

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

A. 510(k) Number:

k080810

B. Purpose for Submission:

New device

C. Measurand:

Direct Bilirubin, Total Bilirubin, Phosphorus, Total Iron, and Magnesium

D. Type of Test:

Quantitative colorimetric chemistry tests

E. Applicant:

Medica Corporation

F. Proprietary and Established Names:

EasyRA Bilirubin-Direct Reagent, EasyRA Bilirubin-Total Reagent, EasyRA Phosphorus-Inorganic Reagent, EasyRA Iron Reagent, EasyRA Magnesium Reagent

G. Regulatory Information:

	Regulation section	Classification	Product Code	Panel
EasyRA Bilirubin-Direct	21 CFR § 862.1110	II	CIG	Chemistry (75)
EasyRA Bilirubin-Total	21 CFR § 862.1110	II	CIG	Chemistry (75)
EasyRA Phosphorus-Inorganic	21 CFR § 862.1580	I, reserved	CEO	Chemistry (75)
EasyRA Iron	21 CFR § 862.1410	I, reserved	JYJ	Chemistry (75)
EasyRA Magnesium	21 CFR § 862.1495	I, reserved	JGJ	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See below.

2. Indication(s) for use:

EasyRA Bilirubin-Direct

The EasyRA DBIL Reagent is for the *in-vitro* measurement of Direct Bilirubin in serum of adults on the Medica Easy RA analyzer. Bilirubin measurements are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

EasyRA Bilirubin- Total

The EasyRA TBIL Reagent is for the *in-vitro* measurement of Total Bilirubin in serum of adults on the Medica Easy RA analyzer. Bilirubin measurements are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

EasyRA Phosphorus-Inorganic

The EasyRA Phosphorus Reagent is for the *in vitro* measurement of phosphorus in serum on the Medica Easy RA analyzer. Phosphorus measurements are used in the diagnosis and treatment of parathyroid gland, kidney diseases, and vitamin D imbalance.

EasyRA Iron

The EasyRA Iron Reagent is for the *in vitro* measurement of iron in serum on the Medica Easy RA analyzer. Iron measurements are used in the diagnosis and treatment of iron deficiency anemia, hemochromatosis, and chronic renal disease.

EasyRA Magnesium

The EasyRA Magnesium Reagent is for the *in vitro* measurement of magnesium in serum on the Medica Easy RA analyzer. 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.

3. Special conditions for use statement(s):

Prescription use only

These devices have not been tested in neonates.

4. Special instrument requirements:

Medica EasyRA Analyzer

I. Device Description:

The EasyRA Bilirubin-Direct, EasyRA Bilirubin-Total, EasyRA Phosphorus-Inorganic, EasyRA Iron and EasyRA Magnesium reagents are dual reagent systems containing reagents, stabilizers and diluents. They are for use on the Easy RA analyzer.

J. Substantial Equivalence Information:

New Device	Predicate Device Name	Predicate K Number(s)
Easy RA Bilirubin-Direct	Roche Diagnostics Direct Bilirubin Reagent	k841892
Easy RA Bilirubin-Total	Roche Total Bilirubin Reagent	k841892
Easy RA Phosphorus-Inorganic	Roche Diagnostics Inorganic Phosphorous Reagent	k870776
Easy RA Iron	Raichem	k864819
Easy RA Magnesium	Diagnostic Chemical Limited	k063208

Comparison with predicate:

Direct Bilirubin		
Item	Device	Predicate
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Direct Bilirubin in human serum using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of Direct Bilirubin in human serum using the Roche Cobas-Mira chemistry analyzer.
Test Methodology	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the

Direct Bilirubin		
Item	Device	Predicate
	EasyRA measures absorbance according to Beer's law.	COBAS-Mira measures absorbance according to Beer's law.
Sample type	Serum	Serum
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	0.06 – 10 mg/dL	Up to 20 mg/dL
Wavelength	550 nm	550 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C

Total Bilirubin		
Item	Device	Predicate
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Total Bilirubin in human serum using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of Total Bilirubin in human serum using the Roche Cobas-Mira chemistry analyzer.
Sample	Serum	Serum
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	0.08 – 20 mg/dL	Up to 20 mg/dL
Wavelength	550/600 nm	550 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C
Test Methodology	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the COBAS-Mira measures absorbance according to Beer's law.

Phosphorus - Inorganic		
Item	Device	Predicate
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Inorganic Phosphorous in human serum using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of Inorganic Phosphorous in human serum using the Roche Cobas-Mira chemistry analyzer.
Sample	Serum	Serum

Phosphorus - Inorganic		
Item	Device	Predicate
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	0.11 – 20 mg/dL	Up to 15 mg/dL
Wavelength	340 nm	340 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C
Test Methodology	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the COBAS-Mira measures absorbance according to Beer's law.

Iron		
Item	Device	Predicate
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Iron in human serum using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of Iron in human serum using the Roche Cobas-Mira chemistry analyzer.
Sample	Serum	Serum
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	4 – 750 mg/dL	Up to 500 mg/dL
Wavelength	600/700 nm	600 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C
Test Methodology	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the COBAS-Mira measures absorbance according to Beer's law.

Magnesium		
Item	Device	Predicate
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Magnesium in human serum using the	Clinical chemistry reagent used to provide a quantitative measurement of Magnesium in human serum using the Roche Cobas-Mira chemistry analyzer.

Magnesium		
Item	Device	Predicate
	EasyRA chemistry analyzer.	
Sample	Serum	Serum
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	0.03 – 6.1 mg/dL	Up to 6.1 mg/dL
Wavelength	520/600 nm	520/600 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C
Test Methodology	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	Non-enzymatic reaction based on the binding of the analyte to an organic/inorganic compound to produce a chromogen at endpoint. The chromogen absorbs light of specific wavelength, where the COBAS-Mira measures absorbance according to Beer's law.

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

Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- Second Edition (CLSI EP5-A2)

Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (CLSI EP6-A)

Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition (CLSI EP9-A2)

Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (CLSI EP17-A)

L. Test Principle:

EasyRA Bilirubin-Direct

This endpoint reaction is based on using a 2,4-dichlorophenyldiazonium salt as the diazo reagent:



Direct bilirubin (conjugated) binds with the diazo reagent to form azobilirubin. The increase in absorbance measured at 550 nm is proportional to the direct bilirubin concentration.

EasyRA Bilirubin-Total

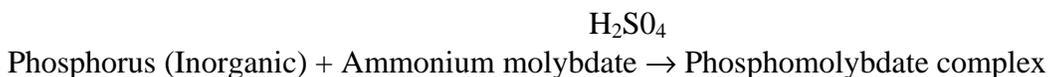
This endpoint reaction method measures total bilirubin (conjugated and unconjugated) binding to the 2,4-dichlorophenyldiazonium salt in the presence of surfactant to form azo-bilirubin.



The increase in absorbance at 550 nm is directly proportional to the Total Bilirubin concentration in the sample.

EasyRA Phosphorus-Inorganic

The 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.

EasyRA Iron

The Medica assay procedure uses a compound called 5,5'-(3-(2-pyridyl)-1,2,4-triazine-5,6 diyl)bis-2-furansulfonic acid, disodium (Ferene)[®]. Ferene[®] is an iron chelating agent that forms a tris complex with ferrous ions, has a higher molar absorptivity than ferrozine and is soluble and stable over the pH range of 4-9. In an acidic medium, the iron bound to the transferrin protein carrier dissociates into ferric ions, which are reduced in the presence of ascorbic acid to ferrous ions:



The ferrous ions then react with the chromogen Ferene[®] to form a blue chromophore:



The absorbance measured at 600 nm of this blue complex is directly proportional to the Iron concentration in the sample.

EasyRA Magnesium

This assay method employs the binding of xylidyl blue-1 dye to magnesium to form the Mg-xylidyl blue complex, according to the following equation:



The increase of absorbance of the red 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 Xylidyl blue-1 dye.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-Run and Total precision evaluations were determined following CLSI EP-A2. Three levels of commercial serum-based Quality Control material were tested on one EasyRA analyzer twice a day over a twenty-day period. In addition, a within-run precision study was performed in the extended measuring range to verify precision. One spiked sample in the extended measuring range was manually diluted and analyzed 20 times on a single EasyRA analyzer. The data summary is below.

EasyRA Bilirubin-Direct

	Level 1	Level 2	Level 3	Extended Measuring Range (10.1-20.0 mg/dL)
Mean (mg/dL)	0.20	1.31	2.47	14.47
Within Run Precision:				
Std. Dev.	0.01	0.02	0.04	0.07
CV %	5.49	1.83	1.59	0.57
Total Precision:				
Std. Dev.	0.01	0.02	0.05	
CV %	6.93	1.87	2.09	

EasyRA Bilirubin-Total

	Level 1	Level 2	Level 3	Extended Measuring Range (20.1-40 mg/dL)
Mean (mg/dL)	0.44	1.66	3.36	35.13
Within Run Precision:				
Std. Dev.	0.01	0.02	0.02	0.51
CV %	2.64	1.13	0.67	1.44
Total Precision:				
Std. Dev.	0.02	0.03	0.05	
CV %	3.81	2.09	1.35	

EasyRA Phosphorus-Inorganic

	Level 1	Level 2	Level 3	Extended Measuring Range (10.1-20.0 mg/dL)
Mean (mg/dL)	1.83	4.54	7.39	27.34
Within Run Precision:				
Std. Dev.	0.02	0.05	0.05	0.23
CV	1.03	1.01	0.68	0.84
Total Precision:				
Std. Dev.	0.04	0.16	0.15	
CV	1.94	3.55	2.10	

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EasyRA Iron

	Level 1	Level 2	Level 3	Extended Measuring Range (751-1,500 mcg/dL)
Mean (mcg/dL)	7.0	107	181	1,478
Within Run Precision:				
Std. Dev.	1.0	0.8	1.2	7.52
CV %	1.4	0.8	0.7	0.51
Total Precision:				
Std. Dev.	1.3	1.8	2.9	
CV %	1.8	1.7	1.6	

EasyRA Magnesium

	Level 1	Level 2	Level 3	Extended Measuring Range (6.2-12.2 mg/dL)
Mean (mg/dL)	1.23	2.34	4.45	8.32
Within Run Precision:				
Std. Dev.	0.03	0.04	0.08	0.19
CV %	2.83	1.83	1.81	2.31
Total Precision:				
Std. Dev.	0.07	0.08	0.13	
CV %	5.67	3.60	2.99	

b. *Linearity/assay reportable range:*

EasyRA Bilirubin-Direct

Linearity was evaluated using the guidelines provided in CLSI EP6-A. A Direct Bilirubin stock solution was prepared. Using the fresh stock solution, ten linearity standards were then prepared. These standards covered the target range from 0.05 mg/dL to 10.74 mg/dL. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial

regression. The third order model fit the data better than the linear and second order models. However, for all dilution points the relative differences between the linear and third order models were within $\pm 10\%$ or ± 0.1 mg/dL, whichever is greater. The results are summarized below.

Fitted regression models are:

$$\text{Linear: } y = 0.9801x + 0.0365$$

$$\text{Second order: } y = -0.0075x^2 + 1.0575x + 0.0482$$

$$\text{Third order: } y = -0.0027x^3 - 0.0351x^2 + 0.891x - 0.0444$$

The results demonstrate that the device is linear across the claimed measuring range of 0.06 mg/dL to 10.0 mg/dL.

The extended measuring range (10.1 mg/dL to 20.0 mg/dL) was evaluated with four standards with target values ranging from 11.0 mg/dL to 19.0 mg/dL for recovery with the Easy RA being compared to manual dilutions. Recoveries ranged from 99.3% to 100.3%.

EasyRA Bilirubin-Total

Linearity was evaluated using the guidelines provided in CLSI EP6-A. A Total Bilirubin stock solution was prepared gravimetrically. Linearity standards were then prepared by volumetric dilution in a saline solution. These standards covered the target range from 0.04 mg/dL to 21.97 mg/dL. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression. The third order model fit the data better than the linear and second order models. However, for all dilution points the relative differences between the linear and third order models were within $\pm 10\%$ (or an absolute specification of 0.2 mg/dL below 1 mg/dL). The results are summarized below.

Fitted regression models are:

$$\text{Linear: } y = 0.9799x + 0.0921, R^2 = 0.9998$$

$$\text{Second order: } y = -0.0011x^2 + 1.0014x + 0.0551, R^2 = 0.9999$$

$$\text{Third order: } y = 6E-05x^3 - 0.0028x^2 + 1.015x + 0.0448, R^2 = 0.9999$$

The results demonstrate that the device is linear across the claimed measuring range of 0.08 mg/dL to 20.0 mg/dL.

The extended measuring range (20.1 mg/dL to 40.0 mg/dL) was evaluated with four standards with target values ranging from 24.3 mg/dL to 39.0 mg/dL for recovery with the Easy RA being compared to manual dilutions. Recoveries ranged from 97.6% to 102.4%.

EasyRA Phosphorus-Inorganic

Commercially available standards ranging in value from 0.1 mg/dL to 21.0 mg/dL were used for the study. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression. The second order regression was the best fit, however, comparison of the first and second order equations demonstrated that the relative differences between the first and second order models were within $\pm 7.5\%$ or ± 0.34 mg/dL, whichever is greater. The results are summarized below.

Fitted regression models are:

$$\text{Linear: } y = 1.0567x - 0.2576, R^2 = 0.9989$$

$$\text{Second order: } y = 0.0051x^2 + 0.9533x + 0.0141, R^2 = 0.9998$$

$$\text{Third order: } y = 4E-05x^3 + 0.0039x^2 + 0.9622x + 0.0047, R^2 = 0.9998$$

The results demonstrate that the device is linear across the claimed measuring range of 0.11 mg/dL to 20.0 mg/dL.

The extended measuring range (20.1 mg/dL to 40.0 mg/dL) was evaluated with three standards with target values ranging from 25 mg/dL to 35 mg/dL for recovery with the Easy RA being compared to manual dilutions. Recoveries ranged from 97.1% to 98.8%.

EasyRA Iron

Twelve linearity standards were prepared covering the target range of 0 – 1000 mcg/dL. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression. The third order regression demonstrated the best fit based on the smallest standard error of estimate. For all dilution points the relative differences between the linear and third order models were within $\pm 10\%$ (or, below the medical decision point of 150 $\mu\text{g/dL}$, an absolute specification of 15 mcg/dL). The results are summarized below.

Fitted regression models are:

$$\text{Linear: } y = 1.0125x + 0.02697, R^2 = 0.9993$$

$$\text{Second order: } y = 4E-05x^2 + 0.9781x + 1.9776, R^2 = 0.9994$$

$$\text{Third order: } y = 3E-07x^3 + 0.0004x^2 + 1.1141x - 1.7113, R^2 = 0.99967$$

The results demonstrate that the device is linear across the claimed measuring range of 4 mcg/dL to 750 mcg/dL.

The extended measuring range (751 mcg/dL to 1500 mcg/dL) was evaluated with four standards with target values ranging from 1,178 mcg/dL to 1918

mcg/dL for recovery with the Easy RA being compared to manual dilutions. Recoveries ranged from 100.0% to 100.9%.

EasyRA Magnesium

Six commercially available standards ranging in value from 0.03 mg/dL to 6.1 mg/dL were used for the study. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression. The first order regression was the best fit based on smallest standard error of estimate. For all dilution points the relative differences between the linear and third order models were within $\pm 12.5\%$ or ± 0.25 mg/dL, whichever is greater. The results are summarized below.

Fitted regression models are:

Linear: $y = 1.0505x - 0.0033$, $R^2 = 0.9997$

Second order: $y = -0.0002x^2 + 1.0517x - 0.0042$, $R^2 = 0.9997$

Third order: $y = 0.0014x^3 - 0.0134x^2 + 1.0814x - 0.0127$,
 $R^2 = 0.9997$

The results demonstrate that the device is linear across the claimed measuring range of 0.03 mg/dL to 6.1 mg/dL.

The extended measuring range (6.2 mg/dL to 12.2 mg/dL) was evaluated with standards target values ranging from 7.2 mg/dL to 10.9 mg/dL for recovery with the Easy RA being compared to manual dilutions. Recoveries ranged from 101.3% to 102.5%.

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

Calibrators and controls are sold separately.

The sponsor performed stability studies at 2°C to 8°C and found them to be adequate for Direct Bilirubin, Total Bilirubin, Phosphorus-Inorganic, Iron and Magnesium. Accelerated stability studies were performed by the sponsor to verify stability in the sponsor's reagent containers. The control recovery for two levels of QC material and the linearity data met the sponsor's acceptance criteria of 95%-105% for recovery and slope of 0.95-1.05, $r > 0.95$ for linearity.

The sponsor also performed on-board stability studies and calibration frequency studies for the various assays and the conclusions are below. This information is included in the labeling.

Assay	On-board Stability (days)	Calibration Frequency (days)
Direct Bilirubin	28	28
Total Bilirubin	28	7
Phosphorus-Inorganic	30	30
Iron	26	26
Magnesium	7	3

d. *Detection limit:*

The sponsor followed the recommendations in CLSI EP-17A for establishing the Limits of Blank (LoB), Limits of Detection (LoD), and Limits of Quantitation (LoQ). The results are summarized below:

Device	Measuring Range	LoB	LoD	LoQ
Direct Bilirubin	0.06-10.0 mg/dL	0.04 mg/dL	0.06 mg/dL	0.06 mg/dL
Total Bilirubin	0.08-20.0 mg/dL	0.02 mg/dL	0.04 mg/dL	0.05 mg/dL
Phosphorus - Inorganic	0.11-20.0 mg/dL	0.04 mg/dL	0.09 mg/dL	Not done
Iron	4-750 mcg/dL	0.09 mcg/dL	1.27 mcg/dL	1.29 mcg/dL
Magnesium	0.03-6.1 mg/dL	0.01 mg/dL	0.03 mg/dL	Not done

e. *Analytical specificity:*

EasyRA Bilirubin-Direct

Endogenous Interferences:

Testing for interfering substances was based on CLSI EP-7A. Testing was performed on a minimum of two concentrations for each analyte. Samples with increasing amounts of hemoglobin, bilirubin or triglycerides (Intralipid®) were tested on these samples and compared to the same sample without the interferent, unless otherwise noted.

The sponsor defined interference as the highest level tested that does not cause > 10% change in analytical result.

The sponsor determined that there is significant interference from hemolysis and lipemia for DBil and TBil and significant interference from hemolysis for Iron. The labeling for DBil and TBil contains precautionary language that

hemolyzed or lipemic samples should not be used. The labeling for Iron contains precautionary language that hemolyzed samples should not be used. See the table below for a summary of endogenous interference levels not previously described.

	No interference up to:
Inorganic Phosphorus	
Hemoglobin	500 mg/dL
Triglyceride	1,740 mg/dL
Bilirubin	25 mg/dL
Iron	
Triglyceride	1,200 mg/dL
Bilirubin	25 mg/dL
Magnesium	
Hemoglobin	500 mg/dL
Triglyceride	500 mg/dL
Bilirubin	25 mg/dL

Exogenous Interference

The sponsor did not perform any studies to investigate the effect of exogenous substances such as pharmaceuticals; however a literature reference is included to alert users that these potential interferences should be checked.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Studies were performed using CLSI EP9-A2 as a guide.

EasyRA Bilirubin-Direct

A method comparison was performed with the Medica EasyRA Bilirubin-Direct test system and the Roche Direct Bilirubin reagent on the COBAS MIRA test system. A total of 41 samples were tested across the range of the assay (0.07 mg/dL to 9.32 mg/dL). Of these 41 samples, 36 were native samples and 5 were diluted to create low level samples. The comparison resulted in a slope of 0.9440, an intercept of 0.0179, and a correlation coefficient of $R^2 = 0.998$.

EasyRA Bilirubin-Total

A method comparison was performed with the Medica EasyRA Bilirubin-Total test system and the Roche Total Bilirubin reagent on the COBAS MIRA test system. A total of 67 samples were tested across the range of the assay (0.08 mg/dL to 19.88 mg/dL). Of these 65 samples, 60 were native samples and 5 were diluted to create low level samples. The comparison resulted in a slope of 1.0041, an intercept of -0.1940, and a correlation coefficient of $R^2 = 0.9958$.

EasyRA Phosphorus-Inorganic

A method comparison was performed with the Medica EasyRA Phosphorus-Inorganic test system and the Roche Inorganic Phosphorus reagent on the COBAS MIRA test system. A total of 46 samples were tested across the range of the assay (0.2 mg/dL to 19.67 mg/dL). Of these 46 samples, 41 were native samples and 5 were spiked or diluted to span the measuring range. The comparison resulted in a slope of 0.9802, an intercept of 0.0058, and a correlation coefficient of $R^2 = 0.9927$, std. error of 0.3258.

EasyRA Iron

A method comparison was performed with the Medica EasyRA Iron test system and the Roche Iron reagent on the COBAS MIRA test system. A total of 48 samples were tested across the range of the assay (4 mcg/dL to 742 mcg/dL). Of these 48 samples, 38 were native samples and 10 were spiked or diluted to span the measuring range. The comparison resulted in a slope of 1.0849, an intercept of -1.0616., and a correlation coefficient of $R^2 = 0.9986$., std. error of 6.6153.

EasyRA Magnesium

A method comparison was performed with the Medica EasyRA Magnesium test system and the DCL reagent on the COBAS MIRA test system. A total of 42 samples were tested across the range of the assay (0.07 mg/dL to 5.50 mg/dL). Of these 42 samples, 37 were native samples and 5 were spiked or diluted to span the measuring range. The comparison resulted in a slope of 0.9183, an intercept of 0.2239, and a correlation coefficient of $R^2 = 0.9924$, std. error of 0.1159.

b. Matrix comparison:

Not applicable. The sponsor is only claiming serum for the Easy RA Bilirubin-Direct, Easy RA Bilirubin-Total, Easy RA Phosphorus-Inorganic, Easy RA Iron, and Easy RA Magnesium.

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:

EasyRA Bilirubin-Direct: Adult: 0.0 – 0.20 mg/dL (0.0 – 3.4 micmol/L)

EasyRA Bilirubin-Total: Adult: 0.2-1.0 mg/dL

EasyRA Phosphorus-Inorganic: Adult: 2.5-4.8 mg/dL

EasyRA Iron Male: 65-170 mcg/dL, Female: 50-170 mcg/dL

EasyRA Magnesium Adult: 1.6-2.6 mg/dL

The reference for Direct and Total Bilirubin, Phosphorus and Iron expected values is: Burtis, C.A. and Ashwood, E.R. (Eds), Tietz Textbook of Clinical Chemistry, 2nd edition, W.B. Saunders Co., Philadelphia (1994).

Magnesium expected values are cited in Tietz NW. Editor, *Clinical Guide to Laboratory Tests* WB Saunders and Co., Philadelphia, PA, (1983) 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.