



September 23, 2026

Abbott Laboratories
Caroline Mendes
Regulatory Affairs Manager
100 Abbott Park Rd., Cp1
Abbott Park, Illinois 60064

Re: K262156
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: June 25, 2026
Received: June 26, 2026

Dear Caroline Mendes:

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

Indications for Use

510(k) Number (if known)

K262156

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 and pediatric (18 months through 21 years) 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, cell, 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

K262156

II. Applicant Name

Abbott Laboratories
Department C2D2
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Date summary prepared: September 22, 2026

III. Device Name

Anti-HCV Next (also referred to as AntiHCVNx)

Trade Name: Anti-HCV Next

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

DiaSorin LIAISON XL Murex HCV Ab (P190011)

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.

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 and pediatric (18 months through 21 years) 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, cell, or tissue donors.

VII. Comparison of Technological Characteristics

The Anti-HCV Next assay (subject device) utilizes a CMIA methodology for the qualitative 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 tables.

Assay Similarities

Characteristics	Subject Device Anti-HCV Next (To Be Determined)	Predicate Device DiaSorin LIAISON XL Murex HCV Ab P190011
Methodology	Chemiluminescent microparticle immunoassay (CMIA)	Chemiluminescent immunoassay (CLIA)
Intended Use and 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 and pediatric (18 months through 21 years) 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, cell, or tissue donors.	The LIAISON XL MUREX HCV Ab assay is an <i>in vitro</i> 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.
Assay Type	Qualitative, 1-step/2-step	Qualitative 2-step
Type of Specimen	Serum and Plasma	Serum and Plasma

Assay Similarities (Continued)

Characteristics	Subject Device Anti-HCV Next (To Be Determined)	Predicate Device DiaSorin Liaison XL Murex HCV Ab P190011
Interpretation of Results	≥ 1.00 S/CO Reactive 0.00 to < 0.90 S/CO Nonreactive 0.90 to < 1.00 S/CO Grayzone Grayzone Instruction: Retest in duplicate • If 2 results are ≥ 1.00 S/CO: Reactive. • If 2 or 3 results (including initial result) are < 1.00 S/CO: Nonreactive S/CO = signal of sample / signal of cutoff.	≥ 1.00 S/CO Reactive < 0.80 S/CO Nonreactive ≥ 0.80 < 1.00 are equivocal Equivocal Instruction: Retest in duplicate. • Reactive if 2 out of 3 retests are ≥ 1.0 S/CO. • Nonreactive if 2 out of 3 retests are < 1.0 S/CO.
Cut Off	1.00 S/CO	1.00 S/CO
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.
Calibrator(s)	1 Calibrator	1 Calibrator
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)

Assay Differences

Characteristics	Subject Device Anti-HCV Next (To Be Determined)	Predicate Device DiaSorin Liaison XL Murex HCV Ab P190011
Components	<u>Microparticles</u> – Streptavidin-coated microparticles precomplexed with biotinylated HCV antigen (<i>E coli</i>, recombinant) and biotinylated HCV core synthetic peptide in pyrophosphate-buffered saline with surfactants. Minimum concentration: 0.05% solids. Preservative: sodium azide. <u>Conjugate 1</u> – Acridinium-labeled HCV antigen (<i>E coli</i>, recombinant) and acridinium-labeled HCV core synthetic peptide conjugate in pyrophosphate-buffered saline. Minimum concentration: 10 ng/mL. Preservative: sodium azide. <u>Conjugate 2</u> – Acridinium-labeled HCV antigen (<i>E coli</i>, recombinant) conjugate in pyrophosphate-buffered saline. Minimum concentration: 0.01 ng/mL. Preservative: sodium azide. <u>Assay Diluent</u> – Pyrophosphate buffer with protein additives (bovine) and detergent. Preservatives: sodium azide and antimicrobial agents.	<u>Magnetic particles [SORB]</u> - Magnetic particles coated with HCV core and NS4 recombinant antigens (produced in baculovirus and <i>E. coli</i> respectively), streptavidin-coated magnetic particles, BSA, PBS buffer, EDTA, preservatives. <u>HCV NS3 Antigen [Ag]</u> -Biotinylated HCV NS3 recombinant antigen (produced in <i>E.coli</i>), MES buffer, preservatives. <u>Conjugate [CONJ]</u> - 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. <u>Specimen diluent [DIL SPE]</u> - BSA, casein, non-specific recombinant protein (produced in <i>E.coli</i>), phosphate buffer, EDTA, preservatives, an inert blue dye.
Calibration Storage	Maximum of 30 days	Maximum of 8 weeks

VIII. Summary of Nonclinical Performance

The following nonclinical performance characteristics of the Anti-HCV Next for Alinity i assay are provided in K252424.

- Within-Laboratory Precision (20-Day)
- Seroconversion Sensitivity
- Analytical Specificity/Interference (Potentially Interfering Endogenous Substances, Potentially Interfering Drugs, Other Specimen Conditions or Disease States)
- Genotype Detection
- High Dose Hook
- Tube Type Equivalence

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 3856 specimens tested in the Anti-HCV Next clinical study, 1840 (47.7%) were from adults (> 21 years of age) with signs and symptoms of hepatitis, 1510 (39.2%) were from adults at risk for HCV infection, 250 (6.5%) were from pregnant females, and 256 (6.6%) were from pediatric individuals ($\leq$ 21 years of age).

Testing of these specimens was performed at 4 clinical sites located in Charleston, SC; Temple, TX; Pompano Beach, FL; and Baltimore, MD.

A demographic summary is provided in the following table.

	Population				
	Overall (n=3856)	Adults		Pregnant Females (n=250)	Pediatric (n=256)
		Signs and Symptoms of Hepatitis (n=1840)	At Risk for HCV Infection (n=1510)		
Race / Ethnic Group n (%)					
Black or African American	1733 (44.9)	773 (42.0)	864 (57.2)	29 (11.6)	67 (26.2)
White	1684 (43.7)	1003 (54.5)	423 (28.0)	87 (34.8)	171 (66.8)
More Than One Reported	38 (1.0)	5 (0.3)	29 (1.9)	1 (0.4)	3 (1.2)
Asian	32 (0.8)	21 (1.1)	8 (0.5)	3 (1.2)	0 (0.0)
American Indian or Alaska Native	19 (0.5)	7 (0.4)	10 (0.7)	2 (0.8)	0 (0.0)
Native Hawaiian or Other Pacific Islander	11 (0.3)	6 (0.3)	2 (0.1)	3 (1.2)	0 (0.0)
Other	3 (0.1)	1 (0.1)	1 (0.1)	1 (0.4)	0 (0.0)
Unknown / Not Reported	336 (8.7)	24 (1.3)	173 (11.5)	124 (49.6)	15 (5.9)
Sex n (%)					
Male	1946 (50.5)	1009 (54.8)	822 (54.4)	N/A	115 (44.9)
Female	1909 (49.5)	830 (45.1)	688 (45.6)	250 (100.0)	141 (55.1)
Unknown	1 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Age Mean (Range)					
Years	43 (1 - 94)	48 (22 - 94)	44 (22 - 89)	26 (16 - 42)	16 (21 Months – 21 Years)

N/A = Not Applicable

Pediatric

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

Age Range	Number of Reactives (%)	Number of Nonreactives (%)	Total
18 Months to 12 Years	5 (16.13)	26 (83.87)	31
13 to 21 Years	7 (3.11)	218 (96.89)	225
Total	12 (4.69)	244 (95.31)	256

The distribution of Anti-HCV Next reactive and nonreactive results among adult individuals with signs and symptoms of hepatitis or at risk for HCV infection, as well as pregnant females, is provided in K252424.

B. System Reproducibility

Reproducibility of the Anti-HCV Next for Alinity i assay is provided in K252424.

C. Percent Agreement

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

A total of 256 specimens from pediatric individuals 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. Specimens with an Intermediate HCV status of “Reactive” or “Indeterminate” 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.

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		
Pediatric	256	6	0	0	0	6	244	100.00 (6/6) (60.97, 100.00)	97.60 (244/250) (94.86, 98.90)

R = Reactive; NR = Nonreactive; CI = Confidence Interval

Adult individuals with signs and symptoms of hepatitis or at risk for HCV infection, as well as pregnant females, were evaluated in K252424. The PPA and NPA are reported in K252424.

D. Pediatric Spiking Study

Due to the low anti-HCV positive prevalence within the pediatric population, a supplemental study was conducted to evaluate the results observed when serum samples from pediatric individuals were tested with the Anti-HCV Next assay. A total of 59 pediatric (aged 17 months to 21 years) and 59 adult negative serum specimens were paired and spiked with anti-HCV positive specimens to yield samples at approximately 2 to 3 times the assay cutoff. The distribution of the absolute % differences between the pediatric and paired adult samples is presented in the following table.

		Distribution of Absolute Percent Differences		
Age Range	n	≤ 10%	> 10% to ≤ 20%	> 20% to < 30%
17 Months to 12 Years	23	69.6% (16/23)	21.7% (5/23)	8.7% (2/23)
13 to 21 Years	36	83.3% (30/36)	11.1% (4/36)	5.6% (2/36)
Total	59	78.0% (46/59)	15.3% (9/59)	6.8% (4/59)

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 (DiaSorin LIAISON XL Murex HCV Ab P190011).