August 10, 2026

Siemens Healthcare Diagnostics, Inc.
Kelly Maher
Regulatory Affairs Professional
511 Benedict Ave.
Tarrytown, New York 10591

Re: K253528
Trade/Device Name: Atellica IM CA 19-9 II
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: NIG
Dated: June 13, 2026
Received: June 13, 2026

Dear Kelly Maher:

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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and
Hematology 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)*
K253528

Device Name
Atellica IM CA 19-9 II

Indications for Use *(Describe)*
The Atellica IM CA 19-9 II (CA 19-9 II) assay is an in vitro diagnostic immunoassay for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and plasma (EDTA and lithium heparin) using the Atellica IM Analyzer. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum or plasma CA 19-9 at some point in their disease process exceeding the upper limit of normal determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

The assigned 510(k) number is: K253528

1. Submitter's Information

Date of Preparation: July 14, 2026

Submitted By:
Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591, USA
(914) 631-8000

Primary Contact Person:
Kelly Maher
Sr. Regulatory Affairs Specialist
Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591, USA

2. Purpose of Submission

To obtain a substantial equivalence determination for the Atellica IM CA 19-9™ II (CA 19-9 II) assay.

3. Measurand

CA 19-9

4. Type of Test

Quantitative, Chemiluminescent Immunoassay

5. Proprietary and Established Names

Atellica IM CA 19-9™ II (CA 19-9 II)

Common Name: Atellica IM CA 19-9 II

6. Regulatory Information

Review Panel	Product Code	Submission Type	Regulation Number	Device Class
Immunology	NIG	Traditional 510(k)	21 CFR 866.6010	II

7. Intended Use

The Atellica IM CA 19-9™ II (CA 19-9 II) assay is an in vitro diagnostic immunoassay for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and plasma (EDTA and lithium heparin) using the Atellica IM Analyzer. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum or plasma CA 19-9 at some point in their disease process exceeding the upper limit of normal determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

8. Special Condition For Use Statement

℞ only.

For Professional Use.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

9. Device Description Summary

The following catalog numbers are provided for the Atellica IM CA 19-9 II assay:

Device	Catalog Number
Atellica IM CA 19-9 II (CA 19-9 II), 50 test kit	11642474
Atellica IM CA 19-9 II (CA 19-9 II), 250 test kit	11642757

Summary of the Components and Materials

Component	Material Description	Volume	Ingredients
Provided in Atellica IM CA 19-9 II			
Atellica IM CA 19-9 II ReadyPack	Lite Reagent	5.8 mL/pack	Mouse monoclonal anti-CA 19-9 (~ 0.4 µg/mL) labeled with acridinium ester; protein stabilizers; sodium azide (< 0.1%); preservatives
	Solid Phase	19.7 mL/pack	Mouse monoclonal anti-CA 19-9 (~ 0.02 µg/mL) bound to paramagnetic particles; protein stabilizers; sodium azide (< 0.1%); preservatives
Atellica IM CA 19-9 II CAL	Calibrator	2.0 mL/vial	After reconstitution, various levels of CA 19-9 (human); bovine

			serum albumin; sodium azide (< 0.1%); preservatives
Materials required but not provided			
Atellica IM APW3 ReadyPack	Wash	25.0 mL/pack	Phosphate-buffered saline; sodium azide (< 0.1%); surfactant
Optional Materials			
Atellica IM Multi-Diluent 10	Diluent	5.0 mL/pack	Human serum albumin; ethanol; acetaminophen; salicylate; sodium azide; MIT (< 0.1%)

10. Assay Principle

The Atellica IM CA 19-9 II assay is a two-step sandwich immunoassay using direct chemiluminescent technology which uses a single monoclonal antibody, 1116-NS-19-9, for both the Solid Phase and Lite Reagent. The antibody is covalently coupled to paramagnetic particles in the Solid Phase and the same clone of antibody is labelled with acridinium ester in the Lite Reagent. The sample and Solid Phase are incubated at 37°C for 12 minutes, followed by a wash step to remove excess unbound antigens. The Lite Reagent is then reacted with the Solid Phase-bound CA 19-9 antigen for an additional 12-minute incubation.

A direct relationship exists between the concentration of CA 19-9 present in a patient sample and the amount of relative light units (RLUs) detected by the system.

11. Predicate Device and Comparison

The predicate device for the Atellica IM CA 19-9 II assay is the ADVIA Centaur CA 19-9 assay, which was submitted and cleared by FDA under 510(k), K031393, on June 24, 2003.

Details for the predicate device are outlined below.

Predicate Device Product Name	Clearance	Product Code	Manufacturer
ADVIA Centaur CA 19-9	K031393	NIG	Siemens Healthcare Diagnostics, Inc.

11.1. Predicate Device and Comparison

The following table describes the similarities and differences between the Atellica IM CA 19-9 II assay and the predicate device, ADVIA Centaur CA 19-9 assay.

Attribute	Candidate Device Atellica IM CA 19-9 II	Predicate Device ADVIA Centaur CA 19-9 (K031393)
Intended Use/ Indications for Use	The Atellica IM CA 19-9™ II (CA 19-9 II) assay is an in vitro diagnostic immunoassay for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and plasma (EDTA and lithium heparin) using the Atellica IM Analyzer. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum or plasma CA 19-9 at some point in their disease process exceeding the upper limit of normal determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.	The ADVIA Centaur CA 19-9 Assay is an in vitro immunoassay for the quantitative measurement of the CA 19-9 tumor-associated antigen, in human serum, using the ADVIA Centaur XP and ADVIA Centaur XPT systems. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined. The ADVIA Centaur CA 19-9 assay is not intended for use on any other system.
Similarities		
Sample Handling/Processing	Same	Automated
Detection Technology	Same	Chemiluminescence
Detection Antibody	Same	Monoclonal mouse anti-CA 19-9 antibody labeled with acridinium ester
Capture Antibody	Same	Monoclonal mouse anti-CA 19-9 antibody covalently coupled to paramagnetic particles
Calibrators	Same	2 Levels
Measurement	Same	Quantitative
Units of Measure	Same	U/mL
Sample Volume	Same	75 µL
Differences		
Sample Type	Serum, Plasma	Serum
Measuring Interval	2.0 – 700.0 U/mL	1.20 – 700.00 U/mL

12. Performance Evaluation Summary

The following FDA-recognized consensus standards were used in the development and evaluation of the Atellica IM CA 19-9 II assay.

- CLSI EP17-A2 2nd Edition: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*, FDA Recognition Number: 7-233
- CLSI EP05-A3: *Evaluation of Precision Performance of Quantitative Measurement Methods,* FDA Recognition Number: 7-251
- ISO 17511 2nd Edition: *In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators trueness control materials and human samples*, FDA Recognition Number: 7-305
- CLSI EP09c 3rd Edition: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples,* FDA Recognition Number: 7-296
- CLSI EP06 2nd Edition: *Evaluation of the Linearity of Quantitative Measurement Procedures,* FDA Recognition Number: 7-306
- CLSI EP07 3rd Edition: *Interference Testing in Clinical Chemistry*, FDA Recognition Number: 7-275
- CLSI EP37 1st Edition: *Supplemental Tables for Interference Testing in Clinical Chemistry*, FDA Recognition Number: 7-284
- CLSI EP28-A3c 3rd Edition: *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory,* FDA Recognition Number: 7-224
- CLSI EP34 1st Edition: *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking,* FDA Recognition Number: 7-290
- CLSI EP25 2nd Edition: *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents* FDA Recognition Number: 7-318

The assay was evaluated for the following performance characteristics:

- Detection Capability (LoB, LoD, LoQ) in accordance with CLSI EP17-A2
- Precision and Reproducibility in accordance with CLSI EP05-A3
- Method Comparison and Specimen Equivalency in accordance with CLSI EP09c-ED3
- Linearity in accordance with CLSI EP06-ED2
- Interferences and Cross-Reactivity in accordance with CLSI EP07-ED3 and CLSI EP37-ED1
- Expected Values in accordance with CLSI EP28-A3c
- Shelf-Life Stability of Reagents and Calibrators in accordance with CLSI EP25-ED2
- Calibration interval and Reagent On-Board Stability in accordance with CLSI EP25-ED2
- Calibrator On-Board Stability and Open Vial Stability in accordance with CLSI EP25-ED2
- Dilution Recovery in accordance with CLSI EP34-ED1
- High-Dose Hook Effect

13. Performance Characteristics

13.1. Precision

A Within-Lab and Repeatability study was performed according to CLSI EP05-A3. Eight (8) samples with varying concentrations of CA 19-9 were assayed in duplicate (2), two (2) runs per day, for twenty (20) days, yielding a total of 80 measurements per sample.

Table 1. Atellica IM CA 19-9 II Precision Results

Sample	N	Mean (U/mL)	Repeatability SD (U/mL)	Repeatability CV (%)	Within-Lab SD (U/mL)	Within-Lab CV (%)
Serum1	80	10.0	0.15	1.5	0.82	8.2
Serum2	80	121.1	2.88	2.4	4.28	3.5
Serum3	80	37.1	0.77	2.1	1.31	3.5
Serum4	80	298.1	9.67	3.2	12.85	4.3
Serum5	80	529.0	16.47	3.1	24.34	4.6
QC1	80	18.8	0.45	2.4	0.76	4.0
QC2	80	90.8	1.92	2.1	4.03	4.4
QC3	80	287.5	8.08	2.8	11.76	4.1

A lot-to-lot reproducibility study was performed according to CLSI EP05-A3. Eight (8) samples with varying concentrations of CA 19-9 were assayed in replicates of five (5), one (1) run per day, for five (5) days, on three (3) reagent lots on one (1) Atellica IM analyzer, yielding a total of 75 measurements per sample.

Table 2. Atellica IM CA 19-9 II Lot-to-Lot Reproducibility Results

Sample	N	Mean (U/mL)	Repeatability		Between-Day		Between-Lot		Reproducibility	
			SD (U/mL)	%CV	SD (U/mL)	%CV	SD (U/mL)	%CV	SD (U/mL)	%CV
Serum1	75	7.6	0.22	2.9	0.15	2.0	1.45	19.1	1.47	19.3
Serum2	75	116.5	2.48	2.1	2.40	2.1	2.73	2.3	4.40	3.8
Serum3	75	36.3	0.71	2.0	0.99	2.7	1.87	5.2	2.24	6.2
Serum4	75	293.3	5.18	1.8	6.81	2.3	5.33	1.8	10.07	3.4
Serum5	75	512.1	11.72	2.3	4.79	0.9	6.79	1.3	14.37	2.8
QC1	75	18.0	0.49	2.7	0.61	3.4	1.72	9.6	1.89	10.5
QC2	75	90.5	2.24	2.5	3.21	3.5	6.37	7.0	7.47	8.3
QC3	75	288.5	7.03	2.4	7.31	2.5	15.85	5.5	18.82	6.5

An instrument-to-instrument reproducibility study was performed according to CLSI EP05-A3. Eight (8) samples with varying concentrations of CA 19-9 were assayed in replicates of five (5), one (1) run per day, for five (5) days, on one (1) reagent lot on three (3) Atellica IM analyzers, yielding a total of 75 measurements per sample.

Table 3. Atellica IM CA 19-9 II Instrument-to-Instrument Reproducibility Results

Sample	N	Mean (U/mL)	Repeatability		Between-Day		Between-Instrument		Reproducibility	
			SD (U/mL)	%CV	SD (U/mL)	%CV	SD (U/mL)	%CV	SD (U/mL)	%CV
Serum1	75	10.4	0.17	1.6	0.21	2.0	1.24	11.9	1.27	12.2
Serum2	75	116.7	2.75	2.4	2.69	2.3	0.00	0.0	3.85	3.3
Serum3	75	35.4	0.84	2.4	0.39	1.1	1.08	3.1	1.42	4.0
Serum4	75	281.5	6.36	2.3	5.32	1.9	5.49	2.0	9.94	3.5
Serum5	75	497.7	13.53	2.7	13.56	2.7	3.46	0.7	19.46	3.9
QC1	75	19.1	0.59	3.1	0.63	3.3	1.45	7.6	1.69	8.8
QC2	75	88.0	1.48	1.7	2.77	3.1	1.15	1.3	3.35	3.8
QC3	75	282.3	6.83	2.4	10.35	3.7	0.00	0.0	12.40	4.4

13.2. Linearity

A Linearity study was performed according to CLSI EP06-ED2. A dilution series with thirteen (13) levels was prepared by mixing high native human serum specimens and low native human serum specimens in a known mathematical relationship. Each level was assayed in replicates of six (6) on (1) one test day using one (1) reagent lot on one (1) Atellica IM analyzer.

The assay was demonstrated to be linear from 2.0 – 700.0 U/mL.

13.3. Detection Capability

Detection capability studies were performed according to CLSI EP17-A2. The Limit of Blank (LoB) is defined as the highest measurement result that is likely to be observed for a blank sample. The Limit of Detection (LoD) is defined as the lowest concentration of CA 19-9 that can be detected with a probability of 95%. The Limit of Quantitation (LoQ) is defined as the lowest amount of CA 19-9 in a sample at which the total CV is ≤ 20%.

Table 4. Atellica IM CA 19-9 II Detection Capability Results

Detection Capability	Result (U/mL)
LoB	1.2
LoD	1.5
LoQ	2.0

13.4. Measuring Interval

The measuring interval of Atellica IM CA 19-9 II was determined by Linearity (Section 5.2) and Limit of Quantification (LoQ) (Section 5.3).

The measuring interval is 2.0 – 700.0 U/mL.

13.5. Interferences

Interference studies including cross-reactivity, endogenous interference, heterophile interference, exogenous interference, and therapeutic drug interference were performed according to CLSI EP07-ED3 and CLSI EP37-ED1.

Clinically significant interference as defined by bias greater than 10% was not observed for the following substances when tested at analyte concentrations of 10.0–11.1 U/mL and 44.2–52.5 U/mL:

Table 5. Interference Results (Hemolysis, Icterus, Lipemia [HIL])

Substance	Substance Test Concentration
Hemoglobin	1000 mg/dL
Bilirubin, conjugated	40 mg/dL
Bilirubin, unconjugated	40 mg/dL
Lipemia (Intralipid)	2000 mg/dL
Lipemia (triglycerides)	1500 mg/dL

Clinically significant interference as defined by bias greater than 10% was not observed for the following substances when tested at analyte concentrations of 8.1–12.0 U/mL and 40.8–60.0 U/mL:

Table 6. Interference Results (Other Substances)

Substance	Substance Test Concentration
Albumin	6 g/dL
Human IgG	40 mg/mL
Rheumatoid Factor	1000 IU/mL
HAMA	1000 µg/L
AFP	300 ng/mL
CA 125	1000 U/mL
CA 15-3	450 U/mL
CA 27.29	230 U/mL
CEA	1 µg/mL
PSA	100 ng/mL
Acetaminophen	15.6 mg/dL
Acetylsalicylic acid	3 mg/dL
Amikacin	14.4 mg/dL
Biotin	3500 ng/mL
Caffeine	108 mg/L
Cortisol/hydrocortisone	100 mg/L
Coumarin	140 mg/L
Cyclosporine	0.18 mg/dL
Digoxin	0.039 mg/L
EDTA	0.099 mg/dL
Gentamicin	3 mg/dL
Heparin	330 U/dL
Ibuprofen	21.9 mg/dL
Levamisole	40.5 mg/mL
Lithium carbonate	0.035 mg/mL
Phenytoin	6 mg/dL
Propranolol	0.101 mg/dL
Salicylate	2.86 mg/dL
Silwet L720	30 mg/L
Theophylline	6 mg/dL
Capecitabine	22.5 mg/L
Cisplatin	225 mg/L
Cyclophosphamide	1000 mg/L
Doxorubicin	75 mg/L
Erlotinib hydrochloride	17.6 mg/L
Etoposide	400 mg/L
Everolimus	0.183 mg/L
5-Fluorouracil	90 mg/L
Gemcitabine	383 mg/L

Substance	Substance Test Concentration
Irinotecan hydrochloride	12.9 mg/mL
Leucovorin	114 mg/L
Mitomycin	25 mg/L
Mitoxantrone	100 mg/L
Nab-paclitaxel	2.16 mg/L
Olaparib	10.8 mg/L
Oxaliplatin	250 mg/L
Streptozotocin	39.6 mg/L
Sunitinib malate	0.303 mg/L

13.6. Traceability

Traceability was established in accordance with ISO 17511.

The assay standardization is traceable to an internal standard manufactured using highly purified material.

13.7. Stability

Stability studies were performed in accordance with CLSI EP25-ED2. Atellica IM CA 19-9 II reagents were tested for a minimum of 28 days after packs were first pierced on-board the analyzer and remained on-board the Atellica IM analyzer for the duration of the study. At each time point (days 0, 7, 14, 21, 23, 28) both pierced (in-use) and fresh packs from each reagent lot were used to assay each sample and control. Samples were assayed in replicates of three (3) on each test day.

The Atellica IM CA 19-9 II reagents are stable until the date printed on the box label when stored at 2-8°C.

The onboard stability of the Atellica IM CA 19-9 II reagents is 23 days with a lot and pack calibration interval of 23 days.

The Atellica IM CA 19-9 II calibrators when reconstituted were determined to be stable at 2-8°C for 30 days.

The Atellica IM CA 19-9 II calibrators are stable for 8 hours when reconstituted and stored on the system at room temperature.

13.8. Hook Effect

A Hook Effect study was performed to evaluate the potential for the high-dose hook effect. In this assay, no hook effect was observed up to 3,845,000.0 U/mL.

13.9. Dilution Recovery

A Dilution Recovery study was performed in accordance with CLSI EP34-ED1. Five (5) native high samples were assayed in replicates of four (4) on one (1) test day using one (1) reagent lot on two (2) Atellica IM analyzers and evaluated for each dilution factor, 10X, 100X, and 200X.

Table 7. Dilution Recovery Results

Sample	Dilution	Sample Volume
Serum and Plasma	1:10	50 µL
Serum and Plasma	1:100	50 µL
Serum and Plasma	1:200	50 µL

13.10. Matrix Comparison

A Matrix Comparison study was performed in accordance with CLSI EP09c-ED3. 62 matched sets of Serum, K2 EDTA Plasma, K3 EDTA Plasma, and Lithium Heparin Plasma were assayed in singlicate (1) using and one (1) reagent lot over five (5) test days on one (1) Atellica IM analyzer.

Table 8. Matrix Comparison Results

Tube (y) vs Serum (x)	Regression Equation	Sample Interval	N	r
K2 EDTA Plasma	y = 1.03x + 0.4 U/mL	4.0 – 674.7	62	0.995
K3 EDTA Plasma	y = 0.99x + 0.4 U/mL	4.0 – 674.7	62	0.991
Lithium Heparin Plasma	y = 1.04x + 0.2 U/mL	4.0 – 674.7	62	0.992

13.11. Clinical Studies

The clinical performance of the Atellica IM CA 19-9 II assay was evaluated as an aid in monitoring disease status in patients with exocrine pancreatic cancer by assessing longitudinal changes in CA 19-9 concentrations in serial patient samples.

The study included 413 observations from 71 patients, with an average of 6 study visits per patient. Clinical concordance was assessed by comparing changes in CA 19-9 concentrations between consecutive visits with corresponding changes in clinical disease status over time.

A significant change in CA 19-9 concentration was defined as an increase of greater than 15% relative to the prior measurement. For each pair of serial measurements, an increase of >15% was interpreted as indicative of disease progression, whereas a change of ≤15% was interpreted as indicative of no progression.

The concordance between changes in CA 19-9 levels and clinical disease status on a per visit level is summarized in the table below.

Table 9. Concordance Between the Atellica IM CA 19-9 II Assay Result and Disease Status

Change in CA 19-9 Concentration (Atellica IM CA 19-9 II)	Change in Disease Status		Total
	Progression	No Progression	
> 15%	43	111	154
≤ 15%	20	168	188
Total	63	279	342*

* Excluding 71 baseline visits

The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated and are shown below.

Table 10. Clinical Performance of the Atellica IM CA 19-9 II Assay

Parameter	N	Estimate	95% Confidence Interval
Sensitivity	63	68.3% (43/63)	59.5%–78.4%
Specificity	279	60.2% (168/279)	54.7%–65.2%
PPV	154	27.9% (43/154)	21.7%–34.4%
NPV	188	89.4% (168/188)	85.6%–93.4%

N=number of measurements

13.12. Reference Range

A verification of reference range study was performed in accordance with EP28-A3c. 40 (20 female and 20 male) apparently healthy native human serum patient samples were assayed in replicates of five (5) using one (1) reagent lot on one (1) test day on one (1) Atellica IM analyzer.

In the US expected range, 95.0% of samples (38/40 [19/20 males, 19/20 females]) recovered within the range for the normal patient population.

14. Conclusion

The Atellica IM CA 19-9 II assay is substantially equivalent to the predicate, ADVIA Centaur CA 19-9 assay (K031393).