September 26, 2023

Medica Corporation
Photios Makris
VP Regulatory Affairs
5 Oak Park Drive
Bedford, MA 01730

Re: K220396
Trade/Device Name: EasyStat 300
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium Test System
Regulatory Class: Class II
Product Code: JFP, CGZ, CEM
Dated: December 1, 2022
Received: December 2, 2022

Dear Photios Makris:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
k220396

Device Name
EasyStat 300

Indications for Use *(Describe)*

The EasyStat 300 is designed for clinical laboratory use, making quantitative measurements of potassium (K+), ionized calcium (Ca++), and chloride (Cl-) in whole blood (arterial/venous) samples from Li-Heparinized Syringes. This Analyzer should only be used by trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte and/or acid-base disturbances.

Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Calcium (Ca++) (ionized) 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).

Chloride (Cl-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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 for k220396

Submitted By:

Medica Corporation
5 Oak Park Drive
Bedford, MA 01730

Contact Person:

Photios Makris, VP. Regulatory Affairs
Phone: 781-541-7443
Fax: 781-275-2731
E-mail: pmakris@medicacorp.com

Summary Prepared:

September 24th, 2023

Trade Name:

EasyStat 300
Common Name: Blood Gas Analyzer
Classification Name: Potassium, chloride, Calcium Test Systems

Regulatory Information:

EasyStat 300

Description	Regulation No.	Device Class	Product Code
Potassium Test system	862.1600	II	CEM
Calcium Test System	862.1145	II	JFP
Chloride Test System	862.1170	II	CGZ

Predicate devices: EasyLyte Calcium/Chloride (k963694)

Description	510(k)	Device Class	Product Code
Calcium Test System	862.1145	II	JFP
Chloride Test System	862.1170	II	CGZ

Device Description:

The EasyStat 300 is a system for use by health care professionals to rapidly analyze venous and arterial whole blood samples in a clinical laboratory setting. The analyzer incorporates a Reagent Module containing the "calibrating" solutions A2, B2, and a "conditioning" solution C2. Calibrations are performed automatically or on-demand by the user to establish the "slope" of each sensor, used in the calculation of the patient sample.

The analyzer employs "Ion Selective Electrode" (ISE) sensors for K^+, Ca^{++}, Cl^-.

The EasyStat 300 uses 175µL of whole blood in the "Syringe" mode to analyze patient samples. The EasyStat 300 reports results for Potassium (K+), Calcium (Ca++), Chloride (Cl-). Additionally, it provides a number of calculated parameters based on the reported results and a number of input parameters as described in the Operator's Manual.

Medica's EasyQC materials (REF 8315/8316/8317) are specifically formulated for the EasyStat 300. Medica requires the use of quality controls every day patient samples are analyzed and after any troubleshooting is performed, as instructed in the Operator's Manual, to validate the performance of the analyzer. The analyzer stores QC results and provides a statistical analysis of its performance using Levey-Jennings plots for the last 30 consecutive days.

The Reagent Module (REF 8101) has a twelve-month shelf-life when stored at 4^0-25^0C.

The electrolyte sensors (K, Ca, Cl) have one-year shelf-life when stored at 4^0-25^0C. Use-Life of the sensors is determined from their calibration profiles and from the reported results during the EasyQC analysis. Sensors are replaced by the operator as described in the Operator's Manual. An automatic calibration is performed after installation to qualify the new sensor(s) and the operator is instructed to use the EasyQC multi-level QC materials to validate the EasyStat 300 performance.

The EasyStat 300 may be equipped with a Medica provided barcode scanner (REF 8420) via a USB port to automatically enter patient sample and EasyQC material information. Details are provided in the operator's Manual.

To maintain the performance of the analyzer Medica provides a cleaning solution (REF 8305) and a troubleshooting kit (REF 8250). Their proper uses are described also in the operator's Manual.

Similarities and Differences to Predicate:

Similarities and Differences Between Devices Used in this Notification

	EasyStat 300	**EasyLyte calcium/Chloride**
510(k) Number	New IVD Device	K963694
Manufacturer	Medica Corp.	Medica Corp.
Address	5 Oak Park Dr. Bedford, MA 01730	5 Oak Park Dr. Bedford, MA 01730
Intended Use	Clinical Laboratories	Clinical Laboratories
Indications for Use	Same with predicate devices	Same with submitted device
Operating Principle	Ion Specific Electrodes	Ion Specific Electrodes
Ca++	Potentiometric	Potentiometric
Cl-	Potentiometric	Potentiometric
Calibrant Base	Aqueous	Aqueous
Measured Parameters on Predicate Utilized for Submission	K+, Ca++, Cl-	Ca++, Cl-
Sample Type	Whole Blood	Whole Blood
Sample Volume	175µL Syringe	100µL Syringe
Analysis Time	110 seconds	55 seconds
Measured Range		
Ca++	0.25-5.00 mmol/L	0.10-6.00 mmol/L
Cl-	50.0 150.0 mM/L	25.0 200.0 mM/L
Communication Ports	USB (5), 1 for Barcode reader	None
	Ethernet (1)	None
	RS232 Serial (1)	RS232 Serial(1)
	SD card port (1)	None
	N/A	Barcode Reader

Indications for Use:

The EasyStat 300 is designed for clinical laboratory use, making quantitative measurements of potassium (K+), ionized calcium (Ca++), and chloride (Cl-) in whole blood (arterial/venous) samples from Li-Heparinized Syringes. This analyzer should only be used by trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte and/or acid-base disturbances.

Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Calcium (Ca++) (ionized) 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).

Chloride (Cl-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Performance Summary:

The following studies were performed in a laboratory setting (Bench test) using venous whole blood from adult volunteers. There were no adverse effects or safety concerns during any of the studies. Summaries of the studies are presented here.

Precision: Repeatability (5-day) and Reproducibility (20-day)

Linearity

Method Comparison

Sensitivity

Selectivity:

Performance Conclusions:

Clinical and Non-clinical (bench) test data included in this submission, indicate that the new device (EasyStat 300) performs equivalently to the predicate device (EasyStat-Cl).

20-Day Precision Study – Aqueous Controls

Medica used the EasyStat 300 tri-level aqueous EasyQC material to establish the Total and Within-Run precision of all analytes reported by the EasyStat 300. Each of the quality control levels were analyzed in three EasyStat 300 analyzers for twenty days taking duplicate readings in the morning (AM) and afternoon (PM). All results were within specification.

Analyte	Precision Estimate	Level	Target	Performance Specs		Actual Performance																	
						System 1 - P21						System 2 - P22						System 3 - P23					
						Sensor 1			Sensor 2			Sensor 1			Sensor 2			Sensor 1			Sensor 2		
				SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
Cl^-	Repeatability (Within-Run)	1	79.0	2.0		79.2	0.04		79.2	0.05		79.2	0.04		79.3	0.04		79.0	0.05		79.1	0.04	
		2	102.0		1.5%	101.3		0.0	101.4		0.0	101.3		0.1	101.5		0.0	101.5		0.0	101.5		0.1
		3	130.0		1.7%	129.7		0.1	129.8		0.0	129.7		0.1	129.8		0.1	130.3		0.1	130.4		0.1
	Within-Device (Total)	1	79.0	2.5		79.2	0.13		79.2	0.13		79.2	0.16		79.3	0.16		79.0	0.24		79.1	0.24	
		2	102.0		1.8%	101.3		0.1	101.4		0.1	101.3		0.1	101.5		0.1	101.5		0.1	101.5		0.1
		3	130.0		2.0%	129.7		0.1	129.8		0.1	129.7		0.1	129.8		0.1	130.3		0.1	130.4		0.1
Ca^{++}	Repeatability (Within-Run)	1	1.72		2.0%	1.72		0.1	1.72		0.2	1.72		0.2	1.72		0.2	1.73		0.2	1.73		0.2
		2	1.10		2.0%	1.10		0.0	1.10		0.0	1.10		0.0	1.10		0.0	1.12		0.3	1.12		0.4
		3	0.52	0.02		0.52	0.00		0.52	0.00		0.52	0.00		0.52	0.00		0.53	0.00		0.53	0.00	
	Within-Device (Total)	1	1.72		2.5%	1.72		0.1	1.72		0.2	1.72		0.2	1.72		0.3	1.73		0.3	1.73		0.3
		2	1.10		2.5%	1.10		0.0	1.10		0.0	1.10		0.0	1.10		0.0	1.12		0.4	1.12		0.5
		3	0.52	0.03		0.52	0.00		0.52	0.00		0.52	0.00		0.52	0.00		0.53	0.00		0.53	0.00	
K^+	Repeatability (Within-Run)	1	2.66	0.07		2.67	0.00		2.66	0.00		2.64	0.00		2.65	0.00		2.70	0.00		2.70	0.00	
		2	4.25		1.5%	4.28		0.1	4.26		0.1	4.24		0.2	4.24		0.2	4.31		0.1	4.31		0.1
		3	6.00		2.0%	6.03		0.1	6.00		0.1	5.99		0.2	5.97		0.3	6.07		0.1	6.07		0.2
	Within-Device (Total)	1	2.66	0.10		2.67	0.00		2.66	0.01		2.64	0.01		2.65	0.01		2.70	0.01		2.70	0.01	
		2	4.25		2.0%	4.28		0.1	4.26		0.2	4.24		0.2	4.24		0.3	4.31		0.2	4.31		0.3
		3	6.00		2.5%	6.03		0.1	6.00		0.2	5.99		0.2	5.97		0.3	6.07		0.4	6.07		0.4

Repeatability (5-Day) Study – Whole blood samples

This study was performed as a substitute to the typical single run with twenty whole blood replicates. It was necessitated by the instability of potassium within the time required to complete the study (about 90 minutes). Instead, we chose to use the option allowed in the CLSI EP05-A3 protocol to run five replicates of whole blood for five days. All results were within specification.

Typical Precision Performance of the EasyStat 300 operating in "Syringe" mode

Within-Run Precision from 5-Day Study - Syringe Mode - Table A																								
Analyte	Stat	Level 1							Level 2							Level 3								
		System 1		System 2		System 3		Spec	System 1		System 2		System 3		Spec	System 1		System 2		System 3		Spec
		Sensor 1	Sensor 2	Sensor 1	Sensor 2	Sensor 1	Sensor 2		Sensor 1	Sensor 2	Sensor 1	Sensor 2	Sensor 1	Sensor 2		Sensor 1	Sensor 2	Sensor 1	Sensor 2	Sensor 1	Sensor 2	
Cl-	Avg	73.8	73.8	73.9	74.0	73.7	73.7		100.8	100.6	101.6	101.4	101.3	101.1		121.7	121.5	123.0	122.7	123.0	122.7	
	SD	0.24	0.28	0.35	0.37	0.22	0.25	2.0	0.25	0.23	0.27	0.26	0.17	0.15		0.17	0.21	0.24	0.21	0.19	0.22	
	CV	0.3	0.4	0.5	0.5	0.3	0.3		0.2	0.2	0.3	0.3	0.2	0.1	1.5	0.1	0.2	0.2	0.2	0.2	0.2	1.7
Ca++	Avg	0.44	0.44	0.45	0.44	0.45	0.44		1.28	1.28	1.29	1.28	1.29	1.29		2.43	2.43	2.42	2.40	2.45	2.45	
	SD	0.001	0.001	0.000	0.001	0.000	0.001	0.02	0.003	0.002	0.005	0.006	0.005	0.006		0.009	0.012	0.013	0.024	0.009	0.018	
	CV	0.2	0.2	0.0	0.2	0.0	0.2		0.2	0.2	0.4	0.5	0.4	0.5	2.0	0.4	0.5	0.5	1.0	0.4	0.7	2.0
K+	Avg	2.15	2.15	2.18	2.18	2.18	2.18		4.60	4.60	4.62	4.58	4.62	4.57		7.79	7.81	7.81	7.68	7.81	7.71	
	SD	0.007	0.008	0.007	0.008	0.008	0.006	0.07	0.025	0.020	0.022	0.021	0.025	0.026		0.061	0.061	0.057	0.062	0.068	0.093	
	CV	0.3	0.4	0.3	0.4	0.4	0.3		0.5	0.4	0.5	0.5	0.6	0.6	1.5	0.7	0.8	0.7	0.8	0.9	1.2	2.0

Conclusion of Precision Studies

Medica's Total precision and Within-Run precision studies, demonstrate that the EasyStat 300 analyzer is precise and true to Medica's performance specifications and comparable to the predicate devices in this submission.

Linearity Study

This study followed the CLSI EP06-A protocol officially recognized by the FDA. The linearity performance on the EasyStat 300 was evaluated using nine (9) to eleven (11) spiked and diluted whole blood specimens to cover the reportable range for each analyte. The pre-assayed whole blood samples were finally tested in triplicate on three EasyStat 300 analyzers to establish the linearity performance for each analyte. The table below shows a summary of the obtained results that met all device specifications.

Linearity Summary for one of the three EasyStat 300 operating in the "Syringe" mode									
Analyte	Date	Predicate	ES300	Syringe					
				Sensor 1			Sensor 2		
				Linearity	Correlation		Linearity	Correlation	
					Slope	R^2		Slope	R^2
Cl-	12/27/19	ES_3	P1	PASS	0.948	1.000	PASS	0.947	0.999
			P2	PASS	0.968	1.000	PASS	0.960	1.000
			P4	PASS	0.971	1.000	PASS	0.964	1.000
Ca++	12/12/19	ES_2	P1	PASS	0.970	1.000	PASS	0.989	0.999
			P2	PASS	0.984	1.000	PASS	0.982	1.000
			P4	PASS	0.962	1.000	PASS	0.981	1.000
K+	12/12/19	ES_2	P1	PASS	0.976	0.999	PASS	0.981	0.999
			P2	PASS	0.983	1.000	PASS	0.962	1.000
			P4	PASS	0.978	0.999	PASS	0.977	1.000

Conclusion of Linearity Study

Data from the linearity study on three EasyStat 300 analyzers performed according to CLSI EP6-A demonstrate that all analytes (K, Ca, Cl) reported by the EasyStat 300 are linear within the advertised reportable range.

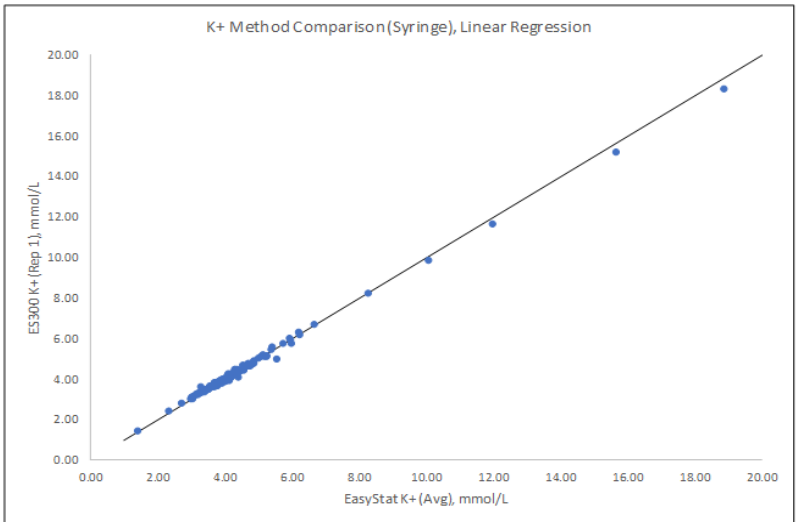
Method Comparison Study

This study followed the CLSI EP9-A2 protocol. For this study we used whole blood from 192 donors plus six modified whole blood samples (spiked and diluted). All blood samples were tested on the reference device twice and on three EasyStat 300 analyzers in duplicate. Some samples were modified to achieve analyte levels covering the reportable range. The samples were spiked with salts or diluted using plasma diluted with saline from the same donor. For electrolytes the reference analyzer was the EasyStat, k063376.

Conclusion of the Method Comparison Study

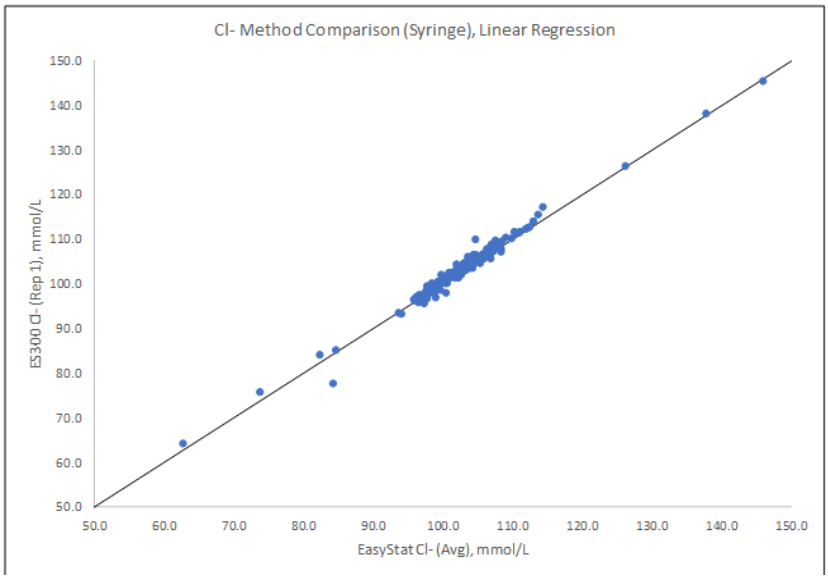
Data from the Method Comparison study on three EasyStat 300 demonstrates that all analytes (K, Ca, Cl) reported by the EasyStat 300 are favorably correlated to the reference device selected for this study. For all analytes, the linear regression slope, the coefficient of variation, and the calculated predicted bias at the decision levels for each analyte were within specifications.

Typical correlation results for all analytes are shown below:



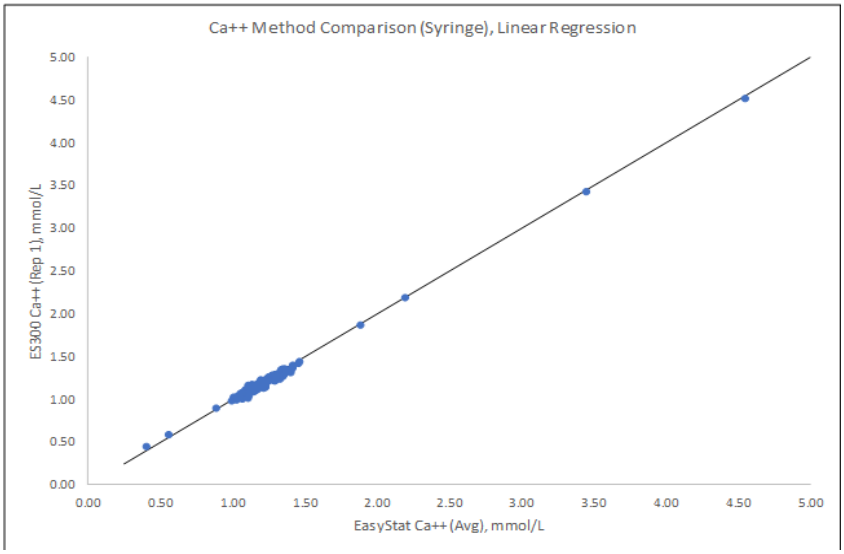
n	Slope	Intercept	R^2	Std Error
198	0.962	0.130	0.997	0.081

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
3.00	0.016	3.01	3.02	2.50	3.50	PASS
5.80	-0.090	5.70	5.72	5.30	6.30	PASS
7.50	-0.155	7.33	7.36	7.00	8.00	PASS



n	Slope	Intercept	R^2	Std Error
198	1.007	-0.378	0.981	0.995

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
90.0	0.25	90.1	90.4	85.5	94.5	PASS
112.0	0.41	112.3	112.5	106.4	117.6	PASS



n	Slope	Intercept	R^2	Std Error
198	0.987	-0.017	0.994	0.025

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
0.37	-0.022	0.34	0.35	0.27	0.47	PASS
0.82	-0.028	0.79	0.79	0.72	0.92	PASS
1.58	-0.038	1.54	1.54	1.42	1.74	PASS

Sensitivity

The sensitivity study is used to validate the low end of the Reportable Range for a particular assay on the EasyStat 300. The study first establishes the Limit of Blank (LoB) that is the starting point for determining the Limit of Detection (LoD) and subsequently the Limit of Quantitation (LoQ).

The sensitivity study in this submission followed the guidelines from **CLSI EP17-A**. It was performed on three ES 300 covering the electrolyte (K^+, Cl^-, Ca^{++}) sensors.

The following table lists the measured LoB, LoD, and LoQ for all analytes reported by the EasyStat 300.

Analyte	LoB	LoD	LoQ	Lowest Detection Limit (LDL)	LoQ < LDL?
K	0.17 mmol/L	0.20 mmol/L	0.20 mmol/L	1.00 mmol/L	Yes
Ca	0.25 mmol/L	0.25 mmol/L	0.25 mmol/L	0.25 mmol/L	Yes
Cl	2.4 mmol/L	3.1 mmol/L	42.4 mmol/L	50.0 mmol/L	Yes

Conclusion of the Sensitivity Study

The lower reportable limit for each assay on the EasyStat 300 was based on the LoQ result calculated or experimentally determined in this sensitivity study. Our studies indicate that the following values may be used as the lowest limit of the reportable range of each assay available on the EasyStat 300.

K+: 1.00 mmol/L
Cl-: 50.0 mmol/L
Ca++: 0.25 mmol/L

Selectivity

The **selectivity** (interference) study has followed in principle the guidelines from CLSI EP07-A. The level chosen is the typical normal value for a particular analyte in whole blood. All collected data are from spiked whole blood samples collected from healthy donors. Analyte changes less than the Total Allowable error (TAE) of nominal value are marked as "No Interference".

Table I below lists substances that were tested with no interference on the listed analytes.

Substance	Concentration	K^+ (mmol/L) No Interference when change <0.30 mmol/L or < ±7%	Cl^- (mmol/L No Interference when change < ±5.0 mmol/L	Ca^{++} (mmol/L No Interference when change <0.10 mmol/L or < ±10%	No Interference on the listed sensors
Acetaminophen	16 mg/dL	3.90	104.6	1.14	K, Cl, Ca
		1.50	78.0	0.57	K, Cl, Ca
Ammonium (Chloride)	0.151 mmol/L	4.79	n/a*	1.20	K, Ca
		2.33	n/a*	0.65	K, Ca
Benzalkonium (Chloride)	5 mg/L	3.75	n/a*	1.24	K, Ca
		1.52	n/a*	0.59	K, Ca
Bromide (Sodium)	37.5 mmol/L	4.15	n/a**	1.16	K, Ca
		2.44	n/a**	0.72	K, Ca
Bilirubin	20 mg/dL	4.30	101.9	1.10	K, Cl, Ca
		1.73	83.4	0.62	K, Cl, Ca
Calcium (Chloride)	5.0 mmol/L	3.91	n/a*	n/a*	K
		1.78	n/a*	n/a*	K
Citrate*** (Sodium)	12 mmol/L	4.25	n/a**	n/a***	K
		1.90	n/a**	n/a***	K
Ethanol	130 mmol/L	4.72	99.9	1.23	K, Cl, Ca
		1.74	79.2	0.56	K, Cl, Ca
Fluoride (Sodium)	63.2 µmol/L	n/a**	102.8	1.22	Cl, Ca
		n/a**	79.9	0.57	Cl, Ca
Heparin-Na	300 U/dL	4.19	103.5	1.32	K, Cl, Ca
		1.45	76.2	0.57	K, Cl, Ca
Hydroxy Urea	3.08 mg/dL	3.80	101.9	1.20	K, Cl, Ca
		1.54	78.2	0.59	K, Cl, Ca
Ibuprofen	1.06 mmol/L	n/a**	104.5	1.17	Cl, Ca
		n/a**	82.6	0.56	Cl, Ca
Intralipid	2%	n/a**	89.2	1.00	K, Cl, Ca
		n/a**	68.7	0.35	K, Cl, Ca
Iodide (Potassium)	3.0 mmol/L	n/a	n/a**	1.23	Ca
		n/a	n/a**	0.58	Ca
Ipratropium (Bromide)	0.08 mg/L	3.94	104.0	1.18	K, Cl, Ca
		1.54	81.5	0.54	K, Cl, Ca
Lithium (Chloride)	3.2 mmol/L	4.04	n/a	1.18	K, Ca
		1.63	n/a*	0.49	K, Ca
Magnesium (Chloride)	4.1 mmol/L	4.08	n/a*	1.20	K, Ca
		1.59	n/a*	0.56	K, Ca
Oxalate (Potassium)	90 µmol/L	n/a*	104.9	1.18	Cl, Ca
		n/a*	80.9	0.57	Cl, Ca

pH	8.0 units	4.23	106.9	n/a**	K, Cl
		1.87	85.8	n/a**	K, Cl
(Sodium) Perchlorate	6 mg/dL	4.14	105.6	1.21	K, Cl, Ca
		1.62	77.5	0.58	K, Cl, Ca
(Sodium) Salicylate	0.207 mmol/L	4.30	105.4	1.20	K, Cl, Ca
		1.71	79.2	0.57	K, Cl, Ca
Na (Chloride)	170 mmol/L	3.70	n/a	1.15	K, Ca
		1.67	n/a	0.59	K, Ca
Thiocyanate (Potassium)	898 µmol/L	n/a*	n/a*	1.12	Ca
		n/a*	n/a*	0.52	Ca
Thiocyanate (Sodium)	600 µmol/L	3.75	n/a**	n/a*	K
	600 µmol/L	2.07	n/a**	n/a*	K

(*) Not tested for this analyte.

(**) See Table II

(***) Citrate is a strong binding substance to ionized calcium.

Table II below lists substances the demonstrated interference with the listed analyte results. The table also provides the concentrations of the interferant level, the bias observed, and the direction (Positive/Negative).

Interfering Substance	Affected Analyte	Analyte concentration	Interferant Concentration Tested	Bias observed	Comments
Bromide	**Chloride** Interference when change > ± 5mmol/L or ± 5%)	105 mmol/L	1.5	+ 4.2mmol/L	No significant interference (< ± 5mmol/L or ± 5%)
		82 mmol/L	1.5	+ 4.2mmol/L	
		121 mmol/L	37.5	+ 49 mmol/L	Significant positive interference from Bromide above 1.5 mmol/L
Citrate (see note)	**Chloride** Interference when change > ± 5mmol/L or ± 5%)	103 mmol/L	3.0 mmol/L	- 3.0 mmol/L	No significant interference (< ± 5mmol/L or ± 5%)
		80 mmol/L	3.0 mmol/L	- 3.0 mmol/L	
		103 mmol/L	6.0 mmol/L	-7.0 mmol/L	Significant negative interference from citrate above 3.0 mmol/L
		103 mmol/L	9.0 mmol/L	-10.5 mmol/L	
Fluoride	**Potassium** Interference when change >0.3 mmol/L or > ± 7%	1.42 mmol/L	55.0 µmol/L	-0.014 mmol/L	No significant interference (< ± 0.3 mmol/L or ± 7%)
		1.93 mmol/L	63.2 µmol/L	-0.3 mmol/L	Significant negative interference from Fluoride above 55.0 µmol/L
		4.3 mmol/L	63.2 µmol/L	-0.4 mmol/L	
Ibuprofen	**Potassium** Interference when change >0.3 mmol/L or > ± 7%	3.85 mmol/L	1.0 mmol/L	+0.11 mmol/L	No significant interference (< ± 0.3 mmol/L or ± 7%)
		2.13 mmol/L	1.0 mmol/L	+0.15 mmol/L	
		4.75 mmol/L	1.06 mmol/L	+0.5 mmol/L	Significant negative interference from Ibuprofen above 1.0 mmol/L
		1.83 mmol/L	1.06 mmol/L	+0.08 mmol/L	
Intralipid	**Potassium** Interference when change >0.3 mmol/L or > ± 7%	1.45 mmol/L	1gr/dL (1%)	-0.07 mmol/L	No significant interference (< ± 0.3 mmol/L or ± 7%)
		3.67 mmol/L	1gr/dL (1%)	-0.02 mmol/L	
		4.6 mmol/L	1.5gr/dL (1.5%)	-0.75 mmol/L	Significant negative interference from Intralipid above 1.0 mg/dL (1.0%)
		1.24 mmol/L	2gr/dL (2%)	-0.18 mmol/L	
		6.6 mmol/L	2gr/dL (2%)	-2.4 mmol/L	
Iodide	**Chloride** Interference when change	84 mmol/L	0.55 mmol/L	+3.6 mmol/L	No significant interference (< ± 5mmol/L or ± 5%)
		103 mmol/L	0.65 mmol/L	+4.7 mmol/L	
		102.9 mmol/L	3.0 mmol/L	+19 mmol/L	

	> ± 5mmol/L or ± 5%)	78.9 mmol/L	3.0 mmol/L	+18.8 mmol/L	Significant positive interference from iodide above 0.55 mmol/L
Thiocyanate	**Chloride** Interference when change > ± 5mmol/L or ± 5%)	82.8 mmol/L	600 µmol/L	+4.4 mmol/L	No significant interference (< ± 5mmol/L or ± 5%)
		106.6 mmol/L	600 µmol/L	+4.5 mmol/L	
		82.0 mmol/L	898 µmol/L	+11.8 mmol/L	Significant positive interference from thiocyanate above 60 µmol/L
		107 mmol/L	898 µmol/L	+11.0 mmol/L	
Thiosulfate	**Chloride** Interference when change > ± 5mmol/L or ± 5%)	84 mmol/L	5 mmol/L	-2.1 mmol/L	No significant interference (< ± 5mmol/L or ± 5%)
		104 mmol/L	5 mmol/L	-2.1 mmol/L	
		85.6 mmol/L	10 mmol/L	-2.2 mmol/L	
		103.2 mmol/L	10 mmol/L	-3.9 mmol/L	
		80.1 mmol/L	20 mmol/L	-8.1 mmol/L	Significant negative interference from thiosulfate above 10 mmol/L
		103.2 mmol/L	20 mmol/L	-8.9 mmol/L	
Thiosulfate	**Potassium** Interference when change >0.3 mmol/L or > ± 7%	3.9 mmol/L	5 mmol/L	-0.12 mmol/L	No significant interference (< ± 0.3 mmol/L or ± 7%)
		1.3 mmol/L	5 mmol/L	-0.01 mmol/L	
		4.64 mmol/L	10 mmol/L	-0.23 mmol/L	
		2.67 mmol/L	10 mmol/L	-0.11 mmol/L	
		4.4 mmol/L	20 mmol/L	-0.34 mmol/L	Significant negative interference from thiosulfate above 10.0 mmol/L
		1.6 mmol/L	20 mmol/L	-0.10 mmol/L	
Thiosulfate	**Ionized Calcium** Interference when change >0.1 mmol/L or > ± 10%	1.22 mmol/L	5 mmol/L	-0.07 mmol/L	No significant interference (< ± 0.1 mmol/L or ± 10%)
		0.53 mmol/L	5 mmol/L	-0.01 mmol/L	
		1.21 mmol/L	10 mmol/L	-0.11 mmol/L	
		0.85 mmol/L	10 mmol/L	-0.06 mmol/L	
		1.22 mmol/L	20 mmol/L	-0.2 mmol/L	Significant negative interference from thiosulfate above 5.0 mmol/L
		0.55 mmol/L	20 mmol/L	-0.05 mmol/L	
pH	**Ionized Calcium** Interference when change >0.1 mmol/L or > ± 10%	1.15 mmol/L	7.75 Units	-0.12 mmol/L	Significant negative interference from high pH at and above 7.75 pH units
		0.84 mmol/L	7.75 units	-0.11 mmol/L	
		1.17 mmol/L	8.0 units	-0.13 mmol/L	
		0.68 mmol/L	8.0 units	-0.24 mmol/L	

Note: Citrate is a strong binding substance to ionized calcium similar to EDTA

Performance Conclusions:

The technological and functional characteristics of the new EasyStat 300 described in the 510(k) summary are substantially equivalent to that of the reference device EasyStat-Cl (k063376) for K^+, Cl^-, and Ca^{++}.

The analytical study results demonstrate the EasyStat 300 is safe and effective for its intended purpose and equivalent in performance to the reference device.