control	3 x 3.0 mL	Blue[a]	1.80 – 5.40

[a] Dye: Acid Blue No. 9

The Anti-HCV Next Positive Control is traceable to internal reference standards.

Biological Principles of the Procedure

This 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.

VI. Intended Use of the Device

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.

WARNING: Not cleared for use in screening blood, plasma, or tissue donors.

VII. Comparison of Technological Characteristics

The Anti-HCV Next assay (subject device) utilizes a CMIA methodology for the quantitative detection of antibodies to hepatitis C virus (anti-HCV) and is intended for use on the Alinity i system.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Assay Similarities and Differences

Subject Device and 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 antibody tests	Same
Regulatory Class	Class II	Class III
Product Code	MZO	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Abbott Anti-HCV Next assay is a hepatitis C virus antibody test with the following Intended 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 blood, plasma, or tissue donors.	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.
Analyte Measured	Antibodies to hepatitis C virus (anti-HCV)	Same
General Device Characteristic Differences		
Test Principle	Chemiluminescent microparticle immunoassay (CMIA) Qualitative 1-step/2-step	Chemiluminescent immunoassay (CLIA) Qualitative 2-step

Subject Device and Predicate Device(s):	K252424	P190011
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 tube types: serum and serum separator Plasma tube types: sodium heparin, lithium heparin, lithium heparin separator, sodium citrate, disodium EDTA, tripotassium EDTA, dipotassium EDTA, and dipotassium EDTA separator	Serum and Plasma Serum tube types: serum and serum separator Plasma tube types: dipotassium (K2) EDTA, lithium heparin, sodium heparin, and sodium citrate
Calibrator(s)	1 Calibrator (recalcified, heat-inactivated, human plasma reactive for anti-HCV)	1 Calibrator (diluted and inactivated serum/plasma containing low anti-HCV levels, BSA, PBS buffer, EDTA)
Calibration Storage	Maximum of 30 days	Maximum of 8 weeks

Subject Device and Predicate Device(s):	K252424	P190011
Control(s)	2 Controls (1 Negative, 1 Positive) Negative Control (negative recalcified human plasma) Positive Control (recalcified, heat-inactivated, human plasma reactive for anti-HCV)	Controls (1 Negative, 1 Positive) Negative Control (human 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

VIII. Summary of Nonclinical Performance

A. 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

N/A = Not Applicable

[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.

[*] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

B. 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
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

Panel ID	Days to First Continuously Reactive Result		Difference in Days[a]
	Anti-HCV Next	Commercially Available Anti-HCV Assay	
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.

C. Analytical Specificity/Interference

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

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

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
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
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

Category	n	Commercially Available Assay			
		Reactive		Nonreactive	
		Anti-HCV Next		Anti-HCV Next	
		Reactive	Nonreactive	Reactive	Nonreactive
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**

D. 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

E. High Dose Hook

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.

F. Tube Type Equivalence

The following tube types are acceptable for use with the Anti-HCV Next assay for Alinity i:

- Serum: serum and serum separator tubes
- Plasma: sodium heparin, lithium heparin, lithium heparin separator, sodium citrate, disodium EDTA, tripotassium EDTA, dipotassium EDTA, and dipotassium EDTA separator

The predicted bias at the evaluation point of 1.00 S/CO ranged from -0.4% to 2.9% when comparing specimens collected in the control tube (serum) to the same specimens collected in the evaluation tube types.

The regression analysis using the weighted Deming regression method is shown in the following table.

Collection Tube	n	Slope (S/CO) (95% CI)	Intercept (S/CO) (95% CI)	Correlation Coefficient (r) (95% CI)
Serum separator	52	1.00 (0.97, 1.02)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)
Sodium heparin plasma	52	1.02 (0.97, 1.06)	0.00 (-0.01, 0.00)	1.00 (1.00, 1.00)
Lithium heparin plasma	51	1.02 (0.99, 1.05)	0.00 (-0.01, 0.00)	1.00 (1.00, 1.00)
Lithium heparin plasma separator	52	1.01 (0.99, 1.04)	0.00 (-0.01, 0.00)	1.00 (1.00, 1.00)
Sodium citrate plasma	52	1.01 (0.97, 1.04)	0.01 (0.00, 0.01)	1.00 (1.00, 1.00)
Disodium EDTA plasma	52	1.03 (0.99, 1.06)	0.00 (0.00, 0.01)	1.00 (1.00, 1.00)
Tripotassium EDTA plasma	52	1.01 (0.98, 1.03)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)
Dipotassium EDTA plasma	52	1.01 (0.97, 1.04)	0.00 (0.00, 0.01)	1.00 (1.00, 1.00)
Dipotassium EDTA plasma separator	52	1.02 (1.01, 1.04)	0.00 (0.00, 0.00)	1.00 (1.00, 1.00)

CI = Confidence Interval

IX. Summary of Clinical Performance

A. Expected Values

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

It is recommended that each laboratory determine 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.

A demographic summary is provided in the following table.

	Population			
	Overall	**Signs and Symptoms of Hepatitis**	**At Risk for HCV Infection**	**Pregnant Females**
Race / Ethnic Group n (%)				
Black or African American	1718 (46.0)	793 (41.8)	896 (56.6)	29 (11.6)
White	1577 (42.3)	1037 (54.6)	453 (28.6)	87 (34.8)
More Than One Reported	36 (1.0)	5 (0.3)	30 (1.9)	1 (0.4)
Asian	32 (0.9)	21 (1.1)	8 (0.5)	3 (1.2)
American Indian or Alaska Native	19 (0.5)	7 (0.4)	10 (0.6)	2 (0.8)
Native Hawaiian or Other Pacific Islander	11 (0.3)	6 (0.3)	2 (0.1)	3 (1.2)
Other	3 (0.1)	1 (0.1)	1 (0.1)	1 (0.4)
Unknown / Not Reported	336 (9.0)	28 (1.5)	184 (11.6)	124 (49.6)
Sex n (%)				
Male	1889 (50.6)	1035 (54.5)	854 (53.9)	N/A
Female	1842 (49.4)	862 (45.4)	730 (46.1)	250 (100.0)
Unknown	1 (0.0)	1 (0.1)	N/A	N/A
Age Mean (Range)				
Years	44 (16 - 94)	47 (18 - 94)	43 (18 - 89)	26 (16 - 42)

N/A = Not Applicable

Individuals with Signs and Symptoms of Hepatitis

The distribution of Anti-HCV Next reactive and nonreactive results among the individuals with signs and symptoms of hepatitis population by age and sex is summarized in the following table.

Age Range (Years)	Sex	Number of Reactives (%)	Number of Nonreactives (%)	Total
18 to 29	Male	6 (4.58)	125 (95.42)	131
	Female	3 (2.33)	126 (97.67)	129
30 to 39	Male	16 (7.96)	185 (92.04)	201
	Female	3 (1.70)	173 (98.30)	176
40 to 49	Male	28 (12.39)	198 (87.61)	226
	Female	12 (7.45)	149 (92.55)	161
	Unknown/Not Reported	0 (0.00)	1 (100.00)	1
50 to 59	Male	29 (12.29)	207 (87.71)	236
	Female	12 (5.48)	207 (94.52)	219
60 to 69	Male	47 (26.11)	133 (73.89)	180
	Female	16 (12.90)	108 (87.10)	124
70 to 79	Male	9 (16.98)	44 (83.02)	53
	Female	7 (17.07)	34 (82.93)	41
80 to 89	Male	0 (0.00)	8 (100.00)	8
	Female	0 (0.00)	11 (100.00)	11
90 to 99	Female	0 (0.00)	1 (100.00)	1
Total		**188 (9.91)**	**1710 (90.09)**	**1898**

Individuals at Risk for HCV Infection

All persons in the individuals at risk for HCV infection population were at risk for HCV infection due to lifestyle, behavior, occupation, or a known exposure event.

The distribution of Anti-HCV Next reactive and nonreactive results among the individuals at risk for HCV infection population by age and sex is summarized in the following table.

Age Range (Years)	Sex	Number of Reactives (%)	Number of Nonreactives (%)	Total
18 to 29	Male	13 (9.29)	127 (90.71)	140
	Female	13 (7.74)	155 (92.26)	168
30 to 39	Male	20 (14.49)	118 (85.51)	138
	Female	13 (7.83)	153 (92.17)	166
40 to 49	Male	35 (20.23)	138 (79.77)	173
	Female	14 (7.95)	162 (92.05)	176
50 to 59	Male	66 (23.91)	210 (76.09)	276
	Female	44 (27.33)	117 (72.67)	161
60 to 69	Male	48 (42.48)	65 (57.52)	113
	Female	10 (19.23)	42 (80.77)	52
70 to 79	Male	5 (41.67)	7 (58.33)	12
	Female	2 (28.57)	5 (71.43)	7
80 to 89	Male	0 (0.00)	2 (100.00)	2
Total		**283 (17.87)**	**1301 (82.13)**	**1584**

Pregnant Females

The distribution of Anti-HCV Next reactive and nonreactive results among the pregnant female population by age is summarized in the following table.

Age Range (Years)	**Number of Reactives (%)**	**Number of Nonreactives (%)**	**Total**
Less than 18	0 (0.00)	5 (100.00)	5
18 to 29	11 (6.47)	159 (93.53)	170
30 to 39	6 (8.82)	62 (91.18)	68
40 to 49	2 (28.57)	5 (71.43)	7
Total	**19 (7.60)**	**231 (92.40)**	**250**

A. 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

N/A = Not Applicable

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

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline–Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

B. Percent Agreement

A clinical study was performed based on guidance from CLSI EP12, 3rd ed.*

A total of 3732 specimens were evaluated using the Anti-HCV Next assay and a commercially available anti-HCV assay (comparator). Specimens reactive by the comparator assay were tested using 2 additional FDA-cleared anti-HCV devices. The consensus of the test results from the comparator assay and the 2 additional FDA-cleared anti-HCV devices was used to determine the intermediate HCV status. Intermediate HCV reactive and indeterminate specimens were further tested with an FDA-cleared HCV RNA assay to determine final HCV status. Percent agreement for the Anti-HCV Next assay was determined using the HCV status.

The algorithm used to determine the HCV status is shown in the following table.

Anti-HCV Comparator	Anti-HCV Assay 2	Anti-HCV Assay 3	Intermediate HCV Status	HCV RNA Result	HCV Status
Nonreactive	N/A	N/A	Nonreactive	N/A	Not Infected
Reactive	Reactive	Reactive	Reactive	Reactive	Infected (Active)
				Nonreactive	Infected (Resolved)
	Reactive	Nonreactive/ Equivocal[a]	Reactive	Reactive	Infected (Active)
				Nonreactive	Infected (Resolved)
	Nonreactive/ Equivocal[a]	Reactive	Reactive	Reactive	Infected (Active)
				Nonreactive	Infected (Resolved)
	Equivocal[a]	Equivocal[a] / Nonreactive	Indeterminate	Reactive	Infected (Active)
				Nonreactive	Indeterminate
	Nonreactive	Equivocal[a]	Indeterminate	Reactive	Infected (Active)
				Nonreactive	Indeterminate
	Nonreactive	Nonreactive	Nonreactive	N/A	Not Infected

N/A = Not Applicable

[a] Equivocal represents samples whose final interpretations fall within the result area between nonreactive and reactive per each manufacturer's labeling.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Qualitative, Binary Output Examination Performance.* 3rd ed. CLSI Guideline EP12. Wayne, PA: CLSI; 2023.

The positive percent agreement (PPA) and negative percent agreement (NPA) 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)
Individuals at Risk for HCV Infection or with Signs and Symptoms of Hepatitis (Combined)	3482	387	2	4	0	80	3009	99.49 (387/389) (98.15, 99.86)	97.28 (3009/3093) (96.65, 97.80)
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; CI = Confidence Interval

X. Conclusion Drawn from Nonclinical and Clinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the subject device (Anti-HCV Next) performance is substantially equivalent to the predicate assay (LIAISON XL HCV Ab P190011).