May 18, 2018

Abbott Laboratories
Kimberly Senseman
Sr. Regulatory Affairs Specialist
1921 Hurd Drive
Irving, TX 75038

Re: K173294
Trade/Device Name: Magnesium
Regulation Number: 21 CFR 862.1495
Regulation Name: Magnesium test system
Regulatory Class: Class I, reserved
Product Code: JGJ
Dated: April 5, 2018
Received: April 10, 2018

Dear Kimberly Senseman:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173294

Device Name
Magnesium

Indications for Use *(Describe)*
The Magnesium assay is used for the quantitation of magnesium in human serum or plasma on the ARCHITECT c8000 System.

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

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) k173294 Summary (Summary of Safety and Effectiveness)

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

1. Applicant Name

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Date Summary prepared: May 11, 2018

2. Device Name

Trade Name: Magnesium
Device Classification: Class I Reserved
Classification Name: Magnesium Reagent
Governing Regulation: CFR 862.1495
Product Code: JGJ

3. Predicate Device

Roche Magnesium Gen.2

4. Description of Device

The Magnesium reagent kit contains:

Component	3P68-22	3P68-32
Number of Tests	1000* (serum or plasma)	3750* (serum or plasma)
Reagent 1 (R1)	5 × 39 mL	10 × 71 mL
Reagent 2 (R2)	5 × 11 mL	10 × 18 mL

* Calculation is based on the minimum reagent fill volume per kit and may vary depending on the mix of serum/plasma samples.

Reagent	Reactive Ingredients	Concentration
Reagent 1	Isocitrate dehydrogenase	2.2 U/mL
	D-Isocitrate potassium salt	1.47 mg/mL
Reagent 2	NADP	8.37 mg/mL
Inactive Ingredients: R1 and R2 contain sodium azide (0.1%) as a preservative.		

Principles of the Procedure

Magnesium present in the sample is a cofactor in an enzymatic reaction with isocitrate dehydrogenase. The rate of increase in absorbance at 340 nm, due to the formation of NADPH, is directly proportional to the magnesium concentration.

$$\text{D-isocitric acid} + \xrightarrow[Mg^{2+}]{\text{Isocitrate dehydrogenase}} \text{2-oxoglutarate} + CO_2 + \text{NADPH}$$

Methodology: Enzymatic

5. Intended Use of the Device

The Magnesium assay is used for the quantitation of magnesium in human serum or plasma on the ARCHITECT *c* 8000 System.

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

6. Comparison of Technological Characteristics

The Magnesium assay is used for the quantitation of magnesium in human serum or plasma on the ARCHITECT *c* 8000 System.

A comparison of the candidate assay (Magnesium, List No. 3P68) and the predicate assay (Roche Magnesium Gen.2 REF 06407358 190) is presented in the table on page 4.

Comparison of Magnesium (LN 3P68) to Roche Magnesium Gen.2

Assay Characteristics	Magnesium LN 3P68	Roche Magnesium Gen.2
Analyte Measured	Magnesium	Same
Intended Use	The Magnesium assay is used for the quantitation of magnesium in human serum or plasma on the ARCHITECT *c* 8000 System. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).	In vitro test for the quantitative determination of magnesium in human serum, plasma and urine on Roche/Hitachi cobas c systems.
Assay Principle	Magnesium present in the sample is a cofactor in an enzymatic reaction with isocitrate dehydrogenase. The rate of increase in absorbance at 340 nm, due to the formation of NADPH, is directly proportional to the magnesium concentration.	Colorimetric endpoint method. In alkaline solution, magnesium forms a purple complex with xylidyl blue, diazonium salt. The magnesium concentration is measured photometrically via the decrease in the xylidyl blue absorbance.
Detection of Analyte	Rate-up Enzymatic	Endpoint
Samples	Serum, plasma	Serum, plasma or urine
Assay Range - Serum/Plasma	0.60 to 9.50 mg/dL (0.25 to 3.90 mmol/L)	0.243-4.86 mg/dL (0.10-2.0 mmol/L) 1:2 Dilution: Up to 9.72 mg/dL
Reference Range - Serum/Plasma	Range (mg/dL) Newborn, 2 to 4 days: 1.5 to 2.2 5 months to 6 years: 1.7 to 2.3 6 to 12 years: 1.7 to 2.1 12 to 20 years: 1.7 to 2.2 Adult: 1.6 to 2.6	Same
Analysis Medium	Aqueous solution	Same
Use of Calibrators	Yes	Yes
Use of Controls	Yes	Yes

7. Summary of Performance Testing

Limit of Blank, Limit of Detection, and Limit of Quantitation

The study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP17-A2. LoB was determined using 4 obtained saline samples (zero-analyte samples). LoD and LoQ were determined using low-level analyte samples prepared from a magnesium standard. A minimum of 2 low-analyte level samples were gravimetrically prepared at each of the following 4 target concentration levels: 0.05, 0.15, 0.30, and 0.60 mg/dL. The zero-analyte samples were tested in replicates of 10. The low-analyte samples were tested in replicates of 10. Testing was performed over 3 days, two runs per day, using 2 lots of reagent, 1 lot of calibrators, and 1 lot of commercially available controls on 1 ARCHITECT *c* 8000 System.

The serum application of the Magnesium assay, had an LoB of 0.03 mg/dL, an LoD of 0.05 mg/dL, and an LoQ of 0.05 mg/dL.

Within-Laboratory Precision (20-Day)

Precision was evaluated using the following control materials.

- Level 1: Bio-Rad Lyphochek Unassayed Chemistry Control Level 1
- Level 2: Bio-Rad Lyphochek Unassayed Chemistry Control Level 2
- LoQ Serum Pool -Low Mg[*]
- Human Serum Pool - Normal Mg[#]
- Human Serum Pool - Elevated Mg[$]
- Human Serum Pool - Abnormal Mg[$]

  * LoQ Serum Pool - Low Mg was prepared by diluting normal human serum with normal saline to a magnesium concentration of approximately 0.6 mg/dL.

  # Human Serum Pool – Normal Mg is a pool of human serum specimens with a magnesium concentration ranging from 1.6 to 2.6 mg/dL.

  $ Human Serum Pool - Elevated Mg and Human Serum Pool - Abnormal Mg were prepared by spiking normal human serum with a $MgCl_2$ stock solution to a magnesium concentration of approximately 5 mg/dL and 9 mg/dL, respectively.

The levels were tested in 2 replicates, 2 times per day (separated by a minimum of 2 hours) for a total of 20 testing days. Testing was performed using 1 lot of reagents, 1 lot

of calibrators and 1 lot of commercially available controls on 1 ARCHITECT *c* 8000 System.

The evaluation was performed by instrument based on guidance from CLSI document EP05-A2.

The within-laboratory imprecision (within-run, between-run, and between-day) for Magnesium serum was as follows:

- 1.4 %CV for Bio-Rad Level 1
- 1.0 %CV for Bio-Rad Level 2
- 3.4 %CV for LoQ Serum Pool -Low Mg
- 1.2 %CV for Human Serum Pool - Normal Mg
- 0.9 %CV for Human Serum Pool - Elevated Mg
- 0.8 %CV for Human Serum Pool - Abnormal Mg

Specimen Tube Type (Matrix Comparison)

The study control tube type was the serum glass tube. The following tubes types were under evaluation: serum with gel separator, sodium heparin plasma (without gel separator), lithium heparin plasma (without gel separator), and lithium heparin plasma with gel separator. Fresh or frozen sample sets were obtained that included the control tube type and at least 1 tube type under evaluation. Each tube type under evaluation was assessed using a minimum of 40 samples. The sample sets spanned the measuring interval (0.60 to 9.50 mg/dL) and included the assay's medical decision levels. Of the 40 sample sets, 36 sample sets were unaltered, three sample sets were spiked and 1 sample set was diluted.

To prepare samples with elevated magnesium levels, magnesium chloride stock solution at 200 mmol/L was prepared. A total of 3 sample sets were spiked with the magnesium chloride stock solution to create sample sets each at the following magnesium levels: 5 to 6 mg/dL, 6 to 7 mg/dL and 7 to 9 mg/dL.

To prepare one sample with a magnesium concentration to be within the measuring interval, the sample was diluted with deionized water to create a sample set at 1.2 to 1.55 mg/dL.

All samples were tested in a minimum of 2 replicates using 1 lot each of reagent, Multiconstituent Calibrator (LN 1E65) and commercially available controls on 1 ARCHITECT *c* 8000 System. All samples collected from the same subject were tested in the same run. The Magnesium assay, which had a mean difference from the control tube ranging from -4.9% to 3.8% met the evaluation criteria of bias from the control tube across all samples of no more than ± 7.5%.

The results demonstrated that the following blood collection tube types are acceptable for use with the Magnesium assay: serum glass, serum with gel separator, lithium heparin, lithium heparin with gel separator, and sodium heparin.

Interference

The interference study for ascorbic acid, bilirubin (conjugated), bilirubin (unconjugated), glucose, hemoglobin, Intralipid, L-dopa, and calcium was performed based on guidance from CLSI document EP07-A2. Interference effects were assessed by comparing test samples containing potentially interfering ascorbic acid, bilirubin (conjugated), bilirubin (unconjugated), glucose, hemoglobin, Intralipid, L-dopa, and calcium samples to control level samples.

The control and test level samples were tested in a minimum of 6 valid replicates using 1 lot of reagents,1 lot of Multiconstituent Calibrator (LN 1E65) and 1 lot commercially available controls on 1 ARCHITECT *c* 8000 System. The control and test level samples for a given potential interferent/magnesium level combination were tested in the same run.

Additionally, a drug interference study was performed for sulfasalazine, sulfapyridine and temozolomide.

For the sulfasalazine and sulfapyridine study, solutions of each potential interferent were prepared by spiking serum with stock solutions in order to generate samples with potential interferent levels of 100 mg/L, 200 mg/L and 300 mg/L. A control sample (serum) and test level samples were tested in 3 replicates using 1 lot of reagents,1 lot of Multiconstituent Calibrator (LN 1E65) and 1 lot commercially available controls on 1 ARCHITECT *c* 8000 System.

Lastly, a study was performed to assess the effects of copper, iron, zinc, ibuprofen, acetaminophen, salicylic acid, and triglycerides.

For the copper, iron, zinc, ibuprofen, acetaminophen, salicylic acid, and triglycerides study, the control and interferent samples were tested in a minimum of 7 replicates using 1 lot of reagent, 1 lot of Multiconstituent Calibrator (LN 1E65), and 1 lot of commercially available controls on 1 ARCHITECT c8000 System. The control and interferent samples for a given potential interferent/magnesium level combination were tested in the same run.

For magnesium samples targeted to ~ 2 mg/dL, the assay showed no more than ± 7.5% interference for the listed substances at the interferent levels indicated in the table.

Interferent	**Interferent Level**
Ascorbic Acid	≤ 3.00 mg/dL
Bilirubin (Conjugated)	≤ 55.3 mg/dL
Bilirubin (Unconjugated)	≤ 60.3 mg/dL
Glucose	≤ 1240 mg/dL
Hemoglobin	≤ 250 mg/dL
Intralipid	≤ 2476 mg/dL
L-dopa	≤ 5.0 mg/dL
Calcium	≤ 28.0 mg/dL
Acetaminophen	≤ 1592 µmol/L
Copper	≤ 6.5 µg/mL
Iron	≤ 641 µg/dL
Ibuprofen	≤ 2915 µmol/L
Salicylic acid	≤ 5.21 mmol/L
Triglyceride	≤ 3647 mg/dL
Zinc	≤ 4.3 µg/mL

For magnesium samples targeted to ~ 4 mg/dL, the assay showed no more than ± 7.5% interference for the listed substances at the interferent levels indicated in the table.

Interferent	Interferent Level
Ascorbic Acid	≤ 3.00 mg/dL
Bilirubin (Conjugated)	≤ 55.9 mg/dL
Bilirubin (Unconjugated)	≤ 60.5 mg/dL
Glucose	≤ 1311 mg/dL
Hemoglobin	≤ 1000 mg/dL
Intralipid	≤ 2471 mg/dL
L-dopa	≤ 5.0 mg/dL
Calcium	≤ 28.0 mg/dL
Acetaminophen	≤ 1592 µmol/L
Copper	≤ 6.5 µg/mL
Iron	≤ 641 µg/dL
Ibuprofen	≤ 2915 µmol/L
Salicylic acid	≤ 5.21 mmol/L
Triglyceride	≤ 3598 mg/dL
Zinc	≤ 4.3 µg/mL

For magnesium samples targeted to ~ 6 mg/dL, the assay showed no more than ± 7.5% interference for the listed substances at the interferent levels indicated in the table.

Interferent	Interferent Level
Ascorbic Acid	≤ 3.00 mg/dL
Bilirubin (Conjugated)	≤ 56.5 mg/dL
Bilirubin (Unconjugated)	≤ 60.9 mg/dL
Glucose	≤ 1199 mg/dL
Hemoglobin	≤ 1200 mg/dL
Intralipid	≤ 2482 mg/dL

Interferent	Interferent Level
L-dopa	≤ 5.0 mg/dL
Calcium	≤ 28.0 mg/dL
Acetaminophen	≤ 1592 µmol/L
Copper	≤ 6.5 µg/mL
Iron	≤ 641 µg/dL
Ibuprofen	≤ 2915 µmol/L
Salicylic acid	≤ 5.21 mmol/L
Triglyceride	≤ 3580 mg/dL
Zinc	≤ 4.3 µg/mL

Additionally, for magnesium samples targeted to ~ 1.45 mg/dL, the assay showed no more than ± 7.5% interference for sulfasalazine and sulfapyridine at concentrations up to 300 mg/L.

Finally, for magnesium samples targeted to ~ 3.490 mg/dL and 7.505 mg/dL, the assay showed no more than ± 7.5% interference for temozolomide at concentrations up to 20 mg/L.

Linearity

Linearity was determined based on guidance from Clinical and Laboratory Standards Institute (CLSI) document EP06-A. Three sets of linearity standards were prepared using a magnesium standard and 4% HSA (diluent). For each sample set, a low and high sample pool was prepared.

- the low sample pool (Level 1) had a concentration greater than 0.0 mg/dL but below the LoQ and
- the high sample pool (Level 12) was 20 to 30% beyond the highest expected measurement concentration.

A sample set was prepared for each combined magnesium pool. Each sample set consisted of 12 levels at the following magnesium target concentrations: 0.30, 0.49,

0.68, 1.07, 1.83, 3.35, 4.88, 6.40, 7.93, 9.45, 10.98 and 12.50 mg/dL. Levels 1 through 12 for each sample set were tested in a random order in a minimum of 4 replicates using 2 lots reagents and 1 lot each of Multiconstituent Calibrator (LN 1E65) and commercially available controls on 1 ARCHITECT *c* 8000 System. All levels in a sample set were tested in the same run.

The Magnesium assay was demonstrated to be linear across the range of 0.26 to 12.98 mg/dL, which spans the measuring interval of 0.60 to 9.50 mg/dL.

Measuring Interval

The measuring interval was determined based on the results from 3 studies: Within Laboratory Precision (20-Day); Linearity; and Limit of Blank, Limit of Detection, and Limit of Quantitation.

The analytical measuring interval for the Magnesium assay was determined to be from 0.60 to 9.50 mg/dL.

Method Comparison

The study was performed based on guidance from CLSI document EP09-A3. A total of 122 patient serum specimens were evaluated with the Magnesium (LN 3P68) and Roche Magnesium Gen.2 (REF 06407358 190) assays. Of these samples, 11 were normal serum samples spiked with magnesium hexachloride to achieve samples with magnesium concentrations in the range of 4.8 to 9.4 mg/dL. Three replicates were run using the Magnesium (LN 3P68) reagent kit where the first valid replicate was used in the analysis. One replicate was run at UT Southwestern Medical Center (UTSW, Dallas) using Roche Magnesium Gen.2 (REF 06407358 190) reagent. Testing was performed over 5 separate days.

The Magnesium (LN 3P68) assay, which had a regression slope of 0.95 and correlation coefficient (r-value) of 0.9979 demonstrated acceptable correlation to the predicate device.

Manual Dilution

Three serum pools were prepared, using human serum and magnesium chloride, at magnesium concentrations of 8, 15, and 25 mg/dL (±10%). Each analyte pool was evaluated without dilution (neat) and after 1:2 and 1:5 manual dilution. Dilutions were performed using 0.85% and 0.90% (NaCl) saline. Samples were tested in a minimum of 7 replicates using 1 lot of reagent, 1 lot of Multiconstituent Calibrator (LN 1E65), and 1 lot of commercially available controls on 1 ARCHITECT c8000 System. The neat and diluted samples at a given magnesium level were tested in the same run.

Magnesium assay results were impacted by not more than ±7.5% for analyte concentrations 8, 15 and 20 mg/dL (±10%) when evaluated neat, with a 1:2, or 1:5 manual dilution (using 0.85% or 0.90% saline).

8. Conclusion Drawn from Performance Testing

The results presented in this 510(k) premarket notification demonstrate that the candidate assay (Magnesium, List No. 3P68) performance is substantially equivalent to the predicate assay (Roche Magnesium Gen.2 (REF 06407358 190)).

The similarities and differences between the candidate assay and the predicate assay are presented in the table on page 4. The results presented in this 510(k) provide reasonable assurance that the Magnesium assay is safe and effective for the stated intended use. Any differences between the candidate assay and the predicate assay shown in the tables do not affect the safety and effectiveness of the candidate assay.

There is no known potential adverse effect to the operator when using this device according to the Magnesium package insert instructions.