



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

I Background Information:

A 510(k) Number

K262156

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	866.3169 - Hepatitis C virus antibody tests	Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain clearance to expand the intended use of the Anti-HCV Next assay (cleared under K252424 for adults aged ≥ 18 years) to include the pediatric population.

B Measurand:

Antibodies to hepatitis C virus (anti-HCV)

C Type of Test:

Qualitative, 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 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.

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:

The Alinity i System

IV Device/System Characteristics:

A Device Description:

A chemiluminescent microparticle immunoassay (CMIA) Used for qualitative detection of antibodies hepatitis C virus (HCV). It is a reusable multi-patient use device and in a Professional Healthcare Facility environment.

This product is composed of 4 components which are packaged as a 2-cartridge reagent set: Microparticles, Conjugate 1, Assay diluent, Conjugate 2. See K252424.

B Principle of Operation:

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.

Interpretation of the results:

Initial Interpretation

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 medical guidelines for recommendations for supplemental testing
	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.

C Instrument Description Information:

1. Instrument Name:

The 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 Alinity i system handles samples using a fully automated, continuous and random-access workflow.

4. Calibration:

The Anti-HCV Next Calibrator is sold separately. Calibration data is valid for up to 30 days. See K252424.

5. Quality Control:

Anti-HCV Next positive and negative controls are sold separately. QC testing is recommended every 24 hours or upon reagent lot changes to ensure results stay within target ranges. See K252424.

V Substantial Equivalence Information:

A Predicate Device Name(s):

LIAISON XL MUREX HCV Ab

B Predicate 510(k) Number(s):

P190011

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K262156 (Candidate device)</u>	<u>P190011 (Predicate device)</u>
Device Trade Name	Anti-HCV Next	LIAISON XL MUREX HCV Ab
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 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 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 dipotassium 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

	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.	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.
Intended use population	Human adult, pediatric and pregnant women.	Human adult, pediatric and pregnant women.
Assay Type	Qualitative	Qualitative
General Device Characteristic Differences		
Technology	Chemiluminescent microparticle immunoassay (CMIA)	Chemiluminescent immunoassay (CLIA)
Pediatric population	Pediatric (18 months through 21 years)	Pediatric (2-21 years).
Sample matrix	Serum SST Plasma (sodium heparin, lithium heparin, lithium heparin separator, sodium citrate, disodium EDTA, tripotassium EDTA, dipotassium EDTA, and dipotassium EDTA separator tubes)	Serum Plasma (lithium and sodium heparin, sodium citrate and di-potassium EDTA)
Calibrator	1 positive level; recalcified, heat-inactivated human plasma reactive for anti-HCV	Diluted, inactivated serum/plasma with low anti-HCV
Instrument Platform	Alinity i system	LIAISON XL Analyzer
Applications/Test Time	- Time to First Result: less than 29 minutes. - Maximum Throughput: Up to 200 tests per hour on the instrument. - Walk-Away Time Up to 5 hours. (minimum 3 hours)	- Time to First Result: 17 minutes. - Maximum Throughput: Up to 171–180 tests per hour on the instrument. - Walk-Away Time: Up to 6 hours.
Calibration Interval	Recalibrate when: - A new reagent lot is used - QC results fall outside accepted limits 30 days have passed since last calibration - Critical maintenance or service has been performed	Calibrate using the calibrator in the reagent integral (4 calibrations per solution). Recalibrate in triplicate when: A new lot of reagent integral or Starter Kit is used

		• More than 8 weeks have passed since last calibration • The analyzer has been serviced • Control values are outside expected ranges
--	--	--

VI Standards/Guidance Documents Referenced:

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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

See K252424 Precision/Reproducibility section VII A 1.

2. Linearity:

Not applicable, as this is a qualitative test.

3. Analytical Specificity/Interference:

See K252424 section VII A 3.

4. Detection Limit and Assay Reportable Range:

Not applicable

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

Stability and Expected Values see K252424 section VII A 5.

6. Assay Cut-Off:

See K252424 section VII A 7.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See K252424 section VII C 3.

2. Matrix Comparison:

See K252424 section VII B 2.

C Clinical Studies:

1. Adults and pregnant women clinical study

See K252424 section VII C 3.

2. Other Clinical Supportive Data:

Clinical Performance Study - Pediatric Population

In this submission, Abbott conducted a two-site clinical study to evaluate performance of the Anti-HCV Next assay (Alinity i system) using 124 de-identified pediatric specimens (ages 21 months through 17 years). Of these, 86 (69.4%) were from individuals at risk for HCV infection and 38 (30.6%) were from individuals with signs and symptoms of hepatitis. The assay produced a Negative Percent Agreement (NPA) of 99.17% (119/120; 95% Confidence Interval (CI): 95.43%–99.85%) and a Positive Percent Agreement (PPA) of 100.00% (4/4; 95% CI: 51.01%–100.00%). The results are presented in table 1.

Table 1. Clinical performance results of the Anti-HCV Next in the pediatric population

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 Individuals at Risk for HCV Infection	86	4	0	0	0	1	81	100.00 (4/4) (51.01-100.00)	98.78 (81/82) (93.41-99.78)
Pediatric Individuals with Signs and Symptoms of Hepatitis	38	0	0	0	0	0	38	NA	100.00 (38/38) (90.82-100.00)
Pediatric Individuals at Risk for HCV Infection or with Signs and Symptoms of Hepatitis	124	4	0	0	0	1	119	100.00 (4/4) (51.01-100.00)	99.17 (119/120) (95.43-99.85)

R = Reactive; NR = Nonreactive; PPA = Positive Percent Agreement; NPA = Negative Percent Agreement; CI = Confidence Interval; NA = Not Applicable

Clinical performance of combined pediatric population from submissions K252424 and K262156

A total of 256 specimens from pediatric individuals with signs and symptoms for hepatitis or at risk for HCV infection were evaluated with the Anti-HCV Next assay. The PPA and NPA are shown in table 2.

Table 2. Clinical performance results of the Anti-HCV Next in pediatric population-combined data (K252424 and K262156)

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 Individuals at Risk for HCV Infection	160	6	0	0	0	6	148	100.00 (6/6) (60.97-100.00)	96.10 (148/154) (91.76-98.20)
Pediatric Individuals with Signs and Symptoms of Hepatitis	96	0	0	0	0	0	96	NA	100.00 (96/96) (96.15-100.00)
Pediatric Individuals at Risk for HCV Infection or with Signs and Symptoms of Hepatitis	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; PPA = Positive Percent Agreement; NPA = Negative Percent Agreement; CI = Confidence Interval; NA = Not Applicable.

Pediatric spiking study

Due to the low prevalence of HCV within the pediatric population, a supplemental spiking study was conducted to determine if equivalent results are obtained in pediatric and adult serum samples on Anti-HCV Next assay. A total of 59 pediatric (aged 17 months to 21 years) and 59 adult negative serum samples 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 in signal between the pediatric and paired adult samples is presented in table 3.

Table 3. Pediatric spiking study data

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

N = Number of samples

D Expected Values/Reference Range:

See K252424 section E.

E Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

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