

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

A. 510(k) Number:

k080823

B. Purpose for Submission:

New device

C. Measurand:

Amylase, Blood Urea Nitrogen (BUN), Glucose, Triglyceride, Uric Acid

D. Type of Test:

Amylase-enzymatic reaction
Blood Urea Nitrogen (BUN)-kinetic reaction
Glucose-enzymatic reaction
Triglyceride-enzymatic reaction
Uric acid

E. Applicant:

Medica Corporation

F. Proprietary and Established Names:

EasyRA Amylase Reagent
EasyRA Blood Urea Nitrogen (BUN) Reagent
EasyRA Glucose-Hexokinase Reagent
EasyRA Triglyceride Reagent
EasyRA Uric Acid Reagent

G. Regulatory Information:

Device Classification Name	Device Classification	Regulation Number	Product Code	Panel
Amylase	Class II	21 CFR 862.1070	JFJ	Chemistry (75)
Urea Nitrogen	Class II	21 CFR 862.1770	CDQ	Chemistry (75)
Hexokinase, glucose	Class II	21 CFR 862.1345	CFR	Chemistry (75)
Triglyceride	Class I *	21 CFR 862.1705	CDT	Chemistry (75)
Uric acid	Class I, reserved	21 CFR 862.1775	KNK	Chemistry (75)

*Meets limitations to exemption in 21 CFR 862.9(c)(4)

H. Intended Use:

1. Intended use(s):

EasyRA Amylase Reagent

The EasyRA amylase Reagent (AMY) is for the measurement of α -Amylase in serum using the “EasyRA chemistry analyzer”. Amylase measurements are used for the diagnosis and treatment of pancreatitis (inflammation of the pancreas) and other pancreatic disorders. For *in vitro* diagnostic use only.

EasyRA Blood Urea Nitrogen (BUN) Reagent

The EasyRA Blood Urea Nitrogen (BUN) Reagent is for the measurement of urea in serum using the “EasyRA chemistry analyzer”. Urea measurements in serum are used for the diagnosis and treatment of certain renal and metabolic diseases. For *in vitro* diagnostic use only.

EasyRA Glucose-Hexokinase Reagent

The EasyRA Glucose hexokinase (GLU-H) Reagent is for the measurement of glucose in serum using the “EasyRA chemistry analyzer”. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and pancreatic islet cell carcinoma. . For *in vitro* diagnostic use only.

EasyRA Triglyceride Reagent

The EasyRA Triglyceride (TRIG) Reagent is for the measurement of triglycerides in serum using the “EasyRA chemistry analyzer”. Triglyceride measurements are used in the diagnosis and treatment of diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism or various endocrine disorders. For *in vitro* diagnostic use only.

EasyRA Uric Acid Reagent

The EasyRA Uric Acid (URIC) Reagent is for the measurement of uric acid in serum using the “EasyRA chemistry analyzer”. Uric Acid measurements are used in the diagnosis and treatment of renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. For *in vitro* diagnostic use only.

2. Indication(s) for use:

See intended use(s) above.

3. Special conditions for use statement(s):

For prescription use.

4. Special instrument requirements:

Medica EasyRA chemistry analyzer

I. Device Description:

The EasyRA Amylase test is provided in 4 ready-to-use plastic wedges, each containing 39 mL of reagent. The reagent consists of a MES buffer with 2-chloro-4-nitrophenol- α -D-maltotrioxide (CNP3), sodium chloride, sodium acetate, calcium acetate, potassium thiocyanate, and sodium azide.

The EasyRA BUN test is provided in 4 ready-to-use plastic wedges, each containing 39 mL of reagent. The reagent consists of buffer with alpha-ketoglutarate, urease, glutamate dehydrogenase, adenosine diphosphate, NADH analog, stabilizers and preservatives.

The EasyRA Glucose test is provided in 4 ready-to-use plastic wedges, each containing 39 mL of reagent. The reagent consists of buffer, nicotinamide adenine dinucleotide (NAD), adenosine triphosphate (ATP), magnesium, hexokinase, glucose-6-phosphate dehydrogenase, stabilizers, and preservatives.

The EasyRA Triglycerides test is provided in 4 ready-to-use plastic wedges, each containing 37 mL of reagent. The reagent consists of buffer, magnesium (Mg^{++}), p-chlorophenol, ATP, 4-aminoantipyrine, lipoprotein lipase, glycerol kinase, G-3-P oxidase, horseradish peroxidase, stabilizers and preservatives.

The EasyRA Uric Acid test is provided in 4 ready-to-use plastic wedges, each containing 37 mL of reagent. The reagent consists of 3,5-dichloro-2-hydroxybenzene sulfonate (DHBS), 4-aminoantipyrine, horseradish peroxidase, uricase, stabilizers and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Diagnostics α –Amylase Reagent
Roche Diagnostics BUN Reagent
Roche Diagnostics Glucose Reagent
Roche Diagnostics Triglycerides Reagent
Roche Diagnostics Uric Acid Reagent

2. Predicate K number(s):

k933397, k011843, k002694, k961282, k961281, k961586

3. Comparison with predicate:

Amylase Similarities and Differences		
Item	Medica Amylase Reagent	Roche α –Amylase Reagent
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of amylase in human serum, using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of amylase in human serum, using an automated chemical analyzer
Test Methodology	An enzymatic reaction based on the catalytic activity of a serum based enzyme, which is quantified by monitoring the reaction rate. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	An enzymatic reaction based on the catalytic activity of a serum based enzyme, which is quantified by monitoring the reaction rate. The chromogen absorbs light of specific wavelength, where the 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	2 – 1200 U/L	Up to 2000 U/L
Wavelength	405 nm	405 nm
Reaction type	Enzyme	Enzyme

BUN Similarities and Differences		
Item	Medica EasyRA BUN	Roche BUN Reagent
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of urea in human serum, using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of urea in human serum, using an automated chemical analyzer
Test Methodology	An enzymatic reaction of Urea to L-glutamate with the concurrent reduction of NADH to NAD. The rate of change in absorption of the NADH chromogen is monitored with time on the EasyRA to establish the amount of urea	An enzymatic reaction of Urea to L-glutamate with the concurrent reduction of NADH to NAD. The rate of change in absorption of the NADH chromogen is monitored with time on the Cobas-

BUN Similarities and Differences		
Item	Medica EasyRA BUN	Roche BUN Reagent
	present.	Mira to establish the amount of urea present.
Sample type	Serum	Serum
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	1.0 – 70.0 mg/dL	Up to 80 mg/dL
Wavelength	340 nm	340 nm
Reaction type	Kinetic	Kinetic
Reagent storage	2 – 8 °C	2 – 8 °C

Glucose Similarities and Differences		
Item	Medica EasyRA Glu	Roche Glucose Reagent
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of Glucose in human serum, using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of Glucose in human serum, using an automated chemical analyzer
Test Methodology	An enzymatic reaction based on the complete oxidation of glucose in serum and the simultaneous reduction on NAD to NADH (chromogen). The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	An enzymatic reaction based on the complete oxidation of glucose in serum and the simultaneous reduction on NAD to NADH (chromogen). The chromogen absorbs light of specific wavelength, where the 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	2 – 600 mg/dL	Up to 800 mg/dL
Wavelength	340 nm	340 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C

Triglycerides Similarities and Differences		
Item	Medica EasyRA Trig	Roche Triglycerides
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of triglycerides in human serum, using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of triglycerides in human serum, using an automated chemical analyzer
Test Methodology	An enzymatic reaction based on the catalytic activity of a serum based enzyme, which is quantified by monitoring the reaction rate. The chromogen absorbs light of specific wavelength, where the EasyRA measures absorbance according to Beer's law.	An enzymatic reaction based on the catalytic activity of a serum based enzyme, which is quantified by monitoring the reaction rate. The chromogen absorbs light of specific wavelength, where the 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	3 – 750 mg/dL	Up to 900 mg/dL
Wavelength	520/700 nm	550 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C

Uric Acid Similarities and Differences		
Item	Medica Easy RA Uric Acid	Roche Uric Acid
Intended Use	Clinical chemistry reagent used to provide a quantitative measurement of uric acid in human serum, using the EasyRA chemistry analyzer.	Clinical chemistry reagent used to provide a quantitative measurement of uric acid in human serum, using an automated chemical analyzer
Test Methodology	An enzymatic reaction based on the oxidation of Uric Acid to produce hydrogen peroxide in the presence of uricase. The H ₂ O ₂ is further reduced to produce a chromogen. The chromogen absorption is	An enzymatic reaction based on the oxidation of Uric Acid to produce hydrogen peroxide in the presence of uricase. The H ₂ O ₂ is further

Uric Acid Similarities and Differences		
Item	Medica Easy RA Uric Acid	Roche Uric Acid
	measured by the EasyRA and is directly related to the Uric Acid concentration using Beer's Law.	reduced to produce a chromogen. The chromogen absorption is measured by the Cobas-Mira and is directly related to the Uric Acid using Beer's Law.
Reagent type	Liquid ready-for-use	Liquid ready-for-use
Linearity range	0.11 – 12 mg/dL	Up to 20 mg/dL
Wavelength	520/600 nm	550 nm
Reaction type	End point	End point
Reagent storage	2 – 8 °C	2 – 8 °C

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

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)

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

L. Test Principle:

The Medica EasyRA Amylase test involves the use of a chromogenic substrate, 2-chloro-4-nitrophenol- α -D-maltotrioxide (CNP3G3). The rate of hydrolysis of CNP3G3 by α -amylase to release 2-Chloro-4-nitrophenol can be detected spectrophotometrically to give a direct measurement of α -amylase activity in the sample.

For the Medica EasyRA BUN test, urea in the sample is first hydrolyzed by urease to give ammonia and carbon dioxide. The ammonia produced reacts with 2-oxoglutarate and stabilized NADH analog in the presence of glutamate dehydrogenase (GLDH) to form glutamate and NAD (II). The decrease in the concentration of the reduced cofactor (NADH), monitored at 340 nm is proportional to the concentration of the Urea in the sample.

For the Medica EasyRA GLU-H test, glucose is phosphorylated to form glucose-6-phosphate (G-6-P). G-6-P is then oxidized by glucose-6-phosphate dehydrogenase in the presence of NAD producing 6-phosphogluconate and NADH. The formation of

NADH causes an increase in absorbance at 340 nm, which is proportional to the concentration of the glucose in the sample.

For the Medica EasyRA TRIG test, serum triglycerides are hydrolyzed to glycerol and free fatty acids by lipase. In the presence of ATP and glycerol kinase (GK), the glycerol is phosphorylated to glycerol-1-phosphate, which is then oxidized by glycerol phosphate oxidase (GPO) to produce hydrogen peroxide. The hydrogen peroxide causes oxidative coupling of p-chlorophenol and 4 amino-antipyrine, which produces a red colored quinoneimine dye complex. The absorbance of the dye at 520 nm is proportional to the concentration of triglyceride in the sample.

For the Medica EasyRA Uric acid test, hydrogen peroxide is formed by the action of uricase on uric acid. The hydrogen peroxide is then reacted with 3,5-dichloro-2-hydroxybenzene sulfonate (DHBS) and 4-aminoantipyrine forming a red colored quinoneimine dye, with maximum absorbance at 520 nm.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within Run and Total precision 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. The data is summarized below.

Additionally, to verify precision in the extended measuring range of each test (see section 1.b. below), one sample was diluted 1:2 with saline on board the analyzer and assayed twenty times (n=20) in one assay run.

Amylase				
	Level 1	Level 2	Level 3	Diluted
Mean (U/L)	45	85	296	1781
Within Run Precision:				
Std. Dev.	0.8	0.7	1.9	
CV %	1.8	0.8	0.6	0.9
Total Precision:				
Std. Dev.	0.9	0.9	2.9	
CV%	1.9	1.1	1.0	

BUN

	Level 1	Level 2	Level 3	Diluted
Mean (mg/dL)	15.2	21.3	55.0	96.2
Within Run Precision:				
Std. Dev.	0.19	0.33	0.41	
CV%	1.28	1.55	0.74	1.4
Total Precision:				
Std. Dev.	0.29	0.39	0.68	
CV%	1.93	1.90	1.24	

Glucose Hexokinase

	Level 1	Level 2	Level 3	Diluted
Mean (mg/dL)	61	111	270	805
Within Run Precision:				
Std. Dev.	0.7	0.7	1.1	
CV%	1.1	0.6	0.4	1.98
Total Precision:				
Std. Dev.	0.9	1.5	2.6	
CV%	1.5	1.4	1.0	

Triglycerides

	Level 1	Level 2	Level 3	Diluted
Mean (mg/dL)	78	90	252	1324
Within Run Precision:				
Std. Dev.	0.7	0.6	1.3	
CV%	0.9	0.6	0.5	1.98
Total Precision:				
Std. Dev.	1.6	1.0	2.8	
CV%	2.0	1.2	1.1	

Uric Acid

	Level 1	Level 2	Level 3	Diluted
Mean (mg/dL)	4.37	4.16	9.70	31.9
Within Run Precision:				
Std. Dev.	0.04	0.05	0.07	
CV%	0.94	1.30	0.70	0.51
Total Precision:				
Std. Dev.	0.19	0.18	0.23	
CV%	4.36	4.36	2.35	

b. *Linearity/assay reportable range:*

Linearity studies were performed following the CLSI protocol EP6-A. Commercially available linearity standards were used unless noted otherwise.

Amylase

For the Amylase assay, the concentrations of samples tested ranged from 1 to 1360 U/L. 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 $\pm 15\%$ or below the medical decision point of 100 U/L ± 15 U/L. The results are summarized below.

Fitted regression models are:

Linear: $y = 1.0007x + 1.2297$, *Std. Error*=16.487

Second order: $y = 2E-05x^2 + 0.9733x + 4.0426$, *Std. Error* 16.559

Third order: $y = 1E-07x^3 - 0.0002x^2 + 1.0785x - 0.1589$,
Std. Error=15.434

The results of this study support the sponsor's claim that the device is linear from 2 U/L to 1200 U/L.

The extended measuring range (1201 to 2400 U/L) was evaluated with four standards with target values ranging from 1100 to 2400 U/L. Recovery with the Easy RA on-board dilution was compared to manual dilutions. Recoveries ranged from 99% to 103%.

BUN

For the BUN assay, the concentrations of samples tested ranged from 0.9 to 73.7 mg/dL. A BUN stock solution was prepared gravimetrically from commercially available material. Dilutions of varying BUN concentration were then prepared using saline and tested. 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 first and third order models were within $\pm 4.5\%$ or ± 1.22 mg/dL at or below the medical decision point of 27 mg/dL. The results are summarized below.

Fitted regression models are:

Linear: $y = 0.9593x + 0.5657$, *Std. Error*=0.715

Second order: $y = -0.0011x^2 + 1.0329x + 0.0669$, *Std. Error*=0.494

Third order: $y = -1E-05x^3 - 0.0004x^2 + 0.9923x - 0.2103$,
Std. Error=0.493

The results of this study support the sponsor's claim that the device is linear from 1 mg/dL to 70 mg/dL.

The extended measuring range (71 to 140 mg/dL) was evaluated with four standards with values ranging from 90 to 130 mg/dL. Recovery with the Easy RA on-board dilution was compared to manual dilutions. Recoveries ranged from 99% to 102%.

Glucose-hexokinase

For the Glucose assay, the concentrations of samples tested ranged from 2 to 716 mg/dL. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression; however, the first order regression had the best fit. The analysis yielded the following equation:

$$\text{Linear: } y = 0.9898 x + 1.39, \text{ Std. Error}=3.451$$

The results of this study support the sponsor's claim that the device is linear from 2 mg/dL to 600 mg/dL.

The extended measuring range (601 to 1200 mg/dL) was evaluated with three standards with values ranging from 675 to 1062 mg/dL. Recovery with the Easy RA on-board dilution was compared to manual dilutions. Recoveries ranged from 98% to 99%.

Triglycerides

For the Triglycerides assay, the concentrations of samples tested ranged from 2 to 852 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 first and third order models were within $\pm 12.5\%$ or ± 20 mg/dL below the medical decision point of 160 mg/dL. The results are summarized below.

Fitted regression models are:

$$\text{Linear: } y = 0.9794 x + 2.085, \text{ Std. Error}=4.094$$

$$\text{Second order: } y = -7E-05x^2 + 1.03 x - 1.6287, \text{ Std. Error}=1.825$$

$$\text{Third order: } y = -6E-08x^3 - 8E-06 x^2 + 1.007 x - 0.9432, \\ \text{Std. Error}= 1.651$$

The results of this study support the sponsor's claim that the device is linear from 3 mg/dL to 750 mg/dL.

The extended measuring range (751 to 1400 mg/dL) was evaluated with three standards with values ranging from 798 to 1228 mg/dL. Recovery with the Easy RA on-board dilution was compared to manual dilutions. Recoveries ranged from 101-102%.

Uric Acid

For the uric acid assay, the concentrations of samples tested ranged from 0.11 to 23.46 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 first and third order models were within $\pm 8.5\%$ or ± 0.51 mg/dL, whichever is greater. The results are summarized below.

Fitted regression models are:

Linear: $y = 1.0336x - 0.173$, *Std. Error*=0.279

Second order: $y = 0.005x^2 + 0.9246x + 0.0315$, *Std. Error*=0.093

Third order: $y = -0.0002x^3 + 0.0017x^2 + 0.867x + 0.0827$,
Std. Error=0.076

The results of this study support a claimed assay range of 0.11 to 12 mg/dL.

The extended measuring range (12 to 24 mg/dL) was evaluated with two standards with values 19.6 and 25 mg/dL. Recovery with the Easy RA on-board dilution was compared to manual dilutions. Recoveries were 98% for each standard tested.

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

Calibrators and controls were reviewed under a separate 510(k) and are sold separately.

d. Detection limit:

To determine the limit of blank (LoB) for each EasyRA test (Amylase, BUN, Glucose, Triglyceride, Uric Acid) deionized water was assayed twenty (20) times on each of three Easy RA analyzers for a total of sixty (60) replicates. The data were analyzed following the recommendations in CLSI EP 17.

To determine the limit of detection (LoD) for each test a serum sample with low analyte concentration was prepared and analyzed 20 times on each of three EasyRA analyzers.

The results for LoB and LoD are summarized in the following table:

Device	LoB	LoD
Amylase	0.78 U/L	1.04 U/L
BUN	0.68 mg/dL	1.0 mg/dL
Glucose	0.56 mg/dL	1.0 mg/dL
Triglycerides	1.35 mg/dL	2.16 mg/dL
Uric Acid	0.065 mg/dL	0.11 mg/dL

e. *Analytical specificity:*

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

Studies to evaluate potential lipid interference in the Glu-H test were performed using LipoClear lipid clearing reagent.

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

The results are summarized in the table below.

	Analyte level tested	No interference up to
Amylase		
Hemoglobin	68 U/L, 92 U/L	125 mg/dL
Triglyceride	57 U/L, 97 U/L	1374 mg/dL
Bilirubin	86 U/L, 93 U/L	25 mg/dL
BUN		
Hemoglobin	16.2 mg/dL, 28 mg/dL	300 mg/dL
Triglyceride	18.1 mg/dL, 31.6 mg/dL	811 mg/dL
Bilirubin	19.6 mg/dL, 30 mg/dL	20 mg/dL
Glu-H		
Hemoglobin	42 mg/dL, 94 mg/dL	31 mg/dL
Triglyceride	150 mg/dL, 250 mg/dL	450mg/dL
Bilirubin	45 mg/dL, 82 mg/dL	10 mg/dL

Triglycerides		
Hemoglobin	136 mg/dL, 149 mg/dL	500 mg/dL
Bilirubin	122 mg/dL, 298 mg/dL	5.5 mg/dL
Uric Acid		
Hemoglobin	3.35 mg/dL, 5.53 mg/dL	52 mg/dL
Triglyceride	3.84 mg/dL, 5.8 mg/dL	400 mg/dL
Bilirubin	2.24 mg/dL, 4.82 mg/dL	25 mg/dL

The labeling for all tests contains precautionary language that hemolyzed samples should not be used. For glucose and triglycerides, there is an additional warning that icteric samples should not be used.

The sponsor did not perform any studies to investigate the effect of exogenous substances however a literature reference is included to alert users that potential interferences from substances such as common over-the-counter and prescription pharmaceuticals should be checked.

The sponsor cites the following references for exogenous interference in the labeling.

Young DS. *Effects of Drugs on Clinical Laboratory Tests* 4th ed. Washington, DC: AACC Press; 1995.

Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 2nd ed. Washington, DC. AACC Press; 1997.

- 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.

Amylase

A total of 99 serum samples were tested with the Medica EasyRA amylase test system and with the Roche Amylase reagent on the COBAS MIRA test system. Of these sera, seven (7) were either spiked with amylase to create samples with high amylase concentration or diluted to create low level samples. Samples ranged in value from 2 to 1150 U/L amylase and were tested in singlicate on the Medica test system and in duplicate on the Roche test system. The comparison resulted in a slope of 1.025, an intercept of 6.11, and a correlation coefficient of $R^2 = 0.996$.

BUN

A total of 60 serum samples were tested with the Medica EasyRA BUN test system and with the Roche BUN reagent on the COBAS MIRA test system. Of these sera, three (3) were spiked with BUN to create samples with high BUN concentration. Samples ranged in value from 5.4 to 65.5 mg/dL BUN and were tested in singlicate on the Medica test system and in duplicate on the Roche test system. The comparison resulted in a slope of 1.04, an intercept of 1.04, and a correlation coefficient of $R^2 = 0.995$.

Glucose

A total of 60 serum samples were tested with the Medica EasyRA Glu-H test system and with the Roche Glu-H reagent on the COBAS MIRA test system. Of these sera three (3) were either spiked with glucose to create samples with high glucose concentration or diluted. Samples ranged in value from 3 to 579 mg/dL and were tested in singlicate on the Medica test system and in duplicate on the Roche test system. The comparison resulted in a slope of 0.999, an intercept of -4.02, and a correlation coefficient of $R^2 = 0.997$.

Triglycerides

A total of 60 serum samples were tested with the Medica EasyRA Triglycerides test system and with the Roche Triglycerides reagent on the COBAS MIRA test system. Of these sera three (3) were spiked to create samples with high triglycerides concentration. Samples ranged in value from 3 to 726 mg/dL and were tested in singlicate on the Medica test system and in duplicate on the Roche test system. The comparison resulted in a slope of 0.994, an intercept of 8.01, and a correlation coefficient of $R^2 = 0.998$.

Uric Acid

A total of 48 serum samples were tested with the Medica EasyRA Uric Acid test system and with the Roche Uric Acid reagent on the COBAS MIRA test system. Of these sera five (5) were spiked to create samples with high uric acid concentration. Samples ranged in value from 1.49 to 12 mg/dL and were tested in singlicate on the Medica test system and in duplicate on the Roche test system. The comparison resulted in a slope of 1.04, an intercept of -0.19, and a correlation coefficient of $R^2 = 0.991$.

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:

The following reference is listed in the package insert: Tietz NW. *Textbook of Clinical Chemistry*, 3rd ed. WB Saunders and Co., Philadelphia, PA, p. 831-832 (1994).

Reference ranges for analytes in this review are as follows:

	<u>Normal Range</u>
Amylase	25-94 U/L
BUN	11-37 mg/dL
Glucose	70-105 mg/dL
Triglycerides	40-160 mg/dL (Men) 35-135 mg/dL (Women)
Uric Acid	3.5-7.2 mg/dL (Men) 2.6-6.0 mg/dL (Women)

The labeling contains recommendations that each laboratory should establish their own range of expected values.

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.