

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

A. 510(k) Number:

k101088

B. Purpose for Submission:

Albumin: Addition of plasma to the already cleared device (k080874)

Calcium: Addition of plasma to the already cleared device (k072249)

Magnesium: Addition of plasma to the already cleared device (k092737)

Phosphorus: Addition of plasma to the already cleared device (k080810)

C. Measurand:

Albumin, Calcium, Magnesium, Phosphorus

D. Type of Test:

Albumin, Magnesium, Phosphorus: Quantitative colorimetric chemistry tests

Calcium: AZO method

E. Applicant:

Medica Corp

F. Proprietary and Established Names:

EasyRA ALB Reagent

Easy RA Calcium Reagent

Easy RA Magnesium Reagent

Easy RA Inorganic Phosphorus Reagent

G. Regulatory Information:

Measurand	Regulation Section	Classification	Product Code	Panel
Albumin	21CFR862.1035	2	CIX- Colorimetric	Clinical Chemistry
Calcium	21CFR862.1145	2	CJY- Azo Dye	Clinical Chemistry
Magnesium	21CFR862.1495	2	JGJ- Photometric	Clinical Chemistry
Phosphorus- Inorganic	21CFR862.1580	2	CEO – Colorimetric	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

EasyRA Albumin Reagent: The EasyRA albumin reagent is intended for the quantitative determination of albumin (ALB) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. For in vitro diagnostic use only.

EasyRA Calcium Reagent: The EasyRA total calcium reagent is intended for the quantitative measurement of total calcium (Ca) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. For in vitro diagnostic use only.

EasyRA Magnesium Reagent: The EasyRA magnesium reagent is intended for the quantitative measurement of magnesium in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Magnesium measurements are used in the diagnosis and treatment of: Hypermagnesemia occurring during renal failure, acute diabetic acidosis, dehydration or in Addison’s disease. Hypomagnesemia observed in cases of chronic alcoholism, malabsorption, acute pancreatitis and kidney disorders.

EasyRA Inorganic Phosphorus Reagent: This reagent is intended for the quantitative measurement of inorganic phosphorus (PHOS) in human serum and

plasma. Phosphorus measurements are used in the diagnosis and treatment of parathyroid gland, kidney diseases, and vitamin D imbalance.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

EasyRA Clinical Chemistry Analyzer

I. Device Description:

The EasyRA albumin (ALB), calcium (Ca), magnesium (Mg), and inorganic phosphorus reagents are *in vitro* diagnostic reagents in ready-for use liquid form. They are designed for use on the Easy RA clinical chemistry analyzer for the measurement of their respective analytes in human serum and plasma.

J. Substantial Equivalence Information:

1. Predicate Device Name(s):

- EasyRA Albumin Reagent
- EasyRA Calcium Reagent
- EasyRA Magnesium Reagent
- EasyRA Phosphorus Inorganic Reagent

2. Predicate 510(k) number(s):

k080874, k080810, k072249, k092737

3. Comparison with predicate:

Similarities and Differences for Albumin		
Item	Candidate Device EasyRA Albumin Reagent	Predicate Device (k080874) EasyRA Albumin Reagent
Intended Use	The EasyRA albumin reagent is intended for the quantitative determination of albumin (ALB) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. For in vitro diagnostic use only.	Same

Specimen Type	Serum and plasma	Serum
Reagent Type	Liquid ready-for-use	Same
Assay Principle	Colorimetric-bromocresol green	Same
Analytical Range	0.4 to 7.0 g/dL	Same

Similarities and Differences for Calcium		
Item	Candidate Device EasyRA Calcium Reagent	Predicate Device (k072249) EasyRA Calcium Reagent
Intended Use	The EasyRA total calcium reagent is intended for the quantitative measurement of total calcium (Ca) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. For in vitro diagnostic use only.	Same
Specimen Type	Serum and plasma	Serum
Reagent Type	Liquid ready-for-use	Same
Assay Principle	AZO dye	Same
Analytical Range	1.0 to 15 mg/dL	Same

Similarities and Differences for Magnesium		
Item	Candidate Device EasyRA Magnesium Reagent	Predicate Device (k092737) EasyRA Magnesium Reagent
Intended Use	The EasyRA total calcium reagent is intended for the quantitative measurement of total calcium (Ca) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and	Same

	tetany. For in vitro diagnostic use only.	
Specimen Type	Serum and plasma	Serum
Reagent Type	Liquid ready-for-use	Same
Assay Principle	Colorimetric	Same
Analytical Range	0.04 to 6.1 mg/dL	Same

Similarities and Differences for Phosphorus-Inorganic		
Item	Candidate Device EasyRA Inorganic Phosphorus Reagent	Predicate Device (k092737) EasyRA Phosphorus Inorganic Reagent
Intended Use	The EasyRA total calcium reagent is intended for the quantitative measurement of total calcium (Ca) in human serum and plasma, using the MEDICA “EasyRA Chemistry Analyzer” in clinical laboratories. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. For in vitro diagnostic use only.	Same
Specimen Type	Serum and plasma	Serum
Reagent Type	Liquid ready-for-use	Same
Assay Principle	Colorimetric	Same
Analytical Range	0.11 to 20.0 mg/dL	Same

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

- **CLSI Guideline, EP5-A2** *Evaluation of Precision Performance of Clinical Chemistry Devices – Second Edition*
- **CLSI Guideline, EP9-A2** *Method Comparison and Bias Estimation Using Patient Samples – Second Edition*

L. Test Principle:

Easy RA Albumin

This method involves the binding of albumin with bromocresol green to produce a

blue-green color. This color is measured at 600 nm with a blanking wavelength of 700 nm. The color intensity is proportional to the concentration of Albumin in the sample.

EasyRA Calcium

This method utilizes Arsenazo III, which has a high affinity for calcium at neutral pH. Interference from magnesium is eliminated by the addition of 8-hydroxyquinoline-5-sulfonic acid. Arsenazo III reacts with calcium to form a 1:1 blue complex with an absorption maximum at 650 nm. The concentration of calcium is proportional to the intensity of the blue color.

EasyRA Magnesium

This method involves the binding of xylydyl blue-1 dye to magnesium to form the Mg-xylydyl blue complex. The increase of absorbance of the complex at 520 nm is directly proportional to the concentration of magnesium in the sample.

The absorbance decrease at 600 nm is directly proportional to the Magnesium in the serum combining with the complex.

EasyRA Phosphorus-Inorganic

This method involves the reaction of inorganic phosphorus with ammonium molybdate in an acidic medium to form a phosphomolybdate complex with a yellow color.

The increase in absorbance at 340 nm is directly proportional to the concentration of inorganic phosphorus in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Serum and Plasma- Precision studies were performed in conjunction with the matrix comparison study with lithium heparin tubes. Duplicate plasma and serum samples from the method studies were calculated for average SD for 3 partitioned bins covering the ranges tested. The average SD in each of the 3 bins for both plasma and serum are comparable.

Albumin

	Low	Medium	High
Analytical Range(g/dL)	0.4 – 4.75	4.75 – 4.99	5.0 – 7.0

No. of Samples	24	25	22
No. of Replicates	2	2	2
Serum Mean	3.72	4.86	5.25
Serum SD	0.060	0.051	0.056
Serum % CV	1.60	1.00	1.10
Plasma Mean	3.57	4.87	5.27
Plasma SD	0.050	0.062	0.054
Plasma % CV	1.40	1.30	1.00

Calcium

	Low	Medium	High
Analytical Range(mg/dL)	1.0 – 9.5	9.5 – 10.0	10.0 – 15.0
No. of Samples	19	31	20
No. of Replicates	2	2	2
Serum Mean	7.89	9.79	10.80
Serum SD	0.15	0.14	0.14
Serum % CV	1.90	1.40	1.30
Plasma Mean	7.78	9.58	10.60
Plasma SD	0.11	0.15	0.15
Plasma % CV	1.40	1.60	1.40

Magnesium

	Low	Medium	High
Analytical Range(mg/dL)	0.03 – 1.8	1.8 – 1.95	1.95 – 6.1
No. of Samples	16	27	29
No. of Replicates	2	2	2
Serum Mean	1.45	1.88	2.81
Serum SD	0.023	0.020	0.036
Serum % CV	1.60	1.10	1.30
Plasma Mean	1.42	1.86	2.80
Plasma SD	0.020	0.026	0.041
Plasma % CV	1.40	1.40	1.50

Phosphorus

	Low	Medium	High
Analytical Range(mg/dL)	0.11 – 3.25	3.25 – 3.75	3.75 – 20.0
No. of Samples	22	29	26
No. of Replicates	2	2	2
Serum Mean	2.67	3.52	8.19
Serum SD	0.041	0.049	0.078
Serum % CV	1.50	1.40	1.00
Plasma Mean	2.46	3.26	8.04
Plasma SD	0.044	0.046	0.094
Plasma % CV	1.80	1.40	1.20

In addition a simplified within-run precision study was performed on the EasyRA analyzer by analyzing 3 plasma patient samples, 20 consecutive times. The within-run precision data is summarized in the table below:

	Mean	SD	%CV
Albumin (g/dL)	Level 1 - 3.21	Level 1 - 0.03	Level 1 - 0.96
	Level 2 – 4.82	Level 2 – 0.09	Level 2 – 1.82
	Level 3 – 6.38	Level 3 – 0.06	Level 3 – 0.86
Calcium (mg/dL)	Level 1 - 5.68	Level 1 - 0.09	Level 1 - 1.56
	Level 2 – 10.66	Level 2 – 0.13	Level 2 – 1.26
	Level 3 – 11.82	Level 3 – 0.10	Level 3 – 0.88
Magnesium (mg/dL)	Level 1 - 1.21	Level 1 - 0.01	Level 1 – 0.99
	Level 2 – 2.02	Level 2 – 0.03	Level 2 – 1.68
	Level 3 – 4.92	Level 3 – 0.07	Level 3 – 1.40
Phosphorus (mg/dL)	Level 1 - 2.11	Level 1 - 0.02	Level 1 - 0.98
	Level 2 – 3.26	Level 2 – 0.04	Level 2 – 1.22
	Level 3 – 15.06	Level 3 – 0.12	Level 3 – 0.77

b. Linearity/assay reportable range:

Plasma - Linearity studies were not conducted in plasma. See previously cleared linearity data in k080810 (ALB), k072249 (Ca), k092737 (Mg), and k080810 (PHOS) for serum samples. The linear reportable ranges for each assay are summarized below.

	Albumin	Calcium	Magnesium	Phosphorus
Linear Reportable Range	0.4 to 7.0 g/dL	1.0 to 15.0 mg/dL	0.04 to 6.1 mg/dL	0.11 to 20.0 mg/dL

An extended linearity study was performed for all analytes with the MEDICA EasyRA analyzer to evaluate accuracy and precision. The sponsor recommends a dilution of 1:2 when the patient albumin, calcium, magnesium, and phosphorus results in plasma fall outside the upper measuring range of 7.0 g/dL, 15.0 mg/dL, 6.1 mg/dL, and 20.0 mg/dL, respectively. A dilution study was performed for albumin on 3 different patient plasma samples spiked with standard albumin stock solution to increase the albumin level in the range of 7.5 to 13.5 g/dL, for calcium 5 different patient plasma samples were spiked with standard calcium stock solution to increase the calcium level in the range of 17.0 to 27.0 mg/dL, for magnesium 5 different patient plasma samples were spiked with standard magnesium stock solution to increase the magnesium level in the range of 6.5 to 11.7 mg/dL, and for phosphorus 5 different patient plasma samples were spiked with standard phosphorus stock solution to increase the phosphorus level in the range of 22.0 to 37.0 mg/dL. Each sample was then diluted with saline at 1:2 dilution by the analyzer or manually. Each diluted sample was run in triplicate on two MEDICA EasyRA analyzers. The % recovery range of the system for each analyte is provided in the table below:

	EasyRA % Recovery
Albumin	101.1 to 102.6
Calcium	99.3. to 102.6
Magnesium	100.7 to 104.0
Phosphorus	96.8 to 104.5

In addition a simplified within-run precision study was performed in the extended linearity range for all analytes by analyzing 3 plasma samples, 20 consecutive times. The within-run precision data is summarized in the table below:

	Mean	SD	CV
Albumin	Level 1 - 7.73	Level 1 – 0.08	Level 1 – 1.04
	Level 2 – 9.75	Level 2 – 0.18	Level 2 – 1.84
	Level 3 – 12.69	Level 3 – 0.23	Level 3 – 1.78
Calcium	Level 1 - 18.73	Level 1 – 0.18	Level 1 – 0.95
	Level 2 – 24.65	Level 2 – 0.25	Level 2 – 1.00
	Level 3 – 26.64	Level 3 – 0.32	Level 3 – 1.20
Magnesium	Level 1 – 6.77	Level 1 – 0.08	Level 1 – 1.15
	Level 2 – 8.20	Level 2 – 0.11	Level 2 – 1.29
	Level 3 – 9.90	Level 3 – 0.13	Level 3 – 1.34
Phosphorus	Level 1 – 26.14	Level 1 – 0.30	Level 1 – 1.14

	Level 2 – 30.35	Level 2 – 0.19	Level 2 – 0.62
	Level 3 – 33.66	Level 3 – 0.47	Level 3 – 1.39

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

Calibrators were previously cleared under k080810 (ALB), k072249 (Ca), k092737 (Mg), and k080810 (PHOS).

d. *Detection limit:*

Limit of detection studies were not conducted for plasma. See cleared serum data under k080810 (Albumin), k072249 (Calcium), k092737 (Magnesium), and k080810 (Phosphorus).

e. *Analytical specificity:*

Plasma interference studies were not performed. See previously cleared interference data in k080810 (Albumin), k072249 (Calcium), k092737 (Magnesium), and k080810 (Phosphorus) for serum samples.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Plasma – See previously cleared method comparison data in k080810 (Albumin), k072249 (Calcium), k092737 (Magnesium), and k080810 (Phosphorus) for serum samples. Plasma matrix comparison data is provided below in part (b) of this section.

b. *Matrix comparison:*

Plasma Lithium Heparin- A matrix comparison study was also performed in conjunction with CLSI EP9-A2 guidelines using lithium heparin tubes. The study was completed with human plasma and serum samples spanning the linear range of each assay. 71 total samples (60 unaltered and 11 altered samples) were analyzed for albumin, 70 total samples (56 unaltered and 14 altered samples) were analyzed for calcium, 72 total samples (59 unaltered and 13 altered) were analyzed for magnesium, and 77 total samples (61 unaltered and 16 altered samples) were analyzed for phosphorus. Each sample was analyzed in duplicate using the MEDICA EasyRA chemistry analyzer.

One single set of plasma samples were used as test samples, while duplicate serum samples were used as references. Determined linear regression correlations are as follows:

Analyte	Slope	Intercept	R ²	Conc. Range Tested
ALB	1.0056	-0.0192	0.9937	0.4 – 6.6 g/dL
Ca	0.9853	-0.0632	0.9891	1.6 – 14.7 mg/dL
Mg	1.0184	-0.0584	0.9983	0.1 – 6.1 mg/dL
PHOS	1.0070	-0.2462	0.9966	0.7 – 19.3 mg/dL

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Reference ranges are provided in the labeling from literature as follows:

	Serum/Plasma
Albumin	3.8 – 5.1 g/dL
Calcium	8.8 – 10.2 mg/dL
Magnesium	1.6 – 2.6 mg/dL
Phosphorus	2.7 – 4.5 mg/dL

Tietz, N.W. Fundamentals of Clinical Chemistry, 5th ed., Philadelphia, PA, WB Saunders and Co., p. 961-1027; 2001.

N. Proposed Labeling:

The labeling is sufficient and does satisfy 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.