September 8, 2023

Siemens Healthcare Diagnostics Products Ltd
Stefani Vinkemeier
Regulatory Affairs Professional
Glyn Rhonwy, Llanberis
Caernarfon
Llanberis, Gwynedd LL55 4EL
United Kingdom

Re: K213510
Trade/Device Name: IMMULITE/IMMULITE 1000 OM-MA
IMMULITE 2000 OM-MA
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: LTK
Dated: February 24, 2023
Received: February 27, 2023

Dear Stefani Vinkemeier:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213510

Device Name
IMMULITE/IMMULITE 1000 OM-MA
IMMULITE 2000 OM-MA

Indications for Use *(Describe)*
I
For in vitro diagnostic use with the IMMULITE® and IMMULITE® 1000 Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second look procedures.

For in vitro diagnostic use with the IMMULITE® 2000 Systems Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.

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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510(k) Summary

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

The assigned 510(k) number is: _____K213510_____

5.1 Submitter

Contact Person: Stefani Vinkemeier
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Phone: 302-489-9232

Date of Preparation: May 11, 2023

5.2 Device

Regulatory Information

Trade Name:	IMMULITE®/IMMULITE 1000 OM-MA, IMMULITE® 2000 OM-MA
Common Name:	Test, Epithelial Ovarian Tumor-associated Antigen (Ca125)
Classification Name:	Tumor-associated antigen immunological test system
Regulation Number:	21 CFR 866.6010
Classification:	Class II
Product Code:	LTK
Review Panel:	Immunology (82)

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?	X	
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

5.3 Predicate Device

The predicate devices, IMMULITE/IMMULITE 1000 OM-MA and IMMULITE 2000 OM-MA, manufactured by Siemens Healthcare Diagnostics Products Ltd, Glyn Rhonwy, Llanberis, Wales, United Kingdom, were cleared by the FDA under K981297 and K983391.

5.4 Device Description

The IMMULITE®/IMMULITE 1000 OM-MA Assay is comprised of the following components:

Component	Volume	Ingredients
OM-MA Test Units (LOP1)	1 bead / test unit	murine monoclonal anti-CA125 antibody
OM-MA Cycle 1 Reagent Wedge (LOPA)	7.5 mL	alkaline phosphatase (bovine calf intestine) conjugated to rabbit polyclonal anti-CA125 antibody in buffer, with preservative
OM-MA Cycle 2 Reagent Wedge (LOPB)	5 mL	buffer, with preservative
OM-MA Adjustors (Low and High, LOPL, LOPH)	3 mL each	CA125 in a nonhuman protein/buffer matrix, with preservative.

The IMMULITE® 2000 OM-MA Assay is a newer generation of the instrument. Rather than conducting the reactions in pre-packaged individual test units, this instrument dispenses an individual bead from a pack into a separate reaction tube. The IMMULITE® 2000 OM-MA Assay is comprised of the following components:

Component	Volume	Ingredients
OM-MA Bead Pack (L2KOP)	200 beads	murine monoclonal anti-CA125 antibody
OM-MA Reagent Wedge (L2OPA2)	Well 1 - 11.5 mL	alkaline phosphatase (bovine calf intestine) conjugated to rabbit polyclonal anti-CA125 antibody in buffer, with preservative
	Well 2 – 6.5 mL	buffer, with preservative
OM-MA Adjustors (Low and High, LOPL, LOPH)	3 mL each	CA125 in a nonhuman protein/buffer matrix, with preservative.

5.5 Test Principle

The IMMULITE/IMMULITE 1000 and IMMULITE 2000 OM-MA are solid-phase, two-site chemiluminescent immunometric assays. There are two incubation cycles of 30 minutes each.

During the initial 30-minute cycle, the patient sample is incubated with biotinylated antibody coated bead and alkaline phosphatase antibody conjugate. This cycle creates a bead pair immunocomplex sandwich consisting of capture Ab-antigen-detection Ab. During the second 30-minute cycle, buffer is added to remove unbound conjugate, which is then removed by centrifugal wash.

The amount of alkaline phosphate bound is directly proportional to the analyte in the patient sample. Following the two 30-minute incubation periods, IMMULITE chemiluminescent substrate (LSUBX or L2SUBM) is added for a further 10-minute incubation period to generate the luminogenic reaction.

The chemiluminescent substrate undergoes hydrolysis in the presence of the alkaline phosphatase to yield an unstable intermediate, which then emits photons. The sustained emissions are measured by the luminometer. The resulting relative light units (RLU) are proportional to the concentration of CA 125 in the sample, which is expressed as U/mL.

5.6 Intended Use / Indications for Use

IMMULITE/IMMULITE® 1000 OM-MA Assay

For *in vitro* diagnostic use with the IMMULITE® and IMMULITE® 1000 Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second look procedures.

IMMULITE® 2000 OM-MA Assay

For *in vitro* diagnostic use with the IMMULITE® 2000 Systems Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.

5.7 Comparison to Predicate Device

Comparison Table of Technological Characteristics for IMMULITE/IMMULITE 1000

Attribute	**Candidate Device:** IMMULITE®/IMMULITE 1000 OM-MA Assay, *modified*	**Predicate Device**: IMMULITE®/IMMULITE 1000 OM-MA Assay, K981297
Intended Use / Indications for Use	For *in vitro* diagnostic use with the IMMULITE® and IMMULITE® 1000 Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second look procedures.	Same
Analyte	Cancer Antigen 125	Same
Automated	Automated assay	Same
Measurement	Quantitative	Same
Sample Type	Human serum	Same
Detection Limit	LoB: 0.14 U/mL LoD: 0.38 U/mL LoQ: 2 U/mL	Analytical Sensitivity: 1 U/mL
Assay Measuring Interval	2 – 500 U/mL	1 – 500 U/mL
Operating Principle	Immunologic sandwich	Same
Technology	Direct chemiluminescent	Same
Instrument	IMMULITE® 1000 systems	Same
Sample Volume	50 µL	Same
Calibrator (Adjustors)	CA125 in a nonhuman protein/buffer matrix, with preservative.	Same
Controls	Commercially available, minimum of 2 levels	Same
Detection Antibody	alkaline phosphatase (bovine calf intestine) conjugated to rabbit polyclonal anti-CA125 antibody	Same
Capture Antibody	monoclonal mouse anti-CA125	Same
Biotin interference	Specimens that contain biotin at a concentration of 3500 ng/mL demonstrate a less than or equal to 10% change in results. Biotin concentrations greater than this may lead to incorrect results for patient samples.	Specimens that contain biotin at a concentration of 2 ng/mL demonstration less than of equal to 10% change in results. Biotin concentrations greater than this may lead to falsely elevated results.

Comparison Table of Technological Characteristics for IMMULITE 2000

Attribute	**Candidate Device:** IMMULITE® 2000 OM-MA Assay, *modified*	**Predicate Device**: IMMULITE® 2000 OM-MA Assay, K983391
Intended Use / Indications for Use	For *in vitro* diagnostic use with the IMMULITE® 2000 Systems Analyzers — for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelian ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.	Same
Analyte	Cancer Antigen 125	Same
Automated	Automated assay	Same
Measurement	Quantitative	Same
Sample Type	Human serum	Same
Detection Limit	LoB: 0.18 U/mL LoD: 0.43 U/mL LoQ: 3 U/mL	Analytical Sensitivity: 1 U/mL
Assay Measuring Interval	3 – 500 U/mL	1 – 500 U/mL
Operating Principle	Immunologic sandwich	Same
Technology	Direct chemiluminescent	Same
Instrument	IMMULITE® 2000 and IMMULITE® 2000 XPi systems	Same
Sample Volume	50 µL	Same
Calibrator (Adjustors)	CA125 in a nonhuman protein/buffer matrix, with preservative.	Same
Controls	Commercially available, minimum of 2 levels	Same
Detection Antibody	alkaline phosphatase (bovine calf intestine) conjugated to rabbit polyclonal anti-CA125 antibody	Same
Capture Antibody	monoclonal mouse anti-CA125	Same
Biotin interference	Specimens that contain biotin at a concentration of 3500 ng/mL demonstrate a less than or equal to 10% change in results. Biotin concentrations greater than this may lead to incorrect results for patient samples.	Specimens that contain biotin at a concentration of 2 ng/mL demonstration less than of equal to 10% change in results. Biotin concentrations greater than this may lead to falsely elevated results.

5.8 Summary of Performance Testing

Substantial equivalence of the modified IMMULITE®/IMMULITE 1000 OM-MA Assay and IMMULITE® 2000 OM-MA Assay were demonstrated by testing performance characteristics including detection capability, linearity, method comparison, precision, spike recovery, hook effect and interference.

The resulting performance data are provided in support of a substantial equivalence determination.

5.8.1 Detection Limits

LoB, LoD, and LoQ were determined in accordance with *Clinical and Laboratory Standards Institute (CLSI) EP17-A2:* Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. The LoB/LoD/LoQ estimates are summarized below:

	IMMULITE 1000 (U/mL)	**IMMULITE 2000 (U/mL)**
Limit of Blank (LoB)	0.14	0.18
Limit of Detection (LoD)	0.38	0.43
Limit of Quantitation (LoQ)	2	3

5.8.2 Measuring Interval / Linearity

Linearity was verified by testing samples spanning the assay range prepared by combining a high serum pool with a low serum sample to produce nine different levels.

For the IMMULITE 1000 OM-MA assay, linearity was confirmed across the assay range by acceptable bias of ≤20% at each individual level. Linear regression analysis of expected versus observed values confirm an overall recovery bias of ≤20% and supports the measuring interval of 2 U/mL to 500 U/mL.

For the IMMULITE 2000 OM-MA assay, linearity was confirmed across the assay range by acceptable bias of ≤15% at each individual level. Linear regression analysis of expected versus observed values confirm an overall recovery bias of ≤15% and supports the measuring interval of 3 U/mL to 500 U/mL.

5.8.3 Method Comparison: Quantitative Assay

Method comparison studies were performed comparing the modified devices to the currently-marketed predicate devices (IMMULITE 1000 and IMMULITE 2000). A total of 253 patient samples covering the full range of the assay were analyzed on both methods.

A single replicate was processed for each sample. Passing-Bablok regression was used to compare the methods.

IMMULITE 1000

Lot	Specimen Type	Comparison Assay (x)	N	Regression Equation	Sample Range (U/mL)
1	Serum	IMMULITE 1000	246	y = 0.995x – 0.199	1.03 – 466
2	Serum	IMMULITE 1000	246	y = 0.999x – 0.047	1.68 – 455
3	Serum	IMMULITE 1000	247	y = 1.022x – 0.821	1.27 – 471

IMMULITE 2000

Lot	Specimen Type	Comparison Assay (x)	N	Regression Equation	Sample Range (U/mL)
1	Serum	IMMULITE 2000	246	y = 1.032x + 0.086	2.47 – 511
2	Serum	IMMULITE 2000	246	y = 0.955x – 0.256	2.11 – 525
3	Serum	IMMULITE 2000	246	y = 0.976x – 0.142	2.29 – 489

5.8.4 Verification of Assay Precision

Precision studies were conducted on one reagent lot per platform in accordance with CLSI EP05-A3 *Evaluation of Precision of Quantitative Measurement Procedures.* For each assay, testing was performed on five serum samples spanning the range of the assays. Each sample was tested in duplicate over a period of 20 days, two runs per day, for a total of 40 runs and 80 replicates. The results are given in the following tables.

Results for Within Run and Total precision for IMMULITE

	Mean Dose (U/mL)	Repeatability		Within-Lab Imprecision	
		S.D.	%CV	S.D.	%CV
Level 1	9.17	0.41	4.5	0.49	5.3
Level 2	19.21	0.86	4.5	0.95	5.0
Level 3	41.36	1.38	3.3	1.77	4.3
Level 4	225.95	8.87	3.9	9.41	4.2
Level 5	427.48	12.40	2.9	12.86	3.0

Results for Within Run and Total precision for IMMULITE 2000

Precision Sample	Mean Dose (U/mL)	Repeatability		Within-Lab Imprecision	
		S.D.	%CV	S.D.	%CV
Level 1	11.23	0.59	5.2	0.68	6.0
Level 2	23.69	1.45	6.1	1.82	7.7
Level 3	42.59	1.86	4.4	2.19	5.1
Level 4	226.17	10.57	4.7	11.66	5.2
Level 5	451.54	22.58	5.0	26.82	5.9

5.8.5 Verification of Assay Reproducibility

Reproducibility studies were conducted on three reagents lot per platform in accordance with CLSI EP05-A3 *Evaluation of Precision of Quantitative Measurement Procedures*, using the 5 x 5 x 3 experimental design. For each assay, testing was performed on five serum samples spanning the range of the assays. Each sample was tested in over a period of five days, with five replicates per sample. The results are given in the following tables.

Reproducibility Results for IMMULITE

Sample	Mean Dose (U/mL)	Between-Lot		Total Reproducibility	
		SD	%CV	SD	%CV
1	9.41	0.54	5.73	0.78	8.33
2	18.72	1.21	6.45	1.75	9.37
3	39.68	2.53	6.38	3.64	9.18
4	215.20	11.30	5.25	16.24	7.55
5	420.97	25.32	6.02	37.57	8.93

Reproducibility Results for IMMULITE 2000

Reproducibility Sample	Mean Dose (U/mL)	Lot-to-Lot		Total Reproducibility	
		SD	%CV	SD	%CV
1	11.26	0.53	4.66	0.81	7.15
2	22.94	1.13	4.94	1.76	7.66
3	40.49	1.34	3.30	2.64	6.52
4	213.03	4.02	1.89	13.18	6.19
5	425.82	18.49	4.34	33.43	7.85

5.8.6 Recovery

Spike and recovery studies were performed by spiking samples 1 to 19 with three CA 125 solutions of differing concentrations.

IMMULITE – Spiking solutions 602, 1218 and 2450 U/mL

	Solution	Observed	Expected	%O/E
1	—	2.7	—	—
	A	32	33	97%
	B	55	63	87%
	C	106	125	85%
2	—	4.3	—	—
	A	37	34	109%
	B	63	65	97%
	C	128	127	101%
3	—	2.9	—	—
	A	32	33	97%
	B	53	64	83%
	C	108	125	86%
4	—	8.7	—	—
	A	38	38	100%
	B	66	69	96%
	C	126	131	96%

IMMULITE 2000 - Spiking solutions 933, 1776 and 3716 U/mL

	Solution	Observed	Expected	%O/E
1	—	16	—	—
	A	56	62	90%
	B	88	104	85%
	C	151	201	75%
2	—	28	—	—
	A	63	73	86%
	B	86	115	75%
	C	165	212	78%
3	—	63	—	—
	A	107	107	100%
	B	135	149	91%
	C	222	246	90%
4	—	95	—	—
	A	119	137	87%
	B	169	179	94%
	C	247	276	89%

5.8.7 Hook Effect

CA 125 concentrations as high as 84,500 U/mL for the IMMULITE and 80,000 U/mL for the IMMULITE 2000 will report as >500 U/mL. The high-dose hook effect information provided in the Instructions for Use for the modified IMMULITE OM-MA and IMMULITE 2000 OM-MA was confirmed and remain as presented in K981297 and K983391, respectively.

5.8.8 Specificity (Cross-reactivity)

Specificity (cross-reactivity) of the modified OM-MA assays to compounds with structural similarities to the CA 125 tumor marker were evaluated. Cross-reactant solutions were prepared by dissolving each potential cross-reactant into an appropriate solvent. The resulting solutions were spiked into patient sample pools to produce final concentrations approximately equal to the concentrations listed in the labeling. The samples were compared to the appropriate level patient sample pool that was mixed with an equal volume of solvent to determine a percent cross-reactivity. The specificity information provided in the Instructions for Use for the modified IMMULITE OM-MA and IMMULITE 2000 OM-MA was confirmed and remains as presented in K981297 and K983391, respectively.

IMMULITE Specificity

Compound	Amount Added	Apparent U/mL	% Cross- reactivity
AFP	10,000 IU/mL	ND	ND
CA15-3	1753 U/mL	7.1	0.41%
CA19-9	4000 U/mL	ND	ND
CEA	10,000 ng/mL	4.8	0.05%

ND: not detectable

IMMULITE 2000 Specificity

Compound	Amount Added	Apparent U/mL	% Cross- reactivity
AFP	10,000 IU/mL	ND	ND
CA15-3	1753 U/mL	7.1	0.41%
CA19-9	4000 U/mL	ND	ND
CEA	10,000 ng/mL	4.8	0.05%

ND: not detectable

5.8.9 Interference

Verification of the assay interference was conducted in accordance with CLSI EP07-ED3, *Interference Testing in Clinical Chemistry*. The tested substances were determined to have no substantial interference.

IMMULITE Interfering Substances

Interfering Substance	Amount Added	% Bias
Conjugated Bilirubin	200 mg/L	≤10%
Unconjugated Bilirubin	200 mg/L	≤10%
Haemoglobin	381 mg/dL	≤10%
Intralipid (Triglycerides)	3000 mg/dL	≤10%
Biotin	3500 mg/mL	≤10%

IMMULITE 2000 Interfering Substances

Interfering Substance	Amount Added	% Bias
Conjugated Bilirubin	200 mg/L	≤10%
Unconjugated Bilirubin	200 mg/L	≤10%
Haemoglobin	192 mg/dL	≤10%
Intralipid (Triglycerides)	3000 mg/dL	≤10%
Biotin	3500 ng/mL	≤10%

5.8.10 Reference Range

The reference range was verified by assaying apparently healthy female samples according to CLSI EP28-A3*, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory*, to verify the existing healthy Reference Interval (Healthy Individuals ≤ 21 U/mL).

IMMULITE Reference Range Results

	Lot 1	**Lot 2**	**Lot 3**
n	50	50	45
***n* < 21 U/mL**	47	47	42
% < 21 U/mL	94%	94%	93%

IMMULITE 2000 Reference Range Results

	Lot 1	**Lot 2**	**Lot 3**
n	50	50	50
***n* < 21 U/mL**	47	47	47
% < 21 U/mL	94%	94%	94%

Siemens provides this information for reference. As with all in vitro diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider these values as a guideline only.

5.8.11 Stability

Siemens conducted an accelerated stability study using native patient samples, following CLSI EP25-A *Evaluation of Stability of In Vitro Diagnostic Reagents*. The shelf-life estimation (t_{stab}) derived from each sample exceeded the kit shelf-life of 365 days for three kit lots tested.

Shelf-life Estimation (t_{stab}) in Days

Sample	Lot 1	Lot 2	Lot 3
Low-Dose (~11 U/mL)	4165	884	30011
MDL-Dose (~21 U/mL)	3175	16257	7623
High-Dose (~110 U/mL)	1092	665	3582

5.9 Conclusion

These performance studies support that the modified IMMULITE®/IMMULITE 1000 OM-MA Assay and IMMULITE® 2000 OM-MA Assay are substantially equivalent to the IMMULITE®/IMMULITE 1000 OM-MA Assay and IMMULITE® 2000 OM-MA Assay that are currently marketed, with the exception of biotin interference.