July 19, 2018

Siemens Healthcare Diagnostics Inc.
Matthew Gee
Senior Manager, Regulatory Affairs
511 Benedict Avenue
Tarrytown, NY 10591

Re: K171566
Trade/Device Name: Atellica IM High-Sensitivity Troponin I (TnIH)
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: June 26, 2018
Received: June 27, 2018

Dear Matthew Gee:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171566

Device Name
Atellica IM High-Sensitivity Troponin I (TnIH)

Indications for Use *(Describe)*
The Atellica IM High-Sensitivity Troponin I (TnIH) assay is for in vitro diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma (lithium heparin) using the Atellica IM Analyzer. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).

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 of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: K171566

1. Date Prepared

July 13, 2018

2. Applicant Information

Contact: Matthew Gee, M.Sc.
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3. Regulatory Information

Table 1. Regulatory Information for Atellica IM High-Sensitivity Troponin I (TnIH)

Trade Name	Atellica® IM High-Sensitivity Troponin I (TnIH)
Model Numbers	10997840 (1-pack); 10997841 (5-pack)
Common Name	Immunoassay Method, Troponin Subunit
Regulation Number	862.1215
Regulation Description	Creatine phosphokinase /creatine kinase or isoenzymes test system
Product Code	MMI
FDA Classification	Class II
Review Panel	Clinical Chemistry (75)

4. Predicate Device Information

Predicate Device Name: Elecsys Troponin T Gen 5 STAT Immunoassay

510(k) Number: K162895

5. Intended Use / Indications for Use

The Atellica® IM High-Sensitivity Troponin I (TnIH) assay is for *in vitro* diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma (lithium heparin) using the Atellica® IM Analyzer. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).

6. Device Description

Table 2. Summary of Ingredients of the Atellica IM TnIH Assay Components

Component	Volume	Ingredients
Atellica IM TnIH Primary Reagent ReadyPack (included in assay kit)		
Atellica IM TnIH Lite Reagent	8.0 mL/pack	Bovine serum albumin (BSA) conjugated to a recombinant monoclonal (sheep) Fab anti-human cTnI (~0.2–0.4 µg/mL) labeled with acridinium ester in HEPES buffer; stabilizers; preservatives
Atellica IM TnIH Solid Phase Reagent	13.0 mL/pack	Streptavidin-coated magnetic latex particles (0.45 mg/mL) with 2 biotinylated (mouse and sheep) monoclonal anti-troponin I antibodies in buffer; stabilizers; preservatives
Atellica IM TnIH Calibrator (included in assay kit)		
Atellica IM TnIH High Calibrator (Cal H)	1.0 mL/vial (lyophilized)	Human serum; human cTnI; preservatives
Atellica IM TnIH Low Calibrator (Cal L)	1.0 mL/vial	HEPES buffer; bovine serum albumin (BSA); surfactants; preservatives

7. Purpose of the Submission

The purpose of this premarket notification is to submit a new device (Atellica IM TnIH) to FDA for consideration for clearance.

8. Comparison of Predicate Device and Modified Device

Table 3. Comparison of Atellica IM TnIH Assay to Predicate

Item	Atellica IM TnIH (Candidate Device)	Elecsys Troponin T Gen 5 STAT Immunoassay (Predicate Device)
Intended Use	The Atellica® IM High-Sensitivity Troponin I (TnIH) assay is for *in vitro* diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma using the Atellica® IM Analyzer. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).	Immunoassay for the in vitro quantitative determination of cardiac troponin T (cTnT) in lithium heparin plasma. The immunoassay is intended to aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas system analyzers.
Indications for Use	The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).	The immunoassay is intended to aid in the diagnosis of myocardial infarction.
Methodology	Chemiluminescence	Electrochemiluminescence
Assay Protocol	Sandwich immunoassay	Same
Analyte	Cardiac troponin I	Cardiac troponin T
Specimen Type	Lithium heparin plasma and serum	Lithium heparin plasma
Lower Limit of Measuring Range	LoQ	Same

Table 3. Comparison of Atellica IM TnIH Assay to Predicate

Item	Atellica IM TnIH (Candidate Device)	Elecsys Troponin T Gen 5 STAT Immunoassay (Predicate Device)
Measuring Range	2.50–25,000 pg/mL (ng/L)	6.0–10,000 pg/mL (ng/L)
Upper 99th Percentile Cutoff	Female-Lithium Heparin: 34.11 pg/mL Male-Lithium Heparin: 53.48 pg/mL Combined-Lithium Heparin: 45.20 pg/mL Female-Serum: 38.64 pg/mL Male-Serum: 53.53 pg/mL Combined-Serum: 45.43 pg/mL *Overall:* 45.20 pg/mL	Female: 14 pg/mL (ng/L) Male: 22 pg/mL (ng/L) Combined: 19 pg/mL (ng/L)
Calibration	2-point calibration	Same

9. Standard/Guidance Document References

The following recognized standards from Clinical Laboratory Standards Institute (CLSI) were used as a basis of the study procedures described in this submission:

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition (CLSI EP05-A3, 2014; Recognition No. 7-251)
- Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (CLSI EP06-A, 2003; Recognition No. 7-193)
- Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition (CLSI EP07-A2, 2005; Recognition No. 7-127)
- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition (CLSI EP17-A2, 2012; Recognition No. 7-233)
- Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (CLSI EP28-A3c – formerly C28-A3c, 2010; Recognition No. 7-224)
- Medical devices – Application of risk management to medical devices (ANSI/AAMI/ISO 14971:2007/(R)2010; Recognition No. 5-70)

10. Performance Characteristics

10.1 Precision

A 20-day precision study was performed according to CLSI EP5-A3. Samples included eight (8) samples (4 serum; 4 lithium heparin plasma) from AMI patients. These samples were diluted with native serum or lithium heparin plasma from healthy subjects. Samples were assayed twice a day in replicates of 2, for 20 days (n = 80 replicates per sample). Testing was performed on 2 instruments. The following are representative of the results obtained:

Sample	Mean (pg/mL)	Repeatability		Within-Lab	
		SD (pg/mL)	%CV	SD (pg/mL)	%CV
Serum 1	12.72	0.55	4.3	0.59	4.7
Serum 2	127.93	2.30	1.8	3.09	2.4
Serum 3	1334.97	22.28	1.7	27.48	2.1
Serum 4	13815.89	192.05	1.4	266.91	1.9
Lithium Heparin Plasma 1	12.03	0.49	4.1	0.64	5.3
Lithium Heparin Plasma 2	131.21	2.23	1.7	2.75	2.1
Lithium Heparin Plasma 3	1363.38	27.11	2.0	32.00	2.3
Lithium Heparin Plasma 4	12862.97	212.91	1.7	291.00	2.3

10.2 Linearity

Two linearity studies were performed according to CLSI EP06-A, each using 9 samples prepared by mixing a high-spiked cTnI sample with a low cTnI sample. The first study spanned the assay range and the second study ranged to ~150 pg/mL. Each study was tested with lithium heparin plasma and serum. The mean was taken from each sample tested in duplicate. The following are representative of the results obtained:

Sample	Deviation from Linear Fit (% or pg/mL)			
	Li Hep Full Range	Serum Full Range	Li Hep ~150 pg/mL	Serum ~150 pg/mL
A	-0.53%	0.27%	2.23%	0.73%
B	3.26%	-6.46%	-0.07%	-0.04%
C	2.08%	-4.50%	-0.11%	-0.06%
D	0.78%	-2.95%	-0.09%	-0.05%
E	-0.01%	-0.27%	-0.04%	-0.03%
F	-1.40%	1.20%	0.01%	-0.01%
G	-2.49%	3.24%	0.07%	0.01%
H	-3.50%	5.43%	0.13%	0.03%
I	-4.58%	7.47%	0.19%	0.06%

10.3 Dilution Recovery

Eight (8) native AMI samples (4 lithium heparin plasma and 4 serum) measuring above the analytical measuring range (i.e. >25000 pg/mL) were diluted to 1:2 and 1:5 with Multi-Diluent 11. Recoveries for individual samples were all within 20%. The mean of all 1:2 dilutions was 99.6%. The mean of all 1:5 dilutions was 91.6%.

10.4 Hook Effect

A study was performed to evaluate hook effect. There is no hook effect with the Atellica IM TnIH assay up to 500,000 pg/mL.

10.5 Detection Limit

The limit of blank (LoB), limit of detection (LoD), and the limit of quantitation (LoQ) were determined as described in CLSI protocol EP17-A2. The Atellica IM TnIH assay has an LoB of 0.50 pg/mL, an LoD of 1.60 pg/mL, and an LoQ of 2.50 pg/mL.

The LoB is defined as the highest measurement result that is likely to be observed for a blank sample. The LoD is defined as the lowest concentration of cardiac troponin I that can be detected with 95% probability. The LoQ is defined as the lowest concentration of cardiac troponin I that can be detected at a total CV of 20%.

10.6 Endogenous Interference

Endogenous interference studies were performed according to CLSI EP07-A2. Sample pools for each matrix (~60 pg/mL cTnI) were spiked with potential interferents. Control samples were prepared by spiking sample pools with the appropriate diluent at the same volume as the interfering substance stock. For substances spiked at doses that caused >10% interference, serial measurements were taken and analyzed by linear regression. Results are presented below.

Endogenous Substance	Matrix	Control Dose (pg/mL)	Test Dose (pg/mL)	% Interference
Bilirubin (Conjugated) 40 mg/dL	Li Hep	58.08	57.14	-1.61%
	Serum	59.24	57.95	-2.17%
Bilirubin (Unconjugated) 60 mg/dL	Li Hep	58.78	58.75	-0.06%
	Serum	58.87	58.26	-1.04%
Biotin 3500 ng/mL	Li Hep	59.16	58.86	-0.51%
	Serum	59.40	59.57	0.28%
Cholesterol 500 mg/dL	Li Hep	50.33	51.90	3.12%
	Serum	51.45	51.47	0.04%
Hemoglobin 500 mg/dL	Li Hep	57.29	56.55	-1.29%
	Serum	58.10	55.31	-4.81%
Protein (Albumin) 6 g/dL	Li Hep	57.57	56.18	-2.40%
	Serum	57.64	58.36	1.25%
Protein (Gamma Globulin) 2.5 g/dL	Li Hep	53.44	53.28	-0.30%
	Serum	52.68	54.78	3.99%
Protein (Total) 12 g/dL	Li Hep	54.89	57.35	4.48%
	Serum	57.04	56.33	-1.25%
Triglycerides 2000 mg/dL	Li Hep	51.83	52.05	0.43%
	Serum	52.20	51.84	-0.70%

10.7 Drug Interference

Therapeutic drug interference studies were performed according to CLSI EP07-A2. Sample pools (~60 pg/mL cTnI) for each matrix were tested. Control samples were prepared by spiking sample pools with the appropriate diluent at the same volume as the interfering substance stock. At the tested concentrations, all drugs caused <10% interference on the Atellica IM TnIH assay.

Drug	Low Concentration	High Concentration
Abciximab	5 µg/mL	40 µg/mL
Acetaminophen	20 µg/mL	200 µg/mL
Acetylsalicylic Acid	261 µg/mL	652 µg/mL
Allopurinol	13 µg/mL	40 µg/mL
Amiodarone	1.8 µg/mL	6.1 µg/mL
Ampicilin	10 µg/mL	53 µg/mL
Ascorbic Acid	12 µg/mL	60 µg/mL
Atenolol	1.1 µg/mL	10 µg/mL
Caffeine	12 µg/mL	60 µg/mL
Captopril	1.0 µg/mL	5.0 µg/mL
Cefoxitin	120 µg/mL	660 µg/mL
Cinnarizine	200 ng/mL	400 ng/mL
Clopidogrel	37.5 µg/mL	75 µg/mL
Cocaine	0.1 µg/mL	10 µg/mL
Digoxin	1.4 ng/mL	6.1 ng/mL
Digitoxin	30 ng/mL	60 ng/mL
Diltiazem	0.2 µg/mL	6.2 µg/mL
Disopyramide	3.5 µg/mL	10 µg/mL
Dopamine	0.3 µg/mL	0.9 µg/mL
Doxycycline	10.0 µg/mL	30 µg/mL
Erythromycin	11 µg/mL	60 µg/mL
Furosemide	20 µg/mL	60 µg/mL
Ibuprofen	40 µg/mL	500 µg/mL
Isosorbide Dinitrate	50 ng/mL	150 ng/mL
Lisinopril	0.10 µg/mL	0.30 µg/mL
Lovastatin	40 ng/mL	80 ng/mL
Low MW Heparin	6.75 U/mL	30 U/mL
Methotrexate	546 µg/mL	910 µg/mL
Methyldopa	4.2 µg/mL	15 µg/mL
Methylprednisolone	N/A	40 µg/mL
Mexiletine	1.3 µg/mL	4.0 µg/mL
Nicotine	37 ng/mL	1000 ng/mL
Nifedipine	125 ng/mL	400 ng/mL
Nitrofurantoin	2.0 µg/mL	4.0 µg/mL
Nitroglycerine	7.5 ng/mL	160 ng/mL
Phenobarbital	24 µg/mL	97 µg/mL
Phenytoin	12 µg/mL	50 µg/mL
Primidone	10.5 µg/mL	40 µg/mL
Propanolol	0.50 µg/mL	2.0 µg/mL

Drug	Low Concentration	High Concentration
Quinidine	3.7 µg/mL	12 µg/mL
Simvastatin	16 µg/mL	32 µg/mL
Theophylline	12 µg/mL	40 µg/mL
Thyroxine	0.08 µg/mL	1.01 µg/mL
Tissue Plasminogen Activator	1.15 µg/mL	2.3 µg/mL
Trimethoprim	12 µg/mL	40 µg/mL
Verapamil	0.33 µg/mL	2.0 µg/mL
Warfarin	2.0 µg/mL	10 µg/mL

10.8 Cross-Reactivity

Cross-reactivity studies were performed using two sample pools per matrix of approximately 0 pg/mL and 60 pg/mL cTnI. These sample pools were spiked with potential cross-reactants. Control samples were prepared by spiking sample pools with the appropriate diluent at the same volume as the interfering substance stock. Results are presented below.

Potential Cross-Reacting Substance	Matrix	cTnI Level	Control Dose (pg/mL)	Test Dose (pg/mL)	% Cross-Reactivity
Actin	Li Hep	Zero	1.47	1.22	0.00%
	Li Hep	Low	56.28	55.18	0.00%
	Serum	Zero	1.04	1.22	0.00%
	Serum	Low	56.31	55.29	0.00%
Cardiac Troponin T	Li Hep	Zero	1.40	21.71	0.00%
	Li Hep	Low	55.38	75.92	0.00%
	Serum	Zero	0.93	22.26	0.00%
	Serum	Low	55.56	78.49	0.00%
CK-MB	Li Hep	Zero	1.57	1.90	0.00%
	Li Hep	Low	55.92	56.65	0.00%
	Serum	Zero	1.18	1.32	0.00%
	Serum	Low	54.12	55.37	0.00%
Myoglobin	Li Hep	Zero	1.16	1.39	0.00%
	Li Hep	Low	55.43	55.05	0.00%
	Serum	Zero	1.28	1.03	0.00%
	Serum	Low	55.61	54.65	0.00%
Myosin Light Chain	Li Hep	Zero	1.36	1.23	0.00%
	Li Hep	Low	55.39	55.79	0.00%
	Serum	Zero	0.93	1.09	0.00%
	Serum	Low	53.90	53.30	0.00%
Skeletal Troponin I	Li Hep	Zero	1.59	0.96	0.00%
	Li Hep	Low	55.52	53.55	0.00%
	Serum	Zero	1.07	0.48	0.00%
	Serum	Low	53.90	54.76	0.00%
Tropomyosin	Li Hep	Zero	1.47	1.04	0.00%
	Li Hep	Low	56.22	56.31	0.00%
	Serum	Zero	0.94	1.01	0.00%
	Serum	Low	54.15	54.56	0.00%

Potential Cross-Reacting Substance	Matrix	cTnI Level	Control Dose (pg/mL)	Test Dose (pg/mL)	% Cross-Reactivity
Troponin C	Li Hep	Zero	1.64	13.51	0.00%
	Li Hep	Low	56.26	69.65	0.00%
	Serum	Zero	1.12	15.38	0.00%
	Serum	Low	55.45	69.16	0.00%

10.9 Heterophile Interference

Heterophile interference studies were performed using lithium heparin plasma and serum spiked with high RF samples, and serum spiked with high HAMA samples. Control samples were prepared by spiking sample pools with the appropriate diluent at the same volume as the interfering substance stock. No interference with HAMA or RF was observed.

10.10 High-Sensitivity Designation

The International Federation of Clinical Chemistry (IFCC) Task Force on Clinical Applications of Cardiac Bio-Markers defines a high-sensitivity troponin test as one that meets the following analytical criteria:[1]

1. % CV at the 99th percentile value should be ≤10%
2. Measurable concentrations should be attainable at a concentration above the LoD for at least 50% of healthy individuals

The Atellica IM TnIH assay meets both of these criteria.

10.11 Method Comparison with Predicate Device

Not applicable.

10.12 Matrix Comparison

Not applicable. All performance studies were performed in all applicable matrices (lithium heparin plasma and serum).

[1] Apple FS, Sandoval Y, Jaffe AS, et al. Cardiac troponin assays: Guide to understanding analytical characteristics and their impact on clinical care. Clin Biochem 2017;63:73-81.

10.13 Clinical Studies

A clinical performance study was conducted to evaluate the diagnostic accuracy of the Atellica IM TnIH assay in terms of the clinical concordance between the 99th percentile cutoff and the presence or absence of an adjudicated acute myocardial infarction (AMI) diagnosis. Specimens were collected at 29 sites from different regions across the United States. Testing of specimens was performed at 3 sites.

In this study, the sites enrolled all patients who presented to the emergency department, or ambulatory care center equivalent, with signs or symptoms suspicious for a possible acute coronary syndrome (ACS) event. The diagnosis of AMI was performed by an independent adjudication committee which included cardiologists. The adjudication was based on the Third universal definition of myocardial infarction consensus guideline endorsed by the European Society of Cardiology (ESC), the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the World Heart Federation (WHF).

The clinical concordance study evaluated clinical sensitivity, clinical specificity, positive predictive value (PPV) and negative predictive value (NPV) of the Atellica IM TnIH assay in terms of its correlation to the diagnosis of AMI.

Results were analyzed according to time from presentation to the emergency department.

Using the female-specific 99th percentiles for lithium heparin plasma (34.11 pg/mL) and serum (38.64 pg/mL), the following results were obtained.

		Sensitivity			Specificity			PPV			NPV		
Matrix	**Timepoint**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**
Li Hep Plasma	**0-1.5hr**	45	84.4%	71.2- 92.3	401	93.5%	90.7- 95.5	64	59.4%	47.1- 70.5	382	98.2%	96.3- 99.1
	≥1.5-2.5 hr	79	89.9%	81.3- 94.8	720	91.8%	89.6- 93.6	130	54.6%	46.0- 62.9	669	98.8%	97.7- 99.4
	≥2.5-3.5 hr	73	94.5%	86.7- 97.8	621	91.6%	89.2- 93.6	121	57.0%	48.1- 65.5	573	99.3%	98.2- 99.7
	≥3.5-4.5 hr	50	94.0%	83.8- 97.9	487	89.5%	86.5- 91.9	98	48.0%	38.3- 57.7	439	99.3%	98.0- 99.8
	≥4.5-6 hr	26	96.2%	81.1- 99.3	238	87.0%	82.1- 90.7	56	44.6%	32.4- 57.6	208	99.5%	97.3- 99.9
	≥6-9 hr	69	94.2%	86.0- 97.7	374	88.0%	84.3- 90.9	110	59.1%	49.7- 67.8	333	98.8%	97.0- 99.5
	≥9-24 hr	74	94.6%	86.9- 97.9	342	87.4%	83.5- 90.5	113	61.9%	52.7- 70.4	303	98.7%	96.7- 99.5
	≥24 hr	27	96.3%	81.7- 99.3	110	80.9%	72.6- 87.2	47	55.3%	41.2- 68.6	90	98.9%	94.0- 99.8
Serum	**0-1.5hr**	42	81.0%	66.7- 90.0	407	93.6%	90.8- 95.6	60	56.7%	44.1- 68.4	389	97.9%	96.0- 99.0
	≥1.5-2.5 hr	77	89.6%	80.8- 94.6	721	92.0%	89.7- 93.7	127	54.3%	45.7- 62.7	671	98.8%	97.7- 99.4
	≥2.5-3.5 hr	67	92.5%	83.7- 96.8	619	92.4%	90.0- 94.2	109	56.9%	47.5- 65.8	577	99.1%	98.0- 99.6
	≥3.5-4.5 hr	48	93.8%	83.2- 97.9	484	90.3%	87.3- 92.6	92	48.9%	38.9- 59.0	440	99.3%	98.0- 99.8
	≥4.5-6 hr	26	96.2%	81.1- 99.3	236	87.7%	82.9- 91.3	54	46.3%	33.7- 59.4	208	99.5%	97.3- 99.9
	≥6-9 hr	63	95.2%	86.9- 98.4	378	88.6%	85.0- 91.4	103	58.3%	48.6- 67.3	338	99.1%	97.4- 99.7
	≥9-24 hr	73	94.5%	86.7- 97.8	342	89.5%	85.8- 92.3	105	65.7%	56.2- 74.1	310	98.7%	96.7- 99.5
	≥24 hr	26	96.2%	81.1- 99.3	111	82.9%	74.8- 88.8	44	56.8%	42.2- 70.3	93	98.9%	94.2- 99.8

Using the male-specific 99th percentiles for lithium heparin plasma (53.48 pg/mL) and serum (53.53 pg/mL), the following results were obtained.

		Sensitivity			Specificity			PPV			NPV		
Matrix	**Timepoint**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**
Li Hep Plasma	**0-1.5hr**	100	75.0%	65.7- 82.5	563	91.5%	88.9- 93.5	123	61.0%	52.1- 69.1	540	95.4%	93.3- 96.8
	≥1.5-2.5 hr	161	87.6%	81.6- 91.8	905	91.2%	89.1- 92.8	221	63.8%	57.3- 69.9	845	97.6%	96.4- 98.5
	≥2.5-3.5 hr	128	89.8%	83.4- 94.0	748	90.0%	87.6- 91.9	190	60.5%	53.4- 67.2	686	98.1%	96.8- 98.9
	≥3.5-4.5 hr	99	90.9%	83.6- 95.1	593	92.2%	89.8- 94.1	136	66.2%	57.9- 73.6	556	98.4%	97.0- 99.1
	≥4.5-6 hr	40	92.5%	80.1- 97.4	223	90.6%	86.0- 93.8	58	63.8%	50.9- 74.9	205	98.5%	95.8- 99.5
	≥6-9 hr	124	91.1%	84.8- 95.0	531	88.5%	85.5- 91.0	174	64.9%	57.6- 71.6	481	97.7%	96.0- 98.7
	≥9-24 hr	141	93.6%	88.3- 96.6	493	85.6%	82.2- 88.4	203	65.0%	58.2- 71.3	431	97.9%	96.1- 98.9
	≥24 hr	35	91.4%	77.6- 97.0	143	88.1%	81.8- 92.4	49	65.3%	51.3- 77.1	129	97.7%	93.4- 99.2
Serum	**0-1.5hr**	98	77.6%	68.3- 84.7	573	91.6%	89.1- 93.6	124	61.3%	52.5- 69.4	547	96.0%	94.0- 97.3
	≥1.5-2.5 hr	162	86.4%	80.3- 90.9	925	91.5%	89.5- 93.1	219	63.9%	57.4- 70.0	868	97.5%	96.2- 98.3
	≥2.5-3.5 hr	128	87.5%	80.7- 92.2	765	89.9%	87.6- 91.9	189	59.3%	52.1- 66.0	704	97.7%	96.3- 98.6
	≥3.5-4.5 hr	99	88.9%	81.2- 93.7	599	92.5%	90.1- 94.3	133	66.2%	57.8- 73.7	565	98.1%	96.5- 98.9
	≥4.5-6 hr	38	94.7%	82.7- 98.5	218	90.8%	86.3- 94.0	56	64.3%	51.2- 75.5	200	99.0%	96.4- 99.7
	≥6-9 hr	122	91.0%	84.6- 94.9	526	89.9%	87.1- 92.2	164	67.7%	60.2- 74.4	484	97.7%	96.0- 98.7
	≥9-24 hr	140	93.6%	88.2- 96.6	499	85.6%	82.2- 88.4	203	64.5%	57.7- 70.8	436	97.9%	96.1- 98.9
	≥24 hr	37	86.5%	72.0- 94.1	144	88.9%	82.7- 93.0	48	66.7%	52.5- 78.3	133	96.2%	91.5- 98.4

Using the overall 99th Percentile (45.20 pg/mL), the following results were obtained for both genders combined.

		Sensitivity			Specificity			PPV			NPV		
Matrix	**Timepoint**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**	**N**	**Estimate**	**95% CI**
Li Hep Plasma	**0-1.5hr**	145	77.2%	69.8- 83.3	964	91.9%	90.0- 93.5	190	58.9%	51.8- 65.7	919	96.4%	95.0- 97.4
	≥1.5-2.5 hr	240	90.0%	85.6- 93.2	1625	90.6%	89.1- 92.0	368	58.7%	53.6- 63.6	1497	98.4%	97.6- 98.9
	≥2.5-3.5 hr	201	92.0%	87.5- 95.0	1369	90.6%	88.9- 92.0	314	58.9%	53.4- 64.2	1256	98.7%	97.9- 99.2
	≥3.5-4.5 hr	149	92.6%	87.3- 95.8	1080	90.8%	89.0- 92.4	237	58.2%	51.9- 64.3	992	98.9%	98.0- 99.4
	≥4.5-6 hr	66	97.0%	89.6- 99.2	461	89.2%	86.0- 91.7	114	56.1%	47.0- 64.9	413	99.5%	98.3- 99.9
	≥6-9 hr	193	92.7%	88.2- 95.6	905	87.6%	85.3- 89.6	291	61.5%	55.8- 66.9	807	98.3%	97.1- 99.0
	≥9-24 hr	215	94.0%	89.9- 96.4	835	86.6%	84.1- 88.7	314	64.3%	58.9- 69.4	736	98.2%	97.0- 99.0
	≥24 hr	62	93.5%	84.6- 97.5	253	83.4%	78.3- 87.5	100	58.0%	48.2- 67.2	215	98.1%	95.3- 99.3
Serum	**0-1.5hr**	140	78.6%	71.1- 84.6	980	92.2%	90.4- 93.8	186	59.1%	52.0- 65.9	934	96.8%	95.5- 97.7
	≥1.5-2.5 hr	239	87.9%	83.1- 91.4	1646	91.0%	89.5- 92.3	358	58.7%	53.5- 63.6	1527	98.1%	97.3- 98.7
	≥2.5-3.5 hr	195	90.8%	85.9- 94.1	1384	90.8%	89.1- 92.2	305	58.0%	52.4- 63.4	1274	98.6%	97.8- 99.1
	≥3.5-4.5 hr	147	91.2%	85.5- 94.8	1083	91.0%	89.1- 92.5	232	57.8%	51.3- 63.9	998	98.7%	97.8- 99.2
	≥4.5-6 hr	64	96.9%	89.3- 99.1	454	89.6%	86.5- 92.1	109	56.9%	47.5- 65.8	409	99.5%	98.2- 99.9
	≥6-9 hr	185	93.5%	89.0- 96.3	904	88.7%	86.5- 90.6	275	62.9%	57.1- 68.4	814	98.5%	97.4- 99.2
	≥9-24 hr	213	93.9%	89.8- 96.4	841	86.7%	84.2- 88.8	312	64.1%	58.6- 69.2	742	98.2%	97.0- 99.0
	≥24 hr	63	90.5%	80.7- 95.6	255	85.5%	80.6- 89.3	94	60.6%	50.5- 69.9	224	97.3%	94.3- 98.8

10.14 Traceability and Value Assignment

The Atellica IM TnIH assay is standardized to an internal standard manufactured using human heart homogenate. Assigned values for calibrators are traceable to this standardization.

10.15 Stability

The Atellica IM TnIH reagents and calibrators are stable until the date printed on the box label when stored at 2-8°C.

The onboard stability of the Atellica IM TnIH reagents is 28 days with a pack calibration interval of 31 days, and a lot calibration interval of 47 days.

11. Conclusions

The Atellica IM High-Sensitivity Troponin I (TNIH) assay (Reagents and Calibrators) is substantially equivalent in principle and performance to the currently-marketed predicate device, the Elecsys Troponin T Gen 5 STAT Immunoassay, cleared under 510(k) K162895.