510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K220328

B Applicant

Medica Corporation

C Proprietary and Established Names

EasyStat 300

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CGA	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
GKF	Class II	21 CFR 864.5600 - Automated hematocrit instrument	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glucose (Glu) and Hematocrit (Hct).

C Type of Test:

Glucose – quantitative, amperometric
Hematocrit – quantitative, electrical conductivity

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The EasyStat 300 is designed for clinical laboratory use, making quantitative measurements of Glucose (Glu) and Hematocrit % (Hct) in whole blood (arterial/venous) samples from Li-Heparinized Syringes or Capillary Tubes. This analyzer should only be used by trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with metabolite disturbances.

Glucose (Glu) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia, and pancreatic inlet cell carcinoma.

Hematocrit (Hct) measurements are used to measure red cell volume in blood. Abnormal states include anemia and erythrocytosis.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use only

D Special Instrument Requirements:

EasyStat 300 Analyzer

IV Device/System Characteristics:

A Device Description

The candidate device is a small bench-top analyzer for use by health care professionals. The analyzer incorporates a replaceable EasyStat 300 ISE cartridge that is comprised of sensors for measurement of glucose (Glu) and hematocrit (Hct). The analyzer draws 175µL of human lithium heparinized venous or arterial whole blood samples when operated in syringe mode, and 100µL of human lithium heparinized venous or arterial whole blood samples when operated in capillary mode.

The analyzer incorporates a replaceable reagent module containing calibrating solutions (A2, B2, and C2) for the sensors. The reagent module contains encoded reagent information (calibration values and expiration date) which is read by the analyzer upon installation of the reagent module. Calibrations are performed automatically or on-demand by the user.

The EasyStat 300 Analyzer was also cleared for making quantitative measurements of pO2 (partial pressure of oxygen), pCO2 (partial pressure of carbon dioxide), and pH (hydrogen ion

activity) in K211559 and K+ (potassium), Ca++ (ionized calcium), and Cl- (Chloride) in K220396.

B Principle of Operation:

The EasyStat 300 uses biosensors incorporated in the Glu-Hct sensor cartridge for the measurement of glucose and hematocrit in patient's blood samples.

Glucose is measured amperometrically on the cartridge using electrodes that measure the change in current at the sensor surface. The sensor uses glucose oxidase to produce hydrogen peroxide (H_2O_2), and the electrons generated in the oxidation process produce an electrical current that is proportional to the glucose concentration in the sample.

Hematocrit is quantified by measuring the electrical impedance of a blood sample following calibration of the Hct sensor using two standard solutions. The Hct concentration obtained is corrected for the concentration of sodium ions.

V Substantial Equivalence Information:

A Predicate Device Name(s):
GEM Premier ChemSTAT

B Predicate 510(k) Number(s):
K223090

C Comparison with Predicate(s):

Device & Predicate Device(s):	K220328	K223090
Device Trade Name	EasyStat 300	GEM Premier ChemSTAT
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the measurement of Glucose (Glu) and Hematocrit % (Hct)	Same
Sample Type	arterial and venous lithium heparinized whole blood	Same
General Device Characteristic Differences		
Use Environment	Clinical Laboratory	Clinical Laboratory and Point of Care
Analytes Measured	Glu and Hct	Sodium (Na+), Potassium (K+), Ionized Calcium (Ca++), Chloride (Cl-), Glucose

Device & Predicate Device(s):	K220328	K223090
		(Glu), Lactate (Lac), Hematocrit (Hct), Creatinine (Crea), Blood Urea Nitrogen (BUN), Total Carbon Dioxide (tCO2), pH, and partial pressure of carbon dioxide (pCO2)

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3 "Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline – 3rd Edition"
- CLSI EP07-A3 "Interference Testing in Clinical Chemistry: Approved Guideline – 3rd Edition"
- CLSI EP09c "Method Procedure Comparison and Bias Estimation Using Patient Samples – 3rd Edition"
- CLSI EP17-A2 "Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures: Approved Guideline – 2nd Edition"
- CLSI EP37 E1 "Supplemental Tables for Interference Testing in Clinical Chemistry"
- IEC 61010-1 "Safety Requirement for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements"
- ISO 17511:2020 "In Vitro Diagnostic Medical Devices – Requirements for Establishing Metrological Traceability of Values Assigned to Calibrators, Trueness Control Materials, and Human Samples
- CLSI EP32-R "Metrological Traceability and Its Implementation; A Report"
- CLSI EP25-Ed2 "Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – 2nd Edition"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The Precision of the EasyStat 300 was evaluated in two studies: a single-site, 20-day study using aqueous QC material and a multi-site, 5-day study using venous whole blood from donors. Each study was performed in both Syringe and Capillary mode.

Single-Site Study – 20-day with aqueous QC material
Three levels of aqueous QC material were assayed for Glucose and two levels of aqueous QC material were assayed for Hematocrit. Testing was performed using three EasyStat 300 analyzers and a single lot of cartridges. Each sample was measured in duplicate per run with two runs per day over twenty non-consecutive days, resulting in a total of 80 measurements

per level. Data collected from each of the three analyzers were evaluated for Repeatability (within-run) and Within-Device precision and the results from one representative analyzer are summarized below:

Single Site 20-day Precision Summary

Analytes	Mode	Level	Mean Value	N	Repeatability		Within-Device	
					SD	%CV	SD	%CV
Glucose	Syringe	1	325	80	4.14	1.3	6.48	2.0
		2	91	80	1.54	1.7	1.98	2.2
		3	46	80	0.97	2.1	1.38	3.0
	Capillary	1	295	80	6.62	2.2	9.69	3.3
		2	86	80	2.49	2.9	2.75	3.2
		3	43	80	2.02	4.7	2.32	5.4
Hematocrit	Syringe	1	27	80	0.32	1.2	0.45	1.7
		2	47	80	0.25	0.5	0.49	1.0
	Capillary	1	26	80	0.70	2.8	0.75	2.9
		2	44	80	0.40	0.9	0.52	1.2

Multi-Site Study – 5-day with venous whole blood

Three levels of venous whole blood were assayed for both Glucose and Hematocrit. Testing was performed by using three EasyStat 300 analyzers and three cartridge lots (one per instrument). Each sample was measured with five replicates per run, with one run per day over five consecutive days, resulting in a total of 25 measurements per level on each instrument. Data collected from each of the three analyzers were evaluated for Repeatability (Within-Run precision) and Within Laboratory precision. The results from one representative analyzer are summarized in the tables below:

Multi Site 5-day Precision Summary - Glucose

Glu (Syringe Mode)					
Sample	Mean	Repeatability		Within Laboratory	
		SD	%CV	SD	%CV
1	54.9	0.5	1.0%	1.2	2.2%
2	40.3	1.0	2.4%	1.1	2.6%
3	51.1	1.0	2.1%	1.1	2.1%
4	40.3	1.4	3.6%	1.4	3.6%
5	45.3	2.1	4.7%	2.1	4.7%
6	117.9	1.6	1.3%	2.5	2.1%
7	115.3	1.6	1.4%	2.1	1.8%
8	76.2	1.3	1.7%	1.3	1.7%
9	94.3	1.8	1.9%	2.1	2.2%
10	114.7	2.1	1.9%	2.4	2.1%
11	265.9	1.8	0.7%	6.0	2.2%
12	256.0	1.5	0.6%	4.9	1.9%
13	235.3	1.6	0.7%	3.2	1.4%
14	248.9	1.9	0.8%	4.1	1.6%

Glu (Capillary Mode)					
Sample	Mean	Repeatability		Within Laboratory	
		SD	%CV	SD	%CV
1	51.1	0.7	1.4%	1.6	3.1%
2	37.4	1.0	2.8%	1.7	4.6%
3	49.5	1.6	3.3%	1.6	3.3%
4	39.0	1.8	4.6%	1.8	4.7%
5	43.7	2.1	4.8%	2.1	4.8%
6	115.8	1.9	1.7%	3.1	2.7%
7	113.3	2.0	1.8%	2.1	1.8%
8	76.2	1.5	2.0%	1.6	2.1%
9	91.9	2.2	2.4%	2.4	2.6%
10	111.1	1.9	1.7%	2.5	2.2%
11	255.1	2.8	1.1%	6.2	2.4%
12	253.3	2.5	1.0%	5.0	2.0%
13	234.3	2.3	1.0%	3.2	1.4%
14	238.8	3.7	1.5%	3.8	1.6%

15	206.3	1.7	0.8%	2.3	1.1%		15	255.1	1.3	0.5%	3.6	1.4%

Multi Site 5-day Precision Summary – Hematocrit

Hct (Syringe Mode)						Hct (Capillary Mode)					
Sample	Mean	Repeatability		Within Laboratory		Sample	Mean	Repeatability		Within Laboratory	
		SD	%CV	SD	%CV			SD	%CV	SD	%CV
1	27.5	0.5	1.8%	0.8	3.0%	1	26.9	0.8	3.0%	1.2	4.6%
2	22.5	0.5	2.3%	0.7	3.0%	2	22.9	0.5	2.4%	1.2	5.3%
3	23.4	0.3	1.1%	1.1	4.5%	3	23.5	0.4	1.6%	1.1	4.9%
4	22.9	0.4	1.8%	0.7	3.1%	4	23.1	1.2	5.4%	1.2	5.4%
5	26.3	0.5	1.8%	0.8	2.9%	5	26.3	0.6	2.3%	1.0	3.7%
6	40.3	0.7	1.8%	0.9	2.1%	6	40.4	0.9	2.3%	1.1	2.7%
7	39.4	0.3	0.7%	1.2	3.1%	7	39.7	0.6	1.5%	1.9	4.9%
8	37.5	0.5	1.3%	1.5	4.0%	8	37.6	0.4	1.2%	1.4	3.6%
9	47.4	0.5	1.0%	0.7	1.4%	9	48.7	0.7	1.5%	1.5	3.1%
10	50.0	0.4	0.9%	0.6	1.1%	10	50.9	0.5	0.9%	2.0	3.9%
11	59.3	2.0	3.3%	2.0	3.3%	11	57.6	2.0	3.5%	2.6	4.6%
12	59.1	1.4	2.4%	2.4	4.1%	12	60.2	1.8	3.0%	3.2	5.3%
13	56.8	0.5	0.9%	1.4	2.4%	13	56.9	0.4	0.6%	2.0	3.6%
14	63.5	0.5	0.8%	0.8	1.3%	14	64.1	0.5	0.8%	0.9	1.5%
15	67.1	0.8	1.2%	0.9	1.4%	15	68.4	0.6	0.8%	2.3	3.3%

2. Linearity:

The linearity study was conducted using 9 samples covering the measuring range assayed in triplicate on each of three EasyStat 300 analyzers. The study was conducted in both syringe mode and capillary mode, using one lot of cartridges over one day. Native lithium heparin venous whole blood samples were spiked with D-glucose (for Glu) or packed red blood cells (for Hct) or diluted with plasma from the same donor. Regression analysis confirmed first order linearity for both glucose and hematocrit within the specified reportable ranges. The maximum % deviation from linearity noted was 9.1%. The summary analysis is included in the table below:

Analyte	Claimed Range	Mode	Analyzer	Tested Range	Slope	Intercept	R^2	Max Deviation
Glucose	25-500 mg/dL	Syringe	1	18-530	0.970	-3.04	0.999	-4.2%
			2	19-558	1.014	-3.13	0.999	-3.7%
			3	18-530	0.971	-2.29	0.999	-3.1%
		Capillary	1	18-536	0.969	0.56	0.999	0.8%
			2	20-556	1.028	-2.86	0.999	-2.7%
			3	20-544	1.001	-3.18	0.999	-3.6%
Hematocrit	10-70%	Syringe	1	8-77	1.007	0.82	0.999	6.4%
			2	9-78	1.007	1.60	0.999	8.3%

Analyte	Claimed Range	Mode	Analyzer	Tested Range	Slope	Intercept	R^2	Max Deviation
			3	9-77	1.000	2.00	1.000	9.1%
		Capillary	1	6-74	0.974	0.37	0.999	2.7%
			2	6-78	1.011	0.34	0.999	2.3%
			3	6-78	1.000	0.78	0.999	4.8%

3. Analytical Specificity/Interference:

Interference with endogenous and exogenous substance was evaluated using lithium heparin venous whole blood samples. Two levels of Glu (ranging from 26.4 to 346.4 mg/dL) and two levels of Hct (ranging from 18.2% to 48.4%) were tested with and without the potential interfering substances.

Bias was calculated as the difference between the average value with interferent and the average value without interferent. Interferents identified with a bias less than the total allowable error (TAE) were listed as non-interfering while those with bias greater than the TAE were listed with their calculated % bias.

Analyte	TAE
Glucose	± 6 mg/dL or 10%
Hematocrit	± 4% or 10%

The potential interferents that were tested are listed in the tables below, along with the highest concentration that each substance did not cause interference:

Glucose

Interferent	Highest Concentration that did not cause interference
Acetaminophen	8.0 mg/dL
Acetoacetate (Lithium)	2 mmol/L
N-Acetylcysteine	15 mg/dL
Albumin	60 g/L
Ascorbic Acid	0.298 mmol/L
Bilirubin (conjugated)	20 mg/dL
Chloropromazine	9 µmol/L
Citrate (Sodium)	12.0 mmol/L
Creatinine	15 mg/dL
Dobutamine	0.121 mg/dL
Dopamine	4.06 µmol/L
Ethanol	130 mmol/L
Fluoride (Sodium)	40 µmol/L
Flaxedil	5 mg/dL

Interferent	Highest Concentration that did not cause interference
Fructose	1 mM
Galactose	3.33 mmol
Glycolic Acid	0.75 mmol/L
Hematocrit	75%
Heparin (Sodium)	330 U/dL
Hemoglobin	22 gr/dL
B-Hydroxybutyrate	2 mmol/L
Hydroxy Urea*	0.12 mg/dL
Ibuprofen	1.06 mmol/L
Isoniazid*	2 mg/dL
Lactate	10 mmol/L
Maltose	10.3 mmol/L
Mannose	20 mg/dL
pO_2	74 mmHg
Pralidoxime Iodide	40 µg/dL
Pyruvate (Sodium)	5 mg/dL
Triglycerides (Intralipids)	2%
Urea	42.9 mmol/L
Xylose	20 mg/dL

*The following substances were shown to exhibit interference with glucose. For hydroxyurea, an interference was noted when tested at 3.08 mg/dL, resulting in a bias of up to 458% for glucose. For isoniazid, an interference was noted when tested at 3mg/dL, resulting in a bias of up to 30% for glucose.

Hematocrit

Interferent	Highest Concentration that did not cause interference
Acetaminophen	15.6 mg/dL
Albumin	60 g/L
Ammonium Chloride	0.1 mM
Benzalkonium Chloride	0.25 mg/dL
Bilirubin	40 mg/dL
Bromide (Sodium)	2.0 mM
Chloropromazine	5 mg/dL
Epinephrine	0.4 µM
Ethanol	130 mmol/L
Fluoride (Sodium)	0.1 mM
Fructose	1 mM

Interferent	Highest Concentration that did not cause interference
Galactose	1 mM
Ibuprofen	1.06 mmol/L
Intralipids	2000 mg/dL
Iodide (Potassium)	0.5 mM
Isoniazid	0.4 µM
Mannose	10 mg/dL
Perchlorate (Sodium)	5.0 mg/dL
Platelets	790 x 10^6 / mL
Pralidoxime Iodide	4 mg/dL
Salicylate (Sodium)	12 mg/dL
Sodium Chloride	193 mM
Thiocyanate (Potassium)	1.0 mg/dL
White Blood Cells	27 x 10^6 / mL
Xylose	20 mg/dL
Li-Heparin (anticoagulant)	126 IU/mL

4. Assay Reportable Range:

   See section VII A.2, Linearity.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   Glucose is traceable to NIST SRM-917c. Hct traceability is performed using internally produced reference standards and is calculated using conductivity measurements.

6. Detection Limit:

   LoB/LoD

   For Glucose, the Limit of Blank (LoB) was evaluated using five pooled plasma samples. Once LoB was established, LoD was evaluated by spiking glucose into the plasma samples.

   For Hematocrit, the LoB was evaluated using five pooled plasma samples that were prepared through centrifugation of blood samples. Once LoB was established, LoD was evaluated by spiking a small number of red blood cells into the plasma samples.

   All studies were performed in both syringe and capillary mode and carried out on a single instrument with two reagent lots over three consecutive days. Five samples were run with four replicates per reagent lot, resulting in a total of 60 blank replicates per lot for LoB and 60 low level replicates per lot for LoD.

LoQ

For Glucose, the Limit of Quantitation (LoQ) was determined using four pooled plasma samples created by using ultrafiltration until the glucose concentrations were sufficiently low. The ultrafiltered plasma was then spiked with concentrated glucose to achieve glucose levels slightly above the LoD. Values were determined by first measuring on a RapidPoint 500 device.

For Hematocrit, the LoQ was determined using four pooled plasma samples that were prepared through centrifugation of blood samples. A small number of red blood cells were then spiked into the plasma to increase hematocrit level to slightly above the LoD. Values were determined by first measuring on an EasyStat pH, pCO_2, pO_2, Hct, NA^+, K^+, CA^{++} analyzer and then diluting the sample with plasma from the same donor.

Studies were performed in both syringe and capillary modes and carried out on a single instrument with two reagent lots over three consecutive days. Each day, the four samples were run with three replicates per reagent lot, resulting in a total of 36 low level sample replicates per lot.

The Detection Limit results are summarized in the tables below:

Limit of Blank, Detection, and Quantitation Summary

Syringe	LoB	LoD	LoQ	LDL* Claim
Glu (mg/dL)	7.5	11.8	25	25
Hct (%)	4	5	8	10

Capillary	LoB	LoD	LoQ	LDL* Claim
Glu (mg/dL)	9.5	14.3	22	25
Hct (%)	4	7	9	10

(*) LDL: Lowest Detection Limit

7. Assay Cut-Off:

Not Applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

The Method Comparison study was conducted using lithium heparin venous and arterial whole blood collected from subjects across two sites. For Glucose, 243 unique samples were analyzed on both an EasyStat 300 candidate device and a Rapidpoint 500 predicate device. For Hematocrit, up to 198 unique samples were analyzed on both an EasyStat 300 candidate device and an EasyStat predicate device. Many of these samples were used to evaluate both Glu and Hct.

Data was obtained in both Syringe and Capillary modes on the EasyStat 300 analyzer and analysis was performed using the Weighted Deming method for linear regression.

Analyte	Mode	N	Sample Range	Slope	Intercept	R^2
Glucose	Syringe	198	42-494 mg/dL	0.960	-1.520	0.972
	Capillary	70	84-463 mg/dL	0.9842	0.9685	0.976
Hematocrit	Syringe	242	16-62%	1.098	-2.653	0.872
	Capillary	71	14-64%	0.9665	0.6540	0.972

2. Matrix Comparison:

Not Applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not Applicable.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

Based on published literature, the sponsor included the following in the labeling:

Glucose: 70-105 mg/dL
Hematocrit: 35-50%

Sources:
1) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th ed. Burtis C.A., Ashwood E.R., Bruns D.E., (WB Saunders Co, 2012).

2) B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economics Books, 1987).

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.