

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k063208

B. Purpose for Submission:

New device

C. Measurand:

Magnesium

D. Type of Test:

Photometric method

E. Applicant:

Diagnostic Chemicals Ltd.

F. Proprietary and Established Names:

Magnesium Assay (XB), Models 125-12, 125-50 and 125-S7

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>Photometric Method, Magnesium (JGJ)</u>	<u>Class I, reserved</u>	<u>21 CFR 862.1495, Magnesium test system.</u>	<u>75 CLINICAL CHEMISTRY (CH)</u>
<u>Calibrator, secondary (JIT)</u>	<u>Class II</u>	<u>21 CFR 862.1150, Calibrator secondary</u>	<u>75 Clinical Chemistry (CH)</u>

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Reagent

The Diagnostic Chemicals Limited Magnesium Assay (XB) is for the quantitative determination of magnesium in human serum. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium). This device is intended for professional use and IN VITRO diagnostic use only.

Standard

The Diagnostic Chemicals Limited Magnesium Assay (XB) Standard is used for the calibration of the Diagnostics Chemicals Limited Magnesium Assay (XB) when used for the quantitative determination of magnesium in human serum.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Analyzer with temperature control of $\pm 0.5^{\circ}\text{C}$ that is capable of reading absorbance accurately with a sensitivity of 0.001 absorbance at 520 or 660 nm. The band width should be 10 nm or less, stray light 0.5% or less, and the wavelength accuracy within 2 nm.

I. Device Description:

The Diagnostic Chemicals Magnesium Assay (XB) Reagents and Calibrator are designed to be used in the Diagnostics Chemicals Magnesium Assay (XB). The reagent is provided in a ready to use format.

Reagents:

The Diagnostic Chemicals Magnesium Assay (XB) is a photometric method assay for the quantitative determination of magnesium in serum and plasma. Each Magnesium Assay (XB) kit contains 1 bottle of each component

- Magnesium Assay (XB) product Cat. No. 125-12
4 x 125 mL Magnesium Reagent
1 x 15 mL Magnesium Standard
- Magnesium Assay (XB) product Cat. No. 125-50
1 x 1000 mL Magnesium Reagent
1 x 15 mL Magnesium Standard
- Magnesium Assay (XB) product Cat. No. 125-S7

2 x 125 mL Magnesium Reagent
1 x 5 mL Magnesium Standard

J. Substantial Equivalence Information:

Predicate	k901758 - Roche Reagent for Magnesium
Describe the item being compared	
In vitro test for the quantitative determination of magnesium in human serum, plasma and urine on Roche automated clinical chemistry analyzers.	
Similarities	
The submission device and the predicate device have the same intended use.	
The submission device and the predicate device are both provided in a ready to use liquid format.	
The submission device and the predicate device both use xylydyl blue as the complexing agent.	
Differences	
The predicate reagent is provided as a two reagent system while the submission reagent is provided as a single reagent system.	
The predicate reagent measures the decrease in optical density while the submission reagent may be used as an increasing or decreasing optical density.	
The submitted device is intended for use with serum only.	

K. Standard/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Medical devices - Application of risk management to medical devices (14971:2000)

L. Test Principle:

This method employs xylydyl blue-1:

Xylydyl blue-1 + Mg^{++} yields Mg-xylydyl blue complex (red)

The absorbance increase, at 520 nm, of the red complex formed is directly proportional to the concentration of Magnesium in the serum. The absorbance decrease, at 660 nm due to the complexing of the xylydyl blue-1 with Mg^{++} , is directly proportional to the concentration of magnesium in serum.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were done according to the National Committee for Clinical Laboratory Standards (NCCLS) protocol EP5-A2. This study assessed repeatability (within-run precision), reproducibility (total precision based on between-day, between-run, and within-day).

Total and Within run imprecision was established by assaying 2 control sera twice a day for 20 days.

Total:

Magnesium	Mean		Standard Deviation		Coefficient of Variation %
	mg/dL	mmol/L	mg/dL	mmol/L	
Serum 1	1.99	0.82	0.12	0.05	5.9
Serum 2	4.03	1.65	0.15	0.06	3.8

Within run:

Magnesium	Mean		Standard Deviation		Coefficient of Variation %
	mg/dL	mmol/L	mg/dL	mmol/L	
Serum 1	1.84	0.75	0.08	0.03	4.5
Serum 2	3.99	1.64	0.10	0.04	2.4

b. Linearity/assay reportable range:

The recovery of the Magnesium (XB) assay was analyzed on a Hitachi 717-S over a measured range of 0.20 to 6.5 mg/dL. A summary of the data is presented in the table below.

	n	Slope	Intercept	Error
Overall	6	1.051	-0.06	0.05 mg/dL or 1.5%

The measuring range of this assay is 0.5 – 6.1 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The Diagnostic Chemicals Calibrator is traceable to NIST 909b Level 1 and the controls are traceable to the calibrator.

The sponsor performed real time, accelerated and ongoing stability testing. Protocols and acceptance criteria were reviewed and found to be acceptable.

The recommended quality control materials (DC-Trol Level 1 and DC-Trol Level 2) have been previously cleared under 510(k) submission k874772.

d. Detection limit:

The analytical sensitivity of this assay was evaluated by repeated testing (n = 10 across one reagent lot) of Diagnostic Chemicals Magnesium Calibrator. The mean of the results plus 3SD was determined to be 0.52 mg/dL and is the lower limit of the assay's measuring range.

e. Analytical specificity:

Serum samples were spiked with potentially interfering substances and tested with the Diagnostic Chemicals Magnesium (XB) Assay. Interferences from Hemolysis, icterus, lipemia and ascorbic acid were evaluated for this magnesium method (> 10% variance from control was defined as interference).

Hemoglobin levels of 0 – 1000 mg/dL (0 – 155 mmol/L) were studied with no significant observed interference to a level of 800 mg/dL (124 µmol/L). At a hemoglobin level of 800 mg/dL (124 µmol/L), a 10% interference was displayed in a 1.9 mg/dL (0.78 mmol/L) magnesium sample. Hemolyzed samples are not recommended.

No significant Bilirubin interference was observed for this method. Bilirubin levels from 0 – 40 mg/dL (0 – 684 mmol/L) were studied in a 1.9 mg/dL (0.78 mmol/L) magnesium sample.

No significant Lipemic interference was observed for this method. Intralipid levels from 0-1000 mg/dL (equivalent to 0-33.9 mmol/L [0-3000 mg/dL triglycerides) were studied in a 2.0 mg/dL (0.82 mmol/L) magnesium sample.

No significant ascorbic acid interference was observed for this method. Ascorbic acid levels from 0 – 121 mmol/L (0 – 3000 mg/dL) were studied in a 0.70 mmol/L (1.7 mg/dL) magnesium sample.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A study was performed comparing the Diagnostic Chemicals Magnesium (XB) Assay to the predicate Roche Magnesium Assay. The results from the linear regression analysis are summarized below.

The correlation coefficient was 0.994. Regression analyses gave the following equations:

Linear: This method = 1.020 (reference method) – 0.100 mmol/L

Deming: This method = 1.026 (reference method) – 0.117 mmol/L

The concentration range tested was 0.90 to 5.90 mg/dL;

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected Values

1.6 – 2.6 mg/dL (0.65 – 1.05 mmol/L)

In the labeling the sponsor recommends that each laboratory determine its own reference range based on its particular locale and population characteristics. The above expected values/ reference range was cited from literature.

[Tietz, N.W., (Editor) Clinical Guide to Laboratory Tests, W.B. Saunders Company, Philadelphia (1983) p.338.]

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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