510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K252336

B Applicant

Diazyme Laboratories, Inc.

C Proprietary and Established Names

Diazyme Immunoglobulin A Assay
Diazyme Immunoglobulin G Assay
Diazyme Immunoglobulin M Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CZP	Class II	21 CFR 866.5510 - Immunoglobulins A, G, M, D, and E Immunological Test System	IM - Immunology
DEW	Class II	21 CFR 866.5510 - Immunoglobulins A, G, M, D, and E Immunological Test System	IM - Immunology
CFN	Class II	21 CFR 866.5510 - Immunoglobulins A, G, M, D, and E Immunological Test System	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

New Assays

B Measurand:

Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)

C Type of Test:

Quantitative immunoturbidimetric assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Diazyme Immunoglobulin A Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin A (IgA) in human serum. Measurement of IgA aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.

Diazyme Immunoglobulin G Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin G (IgG) in human serum. Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.

Diazyme Immunoglobulin M Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin M (IgM) in human serum. Measurement of IgM aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Roche cobas c 701 (K100853)

IV Device/System Characteristics:

A Device Description:

Diazyme Immunoglobulin A (IgA) Assay:

- Reagent 1: Tris Buffer pH 7.5 (≥ 10 mmol/L), Sodium Chloride (≥ 123.20 mmol/L), PEG, and preservative
- Reagent 2: Tris Buffer pH 7.5 (≥ 18.16 mmol/L), Anti IgA antibody, and preservative

Diazyme Immunoglobulin G (IgG) Assay:

- Reagent 1: Tris Buffer pH 7.6 (≥ 18.16 mmol/l), Sodium Chloride (≥ 123.20 mmol/l), PEG, and preservative

- Reagent 2: Tris Buffer, Anti IgG antibody, and preservative

Diazyme Immunoglobulin M (IgM) Assay:

- Reagent 1: Tris Buffer pH 8.0 (≥ 10 mmol/l), Sodium Chloride (≥ 100 mmol/l), PEG, and preservative
- Reagent 2: Tris Buffer pH 7.5 (≥ 10 mmol/l), IgM antibody, and preservative

All assays' calibrators and control materials are sold separately.

B Principle of Operation:

The Diazyme IgA, IgG, and IgM assays are based on the reaction between the specific immunoglobulin antigen and its corresponding antibody to form an insoluble immune complex. The resulting turbidity is measured spectrophotometrically. In each assay, the amount of complex formed, and thus the degree of turbidity, is directly proportional to the amount of the respective immunoglobulin (IgA, IgG, or IgM) present in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):

K-ASSAY IgA Assay; K-ASSAY IgG Assay; K-ASSAY IgM Assay

B Predicate 510(k) Number(s):

K993213

C Comparison with Predicate(s):

Diazyme Immunoglobulin A Assay:

Device & Predicate Device(s):	K252336 (Candidate Device)	K993213 (Predicate Device)
Device Trade Name	Diazyme Immunoglobulin A Assay	K-ASSAY IgA Assay
General Device Characteristic Similarities		
Intended Use/ Indications For Use	Diazyme Immunoglobulin A Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin A (IgA) in human serum. Measurement of IgA aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.	The K-ASSAY IgA Assay is intended to be used for the quantitative determination of IgA in human serum by immunoturbidimetric assay. Measurement of IgA aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents. FOR IN VITRO DIAGNOSTIC USE.
Test Type	Quantitative	Same

Specimen Type	Human serum	Same
Test Principle	Immunoturbidimetric	Same
General Device Characteristic Differences		
Linearity range	28.33 – 655.33 mg/dL	20 – 800 mg/dL

Diazyme Immunoglobulin G Assay:

Device & Predicate Device(s):	**K252336 (Candidate Device)**	**K993281 (Predicate Device)**
Device Trade Name	Diazyme Immunoglobulin G Assay	K-ASSAY IgG Assay
General Device Characteristic Similarities		
Intended Use/ Indications For Use	Diazyme Immunoglobulin G Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin G (IgG) in human serum. Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.	The K-ASSAY IgG Assay is intended to be used for the quantitative determination of IgG in human serum by immunoturbidimetric assay. Measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents. FOR IN VITRO DIAGNOSTIC USE.
Test Type	Quantitative	Same
Specimen Type	Human serum	Same
Test Principle	Immunoturbidimetric	Same
General Device Characteristic Differences		
Linearity range	100 – 3,200 mg/dL	100 – 4,500 mg/dL

Diazyme Immunoglobulin M Assay:

Device & Predicate Device(s):	**K252336 (Candidate Device)**	**K993323 (Predicate Device)**
Device Trade Name	Diazyme Immunoglobulin M Assay	K-ASSAY IgM Assay
General Device Characteristic Similarities		
Intended Use/ Indications For Use	Diazyme Immunoglobulin M Assay is intended as an immunoturbidimetric assay for the quantitative determination of Immunoglobulin M (IgM) in human serum. Measurement of IgM aids in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents. For in vitro diagnostics use only.	The K-ASSAY IgM Assay is intended to be used for the quantitative determination of IgM in human serum by immunoturbidimetric assay. Measurement of IgM aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents. FOR IN VITRO DIAGNOSTIC USE.

Device & Predicate Device(s):	K252336 (Candidate Device)	K993323 (Predicate Device)
Test Type	Quantitative	Same
Specimen Type	Human serum	Same
Test Principle	Immunoturbidimetric	Same
General Device Characteristic Differences		
Linearity range	13.5 – 350 mg/dL	10 – 350 mg/dL

VI Standards/Guidance Documents Referenced:

The following Clinical and Laboratory Standards Institute (CLSI) guidelines were used:

- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06, 2nd ed.: Evaluation of Linearity of Quantitative Measurement, Approved Guideline – Second Edition
- CLSI EP07, 3rd ed.: Interference Testing in Clinical Chemistry; Approved Guideline –Third Edition
- CLSI EP09-A3: Method Comparison and Bias Estimation Using Patient Samples: Approved Guideline – Third Edition
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP25, 2nd ed: Evaluation of Stability of In Vitro Medical Laboratory Test Reagent Reagents– Second Edition
- CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   a. Within-laboratory precision

   The within-laboratory precision for the Diazyme IgA Assay, Diazyme IgG Assay, Diazyme IgM Assay was conducted following CLSI EP05-A3. A panel of five human sera samples for the Diazyme IgA and IgM assays and a panel of six human sera samples

for the Diazyme IgG assay covering the analytical measuring range with levels around the medical decision points were tested in duplicate per run, two runs per day for 20 days using three reagent lots (N=80 x 3 lots). The standard deviation (SD) and %CV of the within-run, between-run, between-day, and total within-laboratory imprecision were calculated for each sample. The within-laboratory precision for each assay using a representative reagent lot (N=80) is shown in the following table:

Diazyme IgA Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	59.1	80	0.9	1.5	0.8	1.3	3.6	6.1	3.8	6.4
2	74.7	80	1.6	2.2	1.3	1.7	4.4	5.9	4.9	6.5
3	91.1	80	1.8	2.0	1.6	1.7	3.3	3.6	4.0	4.4
4	287.2	80	6.0	2.1	0.7	0.3	18.5	6.5	19.5	6.8
5	516.2	80	10.1	2.0	0.0	0.0	26.2	5.1	28.1	5.4

Diazyme IgG Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	262.9	80	6.7	2.6	5.2	2.0	17.2	6.6	19.2	7.3
2	797.6	80	34.7	4.4	0.0	0.0	37.7	4.7	51.3	6.4
3	1187.4	80	40.9	3.5	12.8	1.1	38.0	3.2	57.3	4.8
4	2192.4	80	78.9	3.6	29.0	1.3	69.2	3.2	108.9	5.0
5	2943.1	80	50.8	1.7	49.3	1.7	24.8	0.8	75.0	2.6
6	521.6	80	16.2	3.1	0.0	0.0	10.2	2.0	19.1	3.7

Dizyme IgM Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	38.7	80	1.1	2.9	2.3	5.9	2.4	6.1	3.5	8.9
2	50.0	80	1.1	2.3	2.0	4.1	3.5	7.0	4.2	8.4
3	162.5	80	2.2	1.3	1.9	1.2	5.0	3.1	5.8	3.5
4	227.4	80	2.2	1.0	4.2	1.8	7.0	3.1	8.4	3.7
5	343.5	80	3.5	1.0	1.6	0.5	3.9	1.1	5.5	1.6

b. Lot-to-lot imprecision

The lot-to-lot precision for each assay, following the procedure described above, is summarized in the table below:

Diazyme IgA Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	58.12	240	0.96	1.7	0.62	1.1	3.35	5.8	0.79	1.4	3.63	6.3
2	74.84	240	1.43	1.9	1.35	1.8	5.68	7.6	0.00	0.0	6.01	8.0
3	90.06	240	1.83	2.0	1.84	2.0	3.60	4.0	1.05	1.2	4.56	5.1
4	290.27	240	5.17	1.8	2.81	1.0	22.59	7.8	0.00	0.0	23.35	8.0
5	519.52	240	9.57	1.8	2.55	0.5	21.83	4.2	0.00	0.0	23.97	4.6

Diazyme IgG Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	261.45	240	7.22	2.8	5.00	1.9	15.90	6.1	4.51	1.7	18.72	7.2
2	533.52	240	14.89	2.8	0.00	0.0	17.16	3.2	10.65	2.0	25.09	4.7
3	799.24	240	31.77	4.0	6.35	0.8	32.62	4.1	10.34	1.3	47.12	5.9
4	1186.74	240	46.57	3.9	0.00	0.0	40.75	3.4	21.95	1.9	65.66	5.5
5	2193.18	240	73.86	3.4	13.13	0.6	86.11	3.9	0.00	0.0	114.20	5.2
6	2952.36	240	72.57	2.5	37.75	1.3	52.80	1.8	0.00	0.0	97.36	3.3

Dizyme IgM Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Run		Between-Day		Between-Lot		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	39.27	240	1.11	2.8	1.79	4.6	3.26	8.3	0.84	2.1	3.97	10.1
2	51.95	240	1.01	2.0	1.70	3.3	3.95	7.6	1.74	3.3	4.75	9.1
3	168.24	240	2.62	1.6	1.72	1.0	5.01	3.0	5.44	3.2	8.03	4.8
4	232.70	240	2.62	1.1	3.55	1.5	8.37	3.6	4.33	1.9	10.40	4.5
5	338.25	240	3.58	1.1	1.92	0.6	8.83	2.6	5.04	1.5	10.94	3.2

c. Site-to-Site Reproducibility

The site-to-site reproducibility study was conducted following CLSI EP05-A3. A panel of five human sera samples for the Diazyme IgA and IgM assays and a panel of seven human sera samples for the Diazyme IgG assay, selected to cover the analytical measuring range and include levels around the medical decision points, was tested across three different Roche cobas c701 analyzers by three different operators, with one run per day, five replicates per run over five days using one lot of reagents, yielding a total of 75 datapoints. The standard deviation (SD) and %CV of the within-run, between-day, between-site, and total imprecision were calculated for each sample. The site-to-site reproducibility results for each assay are summarized in the table below:

Diazyme IgA Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	64	75	0.88	1.4	3.78	5.9	5.19	8.1	6.48	10.2
2	77	75	1.05	1.4	3.78	4.9	6.57	8.5	7.65	9.9
3	82	75	0.99	1.2	4.12	5.0	6.42	7.8	7.69	9.4
4	280	75	3.54	1.3	12.00	4.3	4.91	1.8	13.44	4.8
5	535	75	6.74	1.3	15.16	2.8	0.00	0.0	15.61	2.9

Diazyme IgG Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	282	75	3.85	1.4	11.39	4.0	20.93	7.4	24.14	8.6
2	487	75	10.65	2.2	20.45	4.2	31.79	6.5	39.27	8.1
3	639	75	12.79	2.0	27.17	4.3	33.86	5.3	45.25	7.1

Sample	Mean (mg/dL)	N	Within-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
4	1053	75	35.94	3.4	35.55	3.4	23.19	2.2	55.61	5.3
5	1734	75	56.16	3.2	63.18	3.6	7.98	0.5	84.91	4.9
6	2319	75	83.93	3.6	61.39	2.6	0.00	0.0	102.35	4.4
7	2934	75	85.07	2.9	58.94	2.0	77.49	2.6	129.29	4.4

Dizyme IgM Assay:

Sample	Mean (mg/dL)	N	Within-Run		Between-Day		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	43	75	1.40	3.3	1.13	2.6	2.83	6.6	3.36	7.8
2	60	75	1.99	3.3	2.12	3.5	2.91	4.8	4.12	6.8
3	147	75	1.83	1.2	7.41	5.0	0.00	0.0	7.62	5.2
4	201	75	2.59	1.3	7.12	3.5	1.44	0.7	7.71	3.8
5	328	75	2.77	0.8	5.76	1.8	7.53	2.3	9.87	3.0

2. Linearity:

Linearity of each Diazyme IgA, IgG, and IgM assay was evaluated following CLSI EP06-Ed2. For each assay, eleven linearity levels were prepared by mixing a high and low human serum sample in proportional increments to create a dilution series spanning the analytical measuring range. All samples were assayed in quadruplicate within a single run on a Roche cobas c701 analyzer. The linearity results for each assay are summarized in the following tables.

Diazyme IgA Assay:

Dilution Range (mg/dL)	Slope (95% CI)	Intercept (95% CI)	R^2	% Deviation from Linearity
25.5 – 693.5	0.998 (0.988–1.007)	-0.271 (-1.212–0.670)	0.9989	-4.0 – 4.8%

Diazyme IgG Assay:

Dilution Range (mg/dL)	Slope (95% CI)	Intercept (95% CI)	R^2	% Deviation from Linearity
99.25–3705.85	0.951 (0.934–0.967)	-6.781 (-10.263– -3.299)	0.9861	-9.3–10.3%

Diazyme IgM Assay:

Dilution Range (mg/dL)	Slope (95% CI)	Intercept (95% CI)	R^2	% Deviation from Linearity
13.02 – 383.50	0.993 (0.977–1.010)	9.666 (5.895–13.437)	0.9976	-4.1 – 7.7%

The linearity supports the claimed analytical mearing interval (AMI) for each Diazyme IgA, IgG, and IgM assay shown in the table below:

	Analytical Measuring Interval
Diazyme IgA Assay	28.33 – 655.33 mg/dL
Diazyme IgG Assay	100 – 3200 mg/dL
Diazyme IgM Assay	13.5 – 350 mg/dL

3. Analytical Specificity/Interference:

Interference testing of the assay in the presence of common endogenous and exogenous substances was performed following CLSI EP07-3rd Edition. For each assay, three samples (low, medium, and high) were tested with various concentrations of interfering substances. The control was the unspiked sample matrix tested under identical conditions alongside each spiked sample. All samples were tested in triplicate on one Roche cobas c 701 analyzer. No significant interference (< ±10% deviation from control) was observed. The results are summarized in the following table.

Interferent	Diazyme IgA Assay	Diazyme IgG Assay	Diazyme IgM Assay
Endogenous			
Bilirubin (Free)	40 mg/dL	40 mg/dL	40 mg/dL
Bilirubin Conjugated	40 mg/dL	40 mg/dL	40 mg/dL
Triglycerides	1500 mg/dL	1500 mg/dL	1500 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL	1000 mg/dL
Rheumatoid Factor	100 IU/mL	75 IU/mL	100 IU/mL
Exogenous			
Acetaminophen	78 mg/dL	78 mg/dL	78 mg/dL
Acyclovir	66 mg/dL	66 mg/dL	66 mg/dL
Amoxicillin	140 mg/dL	140 mg/dL	140 mg/dL
Atorvastatin	0.756 mg/dL	0.756 mg/dL	0.756 mg/dL
Diphenhydramine	0.3 mg/dL	0.3 mg/dL	0.3 mg/dL
Fluconazole	20 mg/dL	20 mg/dL	20 mg/dL
Ibuprofen	360 mg/dL	360 mg/dL	360 mg/dL
Omeprazole	8.4 mg/dL	8.4 mg/dL	8.4 mg/dL
Rituximab	1 mg/dL	N/A	1 mg/dL
Trimethoprim	18 mg/dL	18 mg/dL	18 mg/dL

4. Detection Limit:

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) of the Diazyme IgA, IgG, and IgM assays were assessed following CLSI EP17-A2.

The LoB for each assay was established by testing four blank serum samples – each prepared from individual human serum samples in which the analyte was depleted – in five replicates per day over three days on Roche cobas c701, generating 60 replicates per reagent lot. Three reagent lots were used for the Diazyme IgA Assay, while two reagent lots were used for the Diazyme IgG Assay and the Diazyme IgM Assay. The LoB was calculated as the 95th percentile of the ranked blank sample measurements, averaged across all reagent lots.

The LoD for each assay was established by testing four low-level serum samples in five replicates per day over three days on Roche cobas c701, generating 60 replicates per reagent lot. Three reagent lots were used for the Diazyme IgA Assay, while two reagent lots were used for the Diazyme IgG Assay and the Diazyme IgM Assay. The LoD was calculated using the equation: LoD = LoB + 1.65 × SD.

The LoQ for each assay was established by testing low-level serum samples on the Roche Cobas c701 analyzer. For the IgA assay, four independent low-level serum samples were tested in triplicate per day over three days with two reagent lots. The LoQ was determined to meet the precision of CV of 20% and using the Westgard total error model (TE = |Bias| + 2s) against a predefined accuracy goal. For the IgG assay, four to six low-level serum samples were tested in five replicates per day over three days with two reagent lots. For the IgM assay, nine low-level serum samples were tested in five replicates per day over three days with two reagent lots. The LoQ for IgG and IgM assays were determined to meet the precision of CV of 20%.

The claimed LoB, LoD, and LoQ values are summarized in the table below.

	LoB (mg/dL)	**LoD (mg/dL)**	**LoQ (mg/dL)**
Diazyme IgA Assay	0.99	2.99	28.33
Diazyme IgG Assay	1.54	5.82	100
Diazyme IgM Assay	0.3	4.66	13.5

5. Assay Reportable Range:

The assay reportable range is the same as the measuring interval of each assay.

- Diazyme IgA Assay: 28.33 – 655.33 mg/dL
- Diazyme IgG Assay: 100 – 3,200 mg/dL
- Diazyme IgM Assay: 13.5 – 350 mg/dL

Samples with analyte concentrations exceeding the upper limit of the measuring range should be reported as greater than the upper limit (i.e., > 655.33 mg/dL for IgA, > 3,200 mg/dL for IgG, or > 350 mg/dL for IgM). Similarly, samples with analyte concentrations less than the lower limit of the measuring range should be reported as less than the lower limit (i.e., < 28.33 mg/dL for IgA, < 100 mg/dL for IgG, or < 13.5 mg/dL for IgM).

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

a. Traceability:

All three Diazyme immunoglobulin assays are traceable to the international reference materials ERM-DA470k/IFCC.

b. Kit stability:

The stability study was conducted following CLSI EP25-A2.

Shelf-life stability: Reagent stability for the Diazyme IgA, IgG, and IgM assays was evaluated using both accelerated stability testing at 37°C and real-time stability testing at

2-8°C, with acceptance criteria requiring recovery within ±10%. The IgA reagents demonstrated stability for 16 days at 37°C, while the IgG and IgM reagents demonstrated stability for 14 days at 37°C. For the on-going real-time stability testing at 2-8°C, three lots of reagents are being evaluated for each assay, with two completed lots demonstrating stability for 12 months for all three assays at 2-8°C for the Diazyme IgA, IgG, and IgM assays.

On-board stability: Reagent on-board stability for the Diazyme IgA, IgG, and IgM assays was evaluated using one lot of reagents per assay loaded onto the Roche cobas c701 analyzer and stored in the instrument reagent chamber throughout the duration of each study. Controls and sample pools were tested at indicated time points, with recalibration performed at biweekly intervals. Results support an on-board stability claim of 4 weeks for the Diazyme IgA, IgG, and IgM assays.

7. Assay Cut-Off:

Not applicable

B. Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were conducted for the Diazyme IgA, IgG, and IgM assays against their respective predicate devices following CLSI EP9-A3. A total of 127, 152, and 132 patient serum samples were tested for the IgA, IgG, and IgM assays, respectively, on the Roche cobas c701, and compared against the Kamiya K-ASSAY IgA, Kamiya K-ASSAY IgG, and Kamiya IgM K-Assay predicate devices run on the Beckman AU400. Deming regression analysis was performed, and results are summarized in the tables below.

Diazyme IgA Assay:

N	Range (mg/dL)*	Slope (95% CI)	Intercept (95% CI)	R^2
127	38 – 655	0.992 (0.970–1.014)	1.3 (-5.8–8.3)	0.9921

*Tested by predicate

Diazyme IgG Assay:

N	Range (mg/dL)*	Slope (95% CI)	Intercept (95% CI)	R^2
152	167 – 3017	1.067 (1.026–1.108)	-30.6 (-81.0–19.8)	0.9714

*Tested by predicate

Diazyme IgM Assay:

N	Range (mg/dL)*	Slope (95% CI)	Intercept (95% CI)	R^2
132	19–312	0.994 (0.973–1.014)	5.8 (2.9–8.7)	0.9927

*Tested by predicate

2. Matrix Comparison:

Not applicable. Only human serum specimens are the intended sample type for the Diazyme IgA, IgG, and IgM Assays.

D Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off:

   Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

E Expected Values/Reference Range:

Reference interval for the Diazyme IgA, IgG, and IgM assays was established following CLSI C28-A3 by using serum samples from apparently healthy adult males and females. The results are summarized in the table below:

	N	Reference Interval
Diazyme IgA Assay	120	104 – 522 mg/dL
Diazyme IgG Assay	129	640 – 1600 mg/dL
Diazyme IgM Assay	122	52 – 217 mg/dL

It is strongly recommended that each laboratory establish a normal range for the population in their region.

VIII Proposed Labeling:

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

IX Conclusion:

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