September 21, 2021

Medicon Hellas, S.A.
Sotia Mitropoulos
Regulatory Manager
Melitona 5-7, 153 44, Gerakas, Greece

Re: K200898
Trade/Device Name: Medicon Hellas Albumin, Medicon Hellas Calcium, Medicon Hellas Creatinine, Medicon Hellas Direct Bilirubin, Medicon Hellas Glucose, Medicon Hellas Total Bilirubin, Medicon Hellas Urea Nitrogen
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Code: CIX, CDQ, CJY, CGX, CIG, CFR
Dated: February 24, 2021
Received: February 24, 2021

Dear Sotia Mitropoulos:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k200898

Device Name
Medicon Hellas Albumin, Medicon Hellas Calcium, Medicon Hellas Creatinine, Medicon Hellas Glucose, Medicon Hellas Total Bilirubin, Medicon Hellas Direct Bilirubin and Medicon Hellas Urea Nitrogen.

Indications for Use *(Describe)*
Medicon Hellas Albumin: Reagent for the quantitative measurement of albumin in serum. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Medicon Hellas Calcium: Reagent for the quantitative measurement of calcium in serum or urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Medicon Hellas Creatinine: Reagent for the quantitative measurement of creatinine in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

Medicon Hellas Glucose: Reagent for the quantitative measurement of glucose in serum and urine. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Medicon Hellas Direct Bilirubin; Reagent for the quantitative measurement of direct bilirubin (conjugated) in serum. Measurements of the level of direct bilirubin is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall blader block.

Medicon Hellas Total Bilirubin; Reagent for the quantitative measurements of total bilirubin in serum. Measurements of the levels of total bilirubin is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

Medicon Hellas Urea Nitrogen: Reagent for the quantitative measurement of urea nitrogen in serum and urine. Measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

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) Summary

This summary of 510k (k200898) safety and effectiveness information is re-submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

807.92 (a)(1): Name: **MEDICON HELLAS S.A.**
Address: **Melitona 5-7, 153 44 Gerakas, Greece**

Phone: +302.1.0660.6000
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Contact: Ms. Sotia Mitropoulos
Email: mitropoulos@mediconsa.com

US Agent: **Diatron US, Inc.**
1.833.228.7931
Mr. Frank Matuszak
frank.matuszak@diatron.com

807.92 (a)(2): Device name- trade name and common name, and classification

Trade Name: Medicon Hellas Albumin, Medicon Hellas Calcium, Medicon Hellas Creatinine, Medicon Hellas Glucose, Medicon Hellas Direct Bilirubin, Medicon Hellas Total Bilirubin, and Medicon Hellas Urea Nitrogen, for use with Diatron Pictus 500 Clinical Chemistry Analyzers.

Common Name: test systems for albumin, calcium, creatinine, glucose, direct and total bilirubin and urea nitrogen for testing human serum and urine where clinically applicable.

Classification Name(s):

21 CFR § 862.1035 - Albumin Test system - Class II- Product Code CIX

21 CFR § 862.1145 - Calcium Test system - Class II- Product Code CJY

21 CFR § 862.1225 - Creatinine Test system - Class II- Product Code CGX

21 CFR § 862.1110 - Direct Bilirubin Test system - Class II- Product Code CIG

21 CFR § 862.1345 - Glucose Test system - Class II- Product Code CFR

21 CFR § 862.1110 - Total Bilirubin Test system - Class II- Product Code CIG

21 CFR § 862.1770 - Urea Nitrogen Test system - Class II- Product Code CDQ

807.92 (a)(3): Identification of the legally marketed predicate devices

21 CFR § 862.1035 - Albumin Test system - Class II-
Beckman Coulter Albumin (k924368)

21 CFR § 862.1145 - Calcium Test system - Class II-
Beckman Coulter Calcium (k061575)

21 CFR § 862.1225 - Creatinine Test system- Class II-
Beckman Coulter Creatinine (k934361)

21 CFR § 862.1345 - Glucose Test system - Class II-
Beckman Coulter Glucose (k944406)

21 CFR § 862.1110 - Direct Bilirubin Test system - Class II-
Abbott Architect Direct Bilirubin (K022180)

21 CFR § 862.1110 - Total Bilirubin Test system - Class II-
Beckman Coulter Total Bilirubin (k924964)

21 CFR § 862.1770 – Urea Nitrogen Test system - Class II-
Beckman Coulter Urea Nitrogen (BUN) (k944250)

807.92 (a)(4): Device Description

Medicon Hellas Albumin:
The BCG method is applied on serum samples, without serum blank. The bi-chromatic photometric determination of albumin is based on albumin binding the anionic dye bromocresol green in mildly acidic pH. The raise in absorbance at 620/750 nm is proportional to the concentration of albumin in the sample. The sample volume used for the assay is 2uL.

Medicon Hellas Calcium:
Calcium ions react with Arsenazo III dye in acidic pH, to form a violet complex. The absorbance at 650/750 nm is proportional to the concentration of calcium in serum or urine samples. The analyzer photometer reads the absorbance at time intervals dictated by the method application stored in the analyzer memory, and the change in absorbance is calculated automatically. The sample volume used by the assay is 2uL for serum or urine samples.

Medicon Hellas Creatinine:
Creatinine forms a yellow-orange complex with picrate anions in alkaline medium. The rate of change of absorbance of the complex at 505/700 nm is proportional to creatinine concentration in serum or urine samples. The sample volume used by the assay is 22uL for serum and urine samples.

Medicon Hellas Glucose: Glucose (Hexokinase)

The determination of glucose is according to the hexokinase method based on the following reactions using 2uL of sample for serum and urine samples. The concentration of glucose is determined bi-chromatically by the absorbance change at 340/380 nm.

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{Hexokinase}} \text{6-phosphate glucose} + \text{ADP}$$

$$\text{6-phosphate glucose} + \text{NAD} \xrightarrow{\text{G-6PDH}} \text{6-phopshate gluconic acid} + \text{NADH}$$

Medicon Hellas Direct Bilirubin :

The modified Malloy-Evelyn method is applied on serum samples. Direct (conjugated) bilirubin reacts with diazotised sulfanilic acid in acidic pH to form azobilirubin, a colored chromophore. The absorbance of chromophore at 550/650 nm is proportional to the concentration of direct bilirubin in the sample. The free (unbound) bilirubin fraction does not react. The reaction is an end-point type. The sample volume used by the assay is 8uL.

Medicon Hellas Total Bilirubin:

The DPD method is applied, whereby 3,5-dichlorophenyldiazonium tetrafluoroborate (DPD) binds directly to total bilirubin in acidic medium, forming azobilirubin, whose rate of absorbance at 550/700 nm is proportional to the concentration of total bilirubin in serum samples. The analyzer photometer reads the absorbance at time intervals dictated by the method application stored in the analyzer memory, and the change in absorbance is calculated automatically. The sample volume used by the assay is 20uL.

Medicon Hellas Urea Nitrogen:

Medicon Hellas Urea Nitrogen is an in vitro diagnostic assay for the quantitative determination of urea nitrogen in human serum and urine. Urea Nitrogen is determined according to the following reactions, using 7uL of sample for serum and urine samples:

$$\text{Urea Nitrogen} + H_2O \xrightarrow{\textbf{Urease}} 2NH_3 + CO_2$$

$$2NH_4^+ + \text{2-}\alpha\text{-Ketoglutarate} + 2\text{NADH} \xrightarrow{\textbf{GLDH}} \text{2-L-Glutamate} + 2NAD^+ 2H_2O$$

The rate of absorbance change at 340/380 nm is proportional to the urea nitrogen concentration in the sample.

For all assays the analyzer photometer reads the absorbances at time intervals dictated by the method application stored in the analyzer memory, and the change in absorbance is calculated automatically.

807.92 (a)(5): Intended Use

Medicon Hellas Albumin: Reagent for the quantitative measurement of albumin in serum. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Medicon Hellas Calcium: Reagent for the quantitative measurement of calcium in serum or urine. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Medicon Hellas Creatinine: Reagent for the quantitative measurement of creatinine in serum and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

Medicon Hellas Glucose: Reagent for the quantitative measurement of glucose in serum and urine. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Medicon Hellas Direct Bilirubin; Reagent for the quantitative measurement of direct bilirubin (conjugated) in serum. Measurements of the level of direct bilirubin is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall blader block.

Medicon Hellas Total Bilirubin; Reagent for the quantitative measurements of total bilirubin in serum. Measurements of the levels of total bilirubin is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

Medicon Hellas Urea Nitrogen: Reagent is for the quantitative measurement of urea nitrogen in serum and urine. Measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

807.92 (a)(6): Technological Similarities and Differences to the Predicates

Characteristic	Candidate- Medicon Hellas (Medicon) reagents	Predicate- Beckman Coulter (BC) AU Reagents run on the BC AU2700 analyzer	Predicate- Abbott Diagnostics (AD) Direct Bilirubin run on the Architect c8000 analyzer
Mode of Detection	Photometric	Same	Same
Photometric Detector	Photodiode	Same	Same
Optical Modes	Monochromatic, Bi-chromatic, Turbidimetric	Same	Same
Analytical Measure	Endpoint and kinetic with sample blanking	Same	Same
Wavelengths	12 (340 – 750nm)	13 (340 – 800nm)	16 (340 - 804nm)
Linear Absorbance Range	-0.1 to 3.6	0.0 to 3.0	-0.1 to 3.2
Device Class, Regulation Code, Product Code	Class I, 21 CFR 862.2160 (discrete photometric chemistry analyzer), JJE	Same	Same
Reagent Platform	Candidate- Medicon Hellas reagents	Predicate – Beckman Coulter AU Reagents	Predicate – Abbott Diagnostics Direct Bilirubin reagent
Test Systems	Albumin	Albumin (k924368)	
	Calcium	Calcium (k061575)	
	Creatinine (picrate based)	Creatinine (k934361)	
	Glucose	Glucose (k944406)	
	Direct Bilirubin	N/A	Direct Bilirubin (K022180)
	Total Bilirubin	Total Bilirubin (k924964)	
	Urea Nitrogen	Urea Nitrogen (k944250)	
Device Class II, Regulation Code, Classification Product Code	Albumin- 21 CFR § 862.1035, CIX	Same	
	Calcium- 21 CFR § 862.1145, CJY	Same	
	Creatinine- 21 CFR § 862.1225, CGX	Same	
	Glucose- 21 CFR § 862.1345, CFR	Same	
	Direct Bilirubin- 21 CFR § 862.1110, CIG		Same
	Total Bilirubin-21 CFR § 862.1110, CIG	Same	
	Urea Nitrogen - 21 CFR § 862.1770, CDQ	Same	
Intended Use	Quantitative determinations of albumin, calcium, creatinine, direct bilirubin, glucose, total bilirubin and urea with serum or urine samples where clinically applicable.	Quantitative determinations of albumin, calcium, creatinine, glucose, total bilirubin and urea with serum or urine samples where clinically applicable.	Quantitative determinations of direct bilirubin on human serum samples.
Testing Environment	Clinical labs	Same	Same
Method Principle	Photometry	Same	Same
Specimen Type	Human serum, and urine if applicable	Same	Same

807.92 (b)(1,2): Brief Description of Nonclinical and Clinical Data

Medicon Hellas (Medicon) has performed a series of studies to confirm the substantial equivalence of their test systems to the predicate devices. Results from each candidate test system were found to be substantially equivalent to their related predicate device. The predicate device used for Medicon Albumin, Medicon Calcium, Medicon Creatinine, Medicon Total Bilirubin and Medicon Urea Nitrogen (BUN) was the Beckman Coulter (BC) AU 2700 analyzer using the corresponding AU reagents. The predicate device for Medicon Direct Bilirubin was the Abbott Diagnostics Architect c8000 analyzer using its corresponding reagent.

Two to three lots of each candidate device were used for the studies. Testing confirmed equivalent performance of the candidate systems to the corresponding predicate devices.

Studies included accuracy (method comparison), reportable range (linearity), sensitivity (limit of quantification), precision including: repeatability, within run, between run and within lab (total), interfering endogenous and exogenous substances, reagent on-board stability and calibration frequency. The following provide performance summary information from the studies for each candidate reagent. The following summarize the type and scope of testing completed for each candidate device. Following this section, the data for each of the candidate devices is provided.

Method Comparison- The protocol followed was according to CLSI EP09c: accuracy testing was run simultaneously in blind fashion with the candidate and the predicate devices. A minimum of 70 clinical specimens, spanning the dynamic ranges, were assayed in singleton and in a blinded fashion on the at least three lots of each candidate system and on a representative lot of each predicate device. Results were tabulated and evaluated using Analyse-it software to generate Deming regression statistics.

> **Summary:** Accuracy studies completed on at least three lots of each candidate reagent confirm that Medicon albumin, calcium, creatinine, glucose, total bilirubin and urea nitrogen are substantially equivalent to the related predicate devices – Beckman Coulter AU reagents used on the AU2700 analyzer. Medicon direct bilirubin reagent used with a Diatron Pictus 500 analyzer is substantially equivalent to its predicate device – Abbott Architect c8000 direct bilirubin used with the Architect c8000 analyzer.

Reportable Range – Linearity - Statistical analysis is performed at a 5% level of significance and the evaluation is according to CLSI EP06-A. At least nine levels of each sample types were tested with at least three lots of the corresponding Medicon reagents. The samples were assigned their reference values arithmetically from serial dilutions of the high-level sample. Each level was tested N=4 on the Pictus P500, results from each level were averaged**.** All statistics were calculated using Analyse-it Software.

> **Summary**: the combined data from various lots of each of the Medicon candidate reagents used with the Pictus 500 chemistry analyzers met statistical acceptance criteria. Reportable ranges were comparable to the predicate device reportable ranges.

Sensitivity (LOD/LOQ) - Medicon completed sensitivity studies following CLSI EP17-A2. LoB was calculated using non-parametrical statistics and LoD was calculated from LoB following equation LoD = LoB+1.654*SD:

LoB/LoD were determined using: 5 Blank samples and 5 Low Levels samples respectively which were measured 4 times each day for a total of 60 measurements in 3 days.

LoQ: 10 samples that span the low end of linearity were measured 5 times each day for a total of 150 measurements in 3 days. LoQ was calculated until a specific concentration generated a CV of <= 20%.

> **Summary** – The lots of each of the candidate reagents of demonstrated acceptable levels of blank, limit of detection and defined the limit of quantification similar to the corresponding predicate devices.

Interferences- at least two lots of each candidate device were tested for interferences from endogenous and exogenous compounds using serum and urine samples, where applicable. Medicon performed comprehensive studies after searching in the bibliography and the FDA database for similar recently cleared devices, to assess and define a list of exogenous substances. The study plan and protocol followed CLSI EP07-A and EP37 guidelines. Serum and urine sample pools at low and high levels were prepared, then spiked with increasing concentrations of the interference compounds. The results define the level at which interferences of the noted compounds will affect results by more than +/- 10%.

> **Summary –** for each of the candidate devices, interferences studies determined the levels at which specific substances may interfere with results. These are tabulated in each of the candidate devices' data tables.

Stability/Calibration frequency:
Different lots of each candidate device were evaluated for on-board stability and calibration frequency covering specific date intervals and the related sample types. The results were tabulated and the data were analyzed for equivalence between lots. Results means, standard deviations and percent coefficient of variation (CV%).

Stability- Reagents were loaded on to the Pictus 500 analyzer's cooled reagent tray. Each reagent was calibrated at the start of each study. Two fresh serum pools and two control pools were assayed in triplicate on Day 0. Samples were frozen from -20ºC to - 70ºC, and then retested at fixed intervals until the reagent failed the acceptance criteria. When a reagent failed acceptance criteria, it was recalibrated. If recalibration did not bring the results within the acceptance criteria, the reagent's on-board useful life limit was established.

Calibration frequency: The un-capped on-board reagent stability claim is defined as the number of days between the start testing date and the last test day that results were within the acceptance limits without re-calibration. Calibration frequency is defined as the required time interval between calibrations that ensures reagents recover values within the acceptance criteria.

Summary – stability -Each lot of each candidate device, with the corresponding sample types passed acceptance criteria. Studies confirmed the on-board stability and calibration frequency limits defined within each candidate device's Instructions for Use document (product insert).

Precision CV% - (repeatability, between run and within lab (total) precision) – testing precisely followed protocol CLSI EP05-A3. Precision study results from running applicable serum and urine samples (Level 1, Level 2 and Level 3) were tested in duplicate, twice a day, for 20 days, for a total of 80 results per level on two or three lots of each candidate device. The three precision elements were calculated from the total data for each sample type and lot generated over the evaluation period. Statistics were calculated using Analyse-it software.

Summary - The results were tabulated and the data were analyzed for means, standard deviations and percent coefficient of variation (CV%). All lots passed acceptance criteria for each applicable sample type at each level.

Tabulated results – for each of the candidate devices follow:

Medicon Hellas Albumin - code # 1419-0192

Reportable Range	Low Value	High Value	
serum	1.50	6.00	g/dL
LOD (limit of detection) - serum		0.40	g/dL
LOQ (limit of quantification) -serum		0.50	g/dL

Precision (g/dL) -serum	Level 1	SD	CV
Repeatability	3.1	0.07	2.21%
Between Run	3.1	0.16	5.25%
Within Lab	3.1	0.18	5.70%
	Level 2	SD	CV
Repeatability	4.0	0.06	1.45%
Between Run	4.0	0.15	3.80%
Within Lab	4.0	0.19	4.80%
	Level 3	SD	CV
Repeatability	5.2	0.07	1.37%
Between Run	5.2	0.12	2.36%
Within Lab	5.2	0.24	4.61%

Interferences - serum	Recovered values within ±10% of neat samples -insignificant		
Unconjugated Bilirubin	insignificant up to	20	mg/dL
Conjugated Bilirubin	insignificant up to	20	mg/dL
Hemoglobin	insignificant up to	500	mg/dL
Triglycerides	insignificant up to	3000	mg/dL
L-ascorbic acid	insignificant up to	3	mg/dL
Acetametophen	insignificant up to	16	mg/dL
Acetylsalicylic Acid	insignificant up to	3	mg/dL
Aminosalicylic Acid	insignificant up to	46	mg/dL
Ibuprofen	insignificant up to	21.9	mg/dL

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Calculated results were as follows:

	Range	# Samples	R_2 Corr.	Slope	Intercept
Serum	1.6 to 5.9	112	0.9862	1.0180	0.05

Medicon Hellas Calcium – code # 1419-0201

Reportable Range	Low Value	High Value	
Serum	4.0	18.0	mg/dL
Urine	2.0	40.0	mg/dL

	Serum		Urine	
LoD (limit of detection)	0.5	mg/dL	1.3	mg/dL
LoQ (limit of quantification)	0.5	mg/dL	1.5	mg/dL

Precision Serum (mg/dL)	Level 1	SD	CV
Repeatability	5.9	0.07	1.16%
Between Run	5.9	0.20	3.37%
Within Lab (Total)	5.9	0.32	5.44%
	Level 2	SD	CV
Repeatability	8.6	0.09	1.06%
Between Run	8.6	0.13	1.51%
Within Lab (Total)	8.6	0.35	4.07%
	Level 3	SD	CV
Repeatability	12.7	0.10	0.82%
Between Run	12.7	0.25	1.95%
Within Lab (Total)	12.7	0.44	3.49%

Precision Urine (mg/dL)	Level 1	SD	CV
Repeatability	6.2	0.16	2.59%
Between Run	6.2	0.09	1.48%
Within Lab (Total)	6.2	0.23	3.73%
	Level 2	SD	CV
Repeatability	12.9	0.25	1.90%
Between Run	12.9	0.49	3.82%
Within Lab (Total)	12.9	0.67	5.21%
	Level 3	SD	CV
Repeatability	30.6	0.40	1.31%
Between Run	30.6	0.90	2.95%
Within Lab (Total)	30.6	1.07	3.51%

Interferences Recovered values within ±10% of neat samples - insignificant up to noted values

	Serum				Urine			
	Lv1	Lv2	Up to		Lv1	Lv2	Up to	
Bilirubin	7.0	13.6	20	mg/dL	N/A	N/A	N/A	
Hemoglobin	7.2	13.6	500	mg/dL	6.2	11.9	500	mg/dL
Triglycerides	7.3	12.8	3000	mg/dL	N/A	N/A	N/A	mg/dL
L-ascorbic acid	7.3	14.2	3	mg/dL	8	12.1	500	mg/dL
Acetaminophen	7.2	11.8	15.6	mg/dL	N/A	N/A	N/A	
Acetylsalycilic Acid	7.7	12.8	3	mg/dL	N/A	N/A	N/A	
Albumin			N/A		6.5	12.7	500	mg/dL
Boric Acid			N/A		7.2	15.6	500	mg/dL
Conjugated Bilirubin	8.3	12.6	20	mg/dL	7.6	16.5	50	mg/dL
Glucose			N/A		6.8	11.9	10	g/dL
Ibuprofen	8.2	13.1	21.9	mg/dL	9.7	15.7	21.9	mg/dL
IgG			N/A		6.6	15.2	500	mg/dL
Magnesium			N/A		7.4	12.8	4	mmol/L
pH			N/A		6.1	12.7	6	
Specific gravity			N/A		5.9	9.7	1.01-1.03	

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Representive results as follows;

Sample type	Low Value	High Value	# Samples	R2 Corr.	Slope	Intercept
Serum (mg/dL)	4.0	18.0	94	0.9949	1.0099	-0.3
Urine (mg/dL)	2.3	39.9	81	0.9965	0.9888	-0.8

Medicon Hellas Creatinine – code # 1419-0030

Reportable Range	Low Value	High Value	
Serum	0.3	25.0	mg/dL
Urine	1.2	300.0	mg/dL

	Serum		Urine	
LoD (limit of detection)	0.2	mg/dL	1.0	mg/dL
LoQ (limit of quantification)	0.2	mg/dL	1.1	mg/dL

Precision Serum (mg/dL)	Level 1	SD	CV
Repeatability	1.3	0.03	2.41%
Between Run	1.3	0.05	3.63%
Within Lab (Total)	1.3	0.08	6.40%
	Level 2	SD	CV
Repeatability	4.9	0.05	1.08%
Between Run	4.9	0.22	4.58%
Within Lab (Total)	4.9	0.23	4.71%
	Level 3	SD	CV
Repeatability	9.6	0.10	1.04%
Between Run	9.6	0.22	2.30%
Within Lab (Total)	9.6	0.28	2.92%

Precision Urine (mg/dL)	Level 1	SD	CV
Repeatability	63.4	1.31	2.07%
Between Run	63.4	1.68	2.66%
Within Lab (Total)	63.4	2.15	3.39%
	Level 2	SD	CV
Repeatability	100.6	1.39	1.38%
Between Run	100.6	1.84	1.83%
Within Lab (Total)	100.6	2.31	2.29%
	Level 3	SD	CV
Repeatability	308.6	3.81	1.23%
Between Run	308.6	6.16	2.00%
Within Lab (Total)	308.6	7.25	2.35%

Interferences Recovered values within ±10% of neat samples - insignificant

	Serum	Insignificant up to	Urine	Insignificant up to
Bilirubin	1.5 to 5.2	10.0 mg/dL	84 to 267	40 mg/dL
Hemoglobin	1.3 to 6.6	220 mg/dL	88 to 269	5.0 g/L
Triglycerides	1.4 to 7.0	1200 mg/dL	N/A	
L-ascorbic acid	1.4 to 6.8	3.0 mg/dL	84 to 268	50 mg/dL
Acetaminophen	1.3 to 6.3	15.6 mg/dL	N/A	
Acetylsalicylic acid	1.2 to 5.6	3.0 mg/dL	N/A	
Cefazolin	1.4 to 6.0	40 mg/dL	N/A	
Cefoxitin	1.5 to 5.9	6.0 mg/dL	N/A	
Cephalothin	1.5 to 5.6	12 mg/dL	N/A	
Chloramphenicol	1.0 to 6.0	7.8 mg/dL	N/A	
Dopamine	0.9 to 6.0	0.062 mg/dL	N/A	
Etamsylate	1.6 to 5.6	6.0 mg/dL	N/A	
Flucytosine	1.2 to 5.7	20.4 mg/dL	N/A	
Furosemide	1.6 to 5.6	1.59 mg/dL	N/A	
Glucose	N/A		86 to 273	3000 mg/dL
Ibuprofen	1.4 to 6.1	23.9 mg/dL	N/A	
Streptomycin	1.3 to 6.1	25.8 mg/dL	N/A	
Boric Acid	N/A		58 to 200	500 mg/dL
pH	N/A		59 to 137	pH 2 to pH 12
Specfic Gravity	N/A		36 to 202	1.01-1.03

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Representive results were;

Sample type	Low Value	High Value	# Samples	R2 Corr.	Slope	Intercept
Serum (mg/dL)	0.3	25.0	126	0.9989	1.0207	-0.10
Urine (mg/dL)	1.9	286.9	98	0.9992	0.9904	-0.81

Medicon Hellas Direct Bilirubin – code # 1419-0152

Reportable Range	Low Limit	High Limit	
serum	0.2	15.0	mg/dL

LOD (limit of detection) -serum	0.1	mg/dL
LOQ (limit of quantification) -serum	0.2	mg/dL

Precision -serum	Level 1	SD	CV
Repeatability	0.7	0.02	3.11%
Between Run	0.7	0.02	2.31%
Total	0.7	0.03	4.98%
	Level 2	SD	CV
Repeatability	1.8	0.04	2.46%
Between Run	1.8	0.06	3.14%
Total	1.8	0.08	4.70%
	Level 3	SD	CV
Repeatability	7.5	0.19	2.48%
Between Run	7.5	0.17	2.29%
Total	7.5	0.34	4.52%

Serum- Interferences Recovered values within ±10% of neat samples - insignificant

Intereferent Substances	Sample Range	Insignificant up to
Hemoglobin	0.74 to 2.10	40 mg/dL
Triglycerides	0.49 to 1.99	3000 mg/dL
L-ascorbic acid	0.56 to 2.03	2.7 mg/dL
Acetaminophen	0.64 to 1.63	15.6 mg/dL
Acetylsalicylic Acid	0.64 to 1.53	3.0 mg/dL
Ibuprofen	0.64 to 1.52	21.9 mg/dL

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a Abbott Labs Architect c8000 analyzer, each run with their corresponding reagents. Representative results from the studies are as follows:

	Range	# Samples	R_2 Corr.	Slope	Intercept
Serum (mg/dL)	0.2 to 14.7	77	0.9978	0.9656	-0.01

Medicon Hellas Glucose – code # 1419-0018

Reportable Range	Low Value	High Value	
Serum	10	700	mg/dL
Urine	10	660	mg/dL

	Serum		**Urine**	
LoD (limit of detection)	1.7	mg/dL	2.4	mg/dL
LoQ (limit of quantification)	4.0	mg/dL	6.0	mg/dL

Precision - Serum (mg/dL)	Level 1	SD	CV	Level 2	SD	CV	Level 3	SD	CV
Repeatability	66	1.1	1.72%	101	1.0	0.99%	303	2.9	0.96%
Between Run	66	0.9	1.35%	101	1.5	1.48%	303	6.3	2.08%
Within Lab (Total)	66	1.9	2.88%	101	1.8	1.78%	303	9.5	3.13%

Precision - Urine (mg/dL)	Level 1	SD	CV	Level 2	SD	CV	Level 3	SD	CV
Repeatability	14	0.5	3.63%	134	2.2	1.67%	532	7.9	1.49%
Between Run	14	0.2	1.12%	134	1.2	0.93%	532	7.6	1.42%
Within Lab (Total)	14	1.0	6.86%	134	3.2	2.43%	532	17.9	3.36%

Interferences Recovered values within ±10% of neat samples - insignificant

	Serum		**Urine**	
Intereferent Substances	Sample Range	Insignificant up to	Sample Range	Insignificant up to
Albumin	85-139 mg/dL	7.5 g/dL	33-252 mg/dL	500 mg/dL
Bilirubin	79-186 mg/dL	20 mg/dL	N/A	N/A
Calcium	N/A	N/A	25-241 mg/dL	50 mg/dL
Conjugated Bilirubin	88-153 mg/dL	20 mg/dL	29-269 mg/dL	50 mg/dL
Acetaminophen	79-142 mg/dL	15.6 mg/dL	N/A	N/A
Acetylsalicylic Acid	80-155 mg/dL	3 mg/dL	N/A	N/A
Ibuprofen	84-157 mg/dL	21.9 mg/dL	N/A	N/A
Creatinine	N/A	N/A	29-255 mg/dL	300 mg/dL
Hemoglobin	77-185 mg/dL	500 mg/dL	24-238 mg/dL	500 mg/dL
IgG	71-132 mg/dL	7500 mg/dL	31-252 mg/dL	500 mg/dL
L-ascorbic acid	76-190 mg/dL	3 mg/dL	21-264 mg/dL	500 mg/dL
Triglycerides	85-192 mg/dL	3000 mg/dL	N/A	N/A
Urea	N/A	N/A	25-229 mg/dL	6000 mg/dL
Uric Acid	79-137 mg/dL	20 mg/dL	27-216 mg/dL	250 mg/dL
pH	N/A	N/A	30-315 mg/dL	pH 2-12
Specific gravity	N/A	N/A	27-232 mg/dL	1.01-1.03

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Representive results were determined as;

Sample type	Low Value	High Value	# Samples	R2 Corr.	Slope	Intercept
Serum (mg/dL)	13	696	99	0.9992	0.9715	2.7
Urine (mg/dL)	10	656	100	0.9989	1.0222	-0.9

Medicon Hellas Total Bilirubin – code # 1419-0142

Reportable Range	Low Value	High Value	
Serum	0.10	30.00	mg/dL

LOD (limit of detection) -serum	0.01	mg/dL
LOQ (limit of quantification) -serum	0.09	mg/dL

Precision -serum (mg/dL)	Level 1	SD	CV
Repeatability	1.4	0.01	0.92%
Between Run	1.4	0.02	1.69%
Total	1.4	0.04	2.97%
	Level 2	SD	CV
Repeatability	5.5	0.02	0.38%
Between Run	5.5	0.08	1.38%
Total	5.5	0.20	3.56%
	Level 3	SD	CV
Repeatability	9.6	0.05	0.57%
Between Run	9.6	0.17	1.79%
Total	9.6	0.27	2.86%

Interferences -serum	Recovered values within ±10% of neat samples - insignificant		
Hemoglobin	insignificant up to	75	mg/dL
Triglycerides	insignificant up to	1800	mg/dL
L-ascorbic acid	insignificant up to	3	mg/dL
Acetametophen	insignificant up to	15.6	mg/dL
Acetylsalicylic Acid	insignificant up to	3	mg/dL
Ibuprofen	insignificant up to	21.9	mg/dL

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Representative results from the studies are as follows:

	Range	# Samples	R_2 Corr.	Slope	Intercept
Serum (mg/dL)	0.3 to 29.1	95	0.9996	1.0125	-0.06

Medicon Hellas Urea Nitrogen – code # 1419-0022

Reportable Range	Low Value	High Value	
Serum	3	100	mg/dL
Urine	24	1300	mg/dL

	Serum		**Urine**	
LoD (limit of detection)	2	mg/dL	21	mg/dL
LoQ (limit of quantification)	3	mg/dL	24	mg/dL

Precision Serum (mg/dL)	Level 1	SD	CV
Repeatability	10	0.2	1.94%
Between Run	10	0.2	2.24%
Within Lab (Total)	10	0.3	2.97%
	Level 2	SD	CV
Repeatability	19	0.4	2.14%
Between Run	19	0.5	2.56%
Within Lab (Total)	19	0.6	3.34%
	Level 3	SD	CV
Repeatability	51	0.5	1.07%
Between Run	51	1.6	3.16%
Within Lab (Total)	51	1.7	3.34%

Precision Urine (mg/dL)	Level 1	SD	CV
Repeatability	371	6.7	1.81%
Between Run	371	8.7	2.35%
Within Lab (Total)	371	11.5	3.10%
	Level 2	SD	CV
Repeatability	700	11.8	1.69%
Between Run	700	20.4	2.92%
Within Lab (Total)	700	23.6	3.37%

Interferences Recovered values within ±10% of neat samples - insignificant

	Serum		Urine	
Intereferent Substance	Sample Range	Insignificant up to	Sample Range	Insignificant up to
Bilirubin	13-39	20 mg/dL	N/A	
Conjugated Bilirubin	15-39	20 mg/dL	412-871	40 mg/dL
Hemoglobin	14-38	250 mg/dL	439-975	500 mg/dL
Triglycerides	13-34	3000 mg/dL	N/A	
L-ascorbic acid	13-39	3 mg/dL	411-900	50 mg/dL
Acetaminophen	14-36	15.6 mg/dL	N/A	
Acetylsalicylic acid	13-39	3 mg/dL	N/A	
Albumin	N/A		464-879	500 mg/dL
Aminosalicylic Acid	12-33	45.5 mg/dL	N/A	
Boric Acid	N/A		450-925	500 mg/dL
Cefoxitin	13-33	220 mg/dL	N/A	
Chloramphenicol	12-34	7.8 mg/dL	N/A	
Furosemide	N/A		362-822	1.59 mg/dL
Glucose	N/A		461-887	5000 mg/dL
Ibuprophen	14-38	23.9 mg/dL	N/A	
Methyldopa	13-36	2.25 mg/dL	N/A	
pH	N/A		391-694	pH 2 to 12
Specific Gravity	N/A		410-857	1.01-1.03
Streptomycin	14-34	25.8 mg/dL	N/A	

Accuracy- A comparison was performed between lots of reagent on a Pictus® 500 analyzer, and a BECKMAN COULTER AU 2700 analyzer, each run with their corresponding reagents. Representive results were determined as;

Sample type	Low Value	High Value	# Samples	R2 Corr.	Slope	Intercept
Serum (mg/dL)	3	93	116	0.9983	1.0001	-0.2
Urine (mg/dL)	31	1244	81	0.9972	0.9844	21.9

807.92 (b)(2): Brief Description of Clinical Data

Not applicable

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Comprehensive study results using multiple lots of each candidate reagent, on serum and or urine samples establish that Medicon Hellas reagents used with the Diatron Pictus 500 analyzer are substantially equivalent to the Beckman Coulter AU and Abbott Diagnostics predicate devices assayed with their associated instruments.