January 27, 2023

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

Re: K211559
Trade/Device Name: EasyStat 300
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (PCO2, PO2) and Blood pH Test System
Regulatory Class: Class II
Product Code: CHL
Dated: September 30, 2022
Received: October 3, 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 Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.01.27 12:07:22 -05'00'

Paula V. Caposino, Ph.D.
Acting Deputy 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)*
k211559

Device Name
EasyStat 300

Indications for Use *(Describe)*

The EasyStat 300 is designed for clinical laboratory use, making quantitative measurements of pO2 (partial pressure of oxygen), pCO2 (partial pressure of carbon dioxide), and pH (hydrogen ion activity) 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 blood gas and/or acid-base disturbances.

Blood gases (pO2, pCO2) and pH measurements in blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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:
January 25th, 2023

Trade Name: EasyStat 300
Common Name: Blood Gas Analyzer
Classification Name: Blood Gases and Blood pH Test System

Regulatory Information:

EasyStat 300 Analyzer

Description	Regulation No.	Device Class	Product Code
Blood Gas and blood pH	862.1120	II	CHL

EasyQC BGEM Material for EasyStat

Description	Regulation No.	Device Class	Product Code
Quality control Material	862.1660	Class I	JJY

Predicate devices:

Description	510(k)	Regulation No.	Device Class	Product Code
EasyStat Blood Gas Analyzer	K021515	862.1120	II	CHL

Device Description and Indications for Use:

The EasyStat 300 is a system for use by health care professionals to rapidly analyze whole blood samples. Good Laboratory Practices (GLPs) are strongly advised when using the EasyStat 300. The analyzer incorporates a Reagent Module containing the "calibrating" solutions A2, B2, and a "conditioning" solution C2, which is also use a calibrant for the Oxygen sensor. 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 EasyStat 300 uses 175µL of whole blood in the "Syringe" mode and 100µL of whole blood in the "Capillary" mode to analyze patient samples. Medica provides a capillary tube kit (REF 8303) used for the capillary data collection in this submission. The EasyStat 300 reports results for blood Gases (*P*CO2, *P*O2), and pH. 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.

The EasyStat 300 is a microprocessor-controlled device with a touch sensitive screen that guides the operator through the different menu options and proper operation. It also incorporates a thermal printer to record all reported results and patient information as described in the Operator's Manual. The device software has incorporated routines to assist the end-user with maintenance, cleaning, and troubleshooting activities also outlined in the manual. The incorporated USB port may be used to download data and also to update the software version based on detailed instructions by Medica Corporation.

The blood gas and pH sensors require calibration and cleaning after a predefined number of samples are analyzed as described in the Operator's Manual. The pH and *P*CO2 sensors are based on potentiometric sensor design, generating a small voltage that is dependent on the concentrations of these analytes in the patient sample. The *P*O2 sensor is based on amperometric sensor design that generates a small current that is dependent on the concentration of oxygen in the patient sample. The theory and mathematical formulas on which the sensor functionality is based are described in detail in the Operator's Manual.

Medica's EasyQC materials (REF 8315/8316/8317 and 8309) are specifically formulated for the EasyStat 300. Medica requires the use of quality controls everyday 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 EasyQC materials for the EasyStat 300 have a minimum of three years shelf-life when stored refrigerated (2^0-8^0C).

The Reagent Module (REF 8101) has a twelve-month shelf-life when stored at 4^0-25^0C. Use-life depends on the number of samples analyzed and the overall performance of the sensors. The analyzer monitors the consumption of calibrant solution A2 and warns the operator when the reagent module is about to expire. A typical Use-life for an average user is expected to be 15

days and/or 350 samples whichever comes first. This feature is the same as the one provided with the predicate EasyStat analyzer.

The sensors have one-year shelf-life when stored at 4^0-25^0C for blood gases (*P*CO2, *P*O2), pH. 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 info. 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.

Intended use and Indications for use of the analytes measured by the EasyStat 300 are:

The EasyStat 300 provides quantitative measurements of pH (hydrogen ion activity), *p*CO2 (partial pressure of carbon dioxide), and *p*O2 (partial pressure of oxygen) in Li-heparinized whole blood (arterial/venous) samples from 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 blood gas and/or acid-base disturbances.

*p*CO2, *P*O2 (blood gases) and pH measurements in blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.

The EasyStat 300 has the same technical characteristics with the predicate device. Sensor technology, Reagent module calibrating solutions, principles of operation, and parameters measured are practically the same. User device display may differ due to the new touch sensitive screen, user menu preferences, and more friendly user interface. None of these differences affect the performance when compared to the predicate EasyStat analyzer. The following sections provide a brief discussion of the performance characteristics of the EasyStat 300 based on the studies submitted to determine substantial equivalency.

All tests on the following sections are non-clinical bench tests except for Method Comparison, which was performed on a clinical laboratory using actual venous and arterial blood. The non-clinical tests also used contrived venous blood of aqueous QC materials that are part of the EasyStat 300 system.

Substantial Equivalency Between EasyStat 300 and predicate EasyStat

	EasyStat 300	EasyStat Ca++
510(k) Number	New IVD Device	K021515
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		
pH	Potentiometric	Potentiometric
PCO2	Potentiometric	Potentiometric
PO2	Amperometric	Amperometric
Calibrant Base	Aqueous	Aqueous
Measured Parameters	pH, *p*CO2, *p*O2	pH, PCO2, PO2
Sample Type	Whole Blood	Whole Blood
Sample Volume	175µL Syringe, 100 µL Capillary	120µL Syringe, 95 µL Capillary
Analysis Time	110 seconds	120 seconds
Measured Range		
pH	6.800 to 8.000 units	6.500 to 8.000 units
*p*CO2	5.0 – 150.0 mmHg	5.0 – 150.0 mmHg
*p*O2	5-700 mHg	5-700 mmHg
Display	TFT LCD, Touch screen	LCD
Printer	Thermal	Thermal
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
Calculated Parameters	Patient Temp. Correction, pH, PCO2, PO2	Patient Temp. Correction, pH, PCO2, O2
	Total Hemoglobin	Total Hemoglobin
	Hematocrit, measured	Hematocrit, measured
	Total CO2 (TCO2)	Total CO2 (TCO2)
	Bicarbonate ($HCO3^-$)	Bicarbonate ($HCO3^-$)
	Base excess of blood (BE_b)	Base excess of blood (BE_b)
	Base excess of Extracellular fluid (BEecf)	Base excess of Extracellular fluid (BEecf)
	Standard Bicarbonate (SBC)	Standard Bicarbonate (SBC)
	Oxygen Saturation calculated at P_{50} ($\%SO_{2c}$)	Oxygen Saturation calculated at P_{50} ($\%SO_{2c}$)
	Total Oxygen Content (ctO2)	Total Oxygen Content (ctO2)
	Alveolar-Arterial O2 Gradient (A-aDO2)	Alveolar-Arterial O2 Gradient (A-aDO2)
	Respiratory Index (RI)	Respiratory Index (RI)
Safety Compliance	EN61010	EN61010
EMC Compliance	EN55011	EN55011
UL Tested	UL3101	UL3101

CSA Tested	C22.2	C22.2
Dimensions	14.5”WX13”HX7”D	14.25”W X 12.5”H X 7”D
Voltage Requirements	110/115VAC, 50-60Hz, 220VAC, 50-60Hz	110/115VAC, 50-60Hz, 220VAC, 50-60Hz

All tests on the following sections are non-clinical bench tests except for Method Comparison, which was performed on a clinical laboratory using actual venous and arterial blood. The non-clinical tests also used contrived venous blood of aqueous QC materials that are part of the EasyStat 300 system.

Performance Summaries:

Precision Studies:

Repeatability 20-Day Precision Study (Syringe & Capillary Modes) – 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.

Typical Repeatability Precision Study (Syringe Mode) – Aqueous Controls

	Precision Estimate	Level	Target	Performance Specs		System 1_P21			System 2_P22			System 3_P23		
				SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
PO2	Within-Device (Total)	1	36	2.5		36	1.39		35	1.33		37	1.18	
		2	98	2.5		99	1.61		98	2.23		99	1.56	
		3	136		2.5%	137		1.4	137		1.4	138		1.5
PCO2	Within-Device (Total)	1	69.0		5.0%	68.9		0.9	68.1		0.9	68.3		0.8
		2	45.0		4.0%	45.4		1.2	45.2		1.0	45.2		0.9
		3	21.0	2.0		21.2	0.28		21.4	1.13		21.1	0.23	
pH	Within-Device (Total)	1	7.186	0.020		7.183	0.002		7.182	0.002		7.185	0.001	
		2	7.411	0.015		7.410	0.002		7.410	0.003		7.408	0.002	
		3	7.621	0.020		7.622	0.004		7.623	0.002		7.618	0.002	

Typical Repeatability Precision Study (Capillary Mode) – Aqueous Controls

20 Day QC Precision (Capillary Mode)														
Analyte	Precision Estimate	Level	Target	Performance Specs		Actual Performance								
						Unit 1			Unit 2			Unit 3		
				SD	CV	Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
PO_2	Repeatability (Within-Run)	1	36	3		53	2.70	5.1	53	1.70	3.2	52	2.41	4.6
		2	98	3		107	1.51	1.4	108	1.84	1.7	108	1.99	1.8
		3	136		3.0%	140	1.85	1.3	140	1.52	1.1	141	2.50	1.8
	Within-Device (Total)	1	36	4		53	3.67	7.0	53	2.81	5.3	52	4.00	7.7
		2	98	4		107	2.49	2.3	108	2.37	2.2	108	2.25	2.1
		3	136		4.0%	140	2.30	1.6	140	3.17	2.3	141	2.72	1.9
PCO_2	Repeatability (Within-Run)	1	69.0		5.0%	63.4	0.96	1.5	63.0	0.93	1.5	63.2	0.68	1.1
		2	45.0		4.0%	41.4	0.45	1.1	41.1	0.50	1.2	41.2	0.42	1.0
		3	21.0	1.5		21.2	0.19	0.9	21.4	0.21	1.0	21.2	0.23	1.1
	Within-Device (Total)	1	69.0		5.0%	63.4	1.14	1.8	63.0	1.15	1.8	63.2	1.00	1.6
		2	45.0		4.0%	41.4	0.52	1.3	41.1	0.55	1.3	41.2	0.46	1.1
		3	21.0	2.0		21.2	0.23	1.1	21.4	0.27	1.3	21.2	0.25	1.2
pH	Repeatability (Within-Run)	1	7.186	0.020		7.209	0.004	0.06	7.192	0.006	0.08	7.197	0.007	0.09
		2	7.411	0.015		7.433	0.003	0.04	7.421	0.003	0.04	7.423	0.002	0.03
		3	7.621	0.020		7.619	0.004	0.05	7.612	0.003	0.03	7.609	0.003	0.04
	Within-Device (Total)	1	7.186	0.020		7.209	0.011	0.16	7.192	0.008	0.10	7.197	0.011	0.16
		2	7.411	0.015		7.433	0.009	0.12	7.421	0.003	0.04	7.423	0.005	0.06
		3	7.621	0.020		7.619	0.007	0.10	7.612	0.004	0.05	7.609	0.004	0.06

Reproducibility (5-Day) Precision Study – Syringe & Capillary Modes

This study was performed as a substitute to the typical single run with twenty whole blood replicates. 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 Repeatability Performance of the EasyStat 300 operating in "Syringe" mode

		Within-Run, 5-day w. Blood Study		
Analyte	Metric	Level 1	Level 2	Level 3
	Avg (mmHg)	39	78	223
PO2	SD (mmHg)	0.6	1.7	3.3
	CV(%)	1.5	2.1	1.5
specification		2.5mmHg	2.5mmHg	3.0%
	Avg (mmHg)	36.9	67.4	132.6
PCO2	SD (mmHg)	0.5	1.3	2.7
	CV(%)	1.3	1.9	2.1
specification		2.0%	3.0%	3.0%
	Avg (pH units)	7.410	7.216	7.588
pH	SD (pH units)	0.007	0.010	0.007
	CV(%)	0.1	0.1	0.1
specification		0.015 units	0.015 units	0.015 units

Typical Reproducibility Performance of the EasyStat 300 operating in "Capillary" mode

		Within-Run, 5-day w. Blood Study		
Analyte	Metric	Level 1	Level 2	Level 3
	Avg (mmHg)	39.7	80.8	225.2
PO2	SD (mmHg)	0.9	1.1	2.2
	CV(%)	2.3	1.4	1
specification		2.4mmHg	3.0%	3.0%
	Avg (mmHg)	36.0	65.9	131.1
PCO2	SD (mmHg)	0.91	1.91	2.62
	CV(%)	2.5	2.9	2
specification		4.0%	5.0%	5.0%
	Avg (pH units)	7.409	7.218	7.561
pH	SD (pH units)	0.008	0.011	0.006
	CV(%)	0.1	0.1	0.1
specification		0.015 units	0.015 units	0.015 units

Conclusion of Precision Studies

Medica's Total precision and Within-Run precision studies, demonstrate that the EasyStat 300 Blood-Gas/Electrolyte/metabolite analyzer is precise and true to Medica's performance specifications and comparable to the predicate device 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 analyzers operating in the "Syringe" mode									
Analyte	Date	Predicate	ES300	Syringe					
				Sensor 1			Sensor 2		
				Linearity	Correlation		Linearity	Correlation	
					Slope	R^2		Slope	R^2
PO2	12/26/19	ES_4	P7	PASS	1.016	0.999			
			P8	PASS	1.027	0.998			
			P17	PASS	1.013	0.999			
PCO2	12/26/19	ES_3	P7	PASS	1.066	0.999			
			P8	PASS	0.984	0.998			
			P17	PASS	0.983	0.996			
pH	01/22/20	ES_4	P7	PASS	1.008	0.996	PASS	1.011	0.996
			P8	PASS	1.022	0.997	PASS	0.981	0.997
			P17	PASS	1.027	0.997	PASS	1.061	0.997

Conclusion of Linearity Study

Data from the linearity study on three EasyStat 300 analyzers performed according to CLSI EP6-A demonstrate that all analytes (pH, *p*CO2, *p*O2) 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 more than 200 donors plus six modified whole blood samples (spiked and diluted). All blood samples were tested on the predicate devices twice and on three EasyStat 300 analyzers. Some samples were modified to achieve analyte levels covering the reportable range using tonometry.

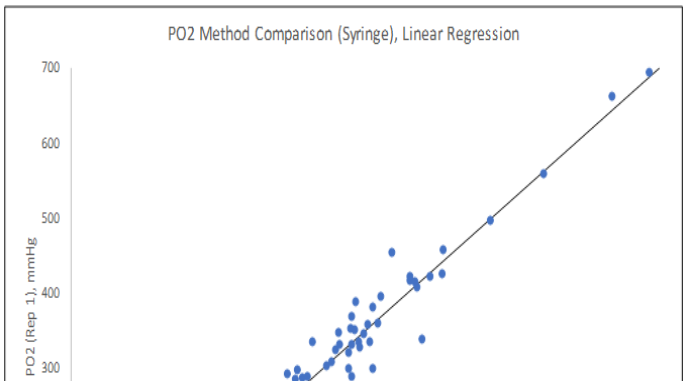
In addition, the "Capillary" mode on The EasyStat 300 was evaluated against the "Capillary" mode on the predicate EasyStat analyzer using the same whole blood samples collected with the same capillary tubes.

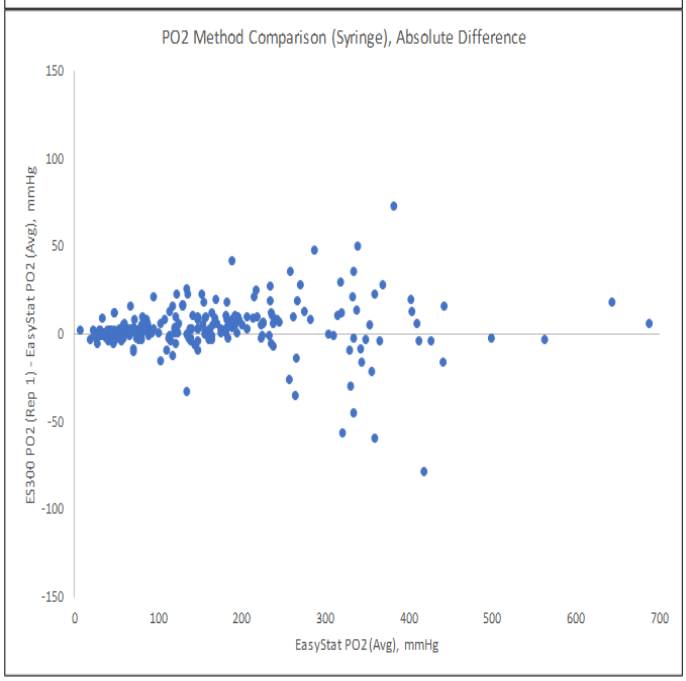
Conclusion of the Method Comparison Study

Data from the Method Comparison study on three EasyStat 300 analyzers demonstrate that all analytes (pH, *p*CO2, *p*O2) reported by the EasyStat 300 are favorably correlated to the predicate/reference device selected for this study. For all analytes (pH, *p*CO2, *p*O2), 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 (*p*O2, *p*CO2, pH) are shown below:

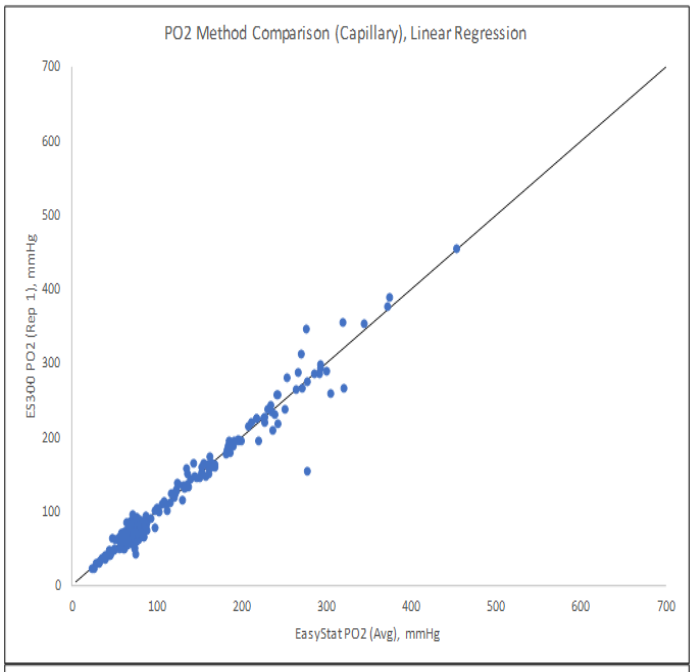
*p*O2 Method Comparison Analysis (Syringe & Capillary Modes)

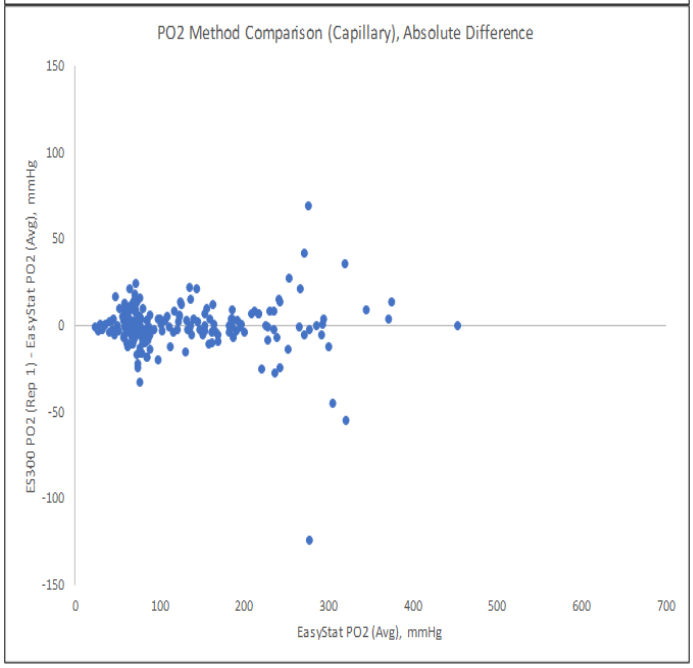




n	Slope	Intercept	R^2	Std Error
272	1.028	-0.887	0.987	13.577

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
30	0.0	29	31	25	35	PASS
45	0.4	44	47	40	50	PASS
60	0.8	59	62	55	65	PASS

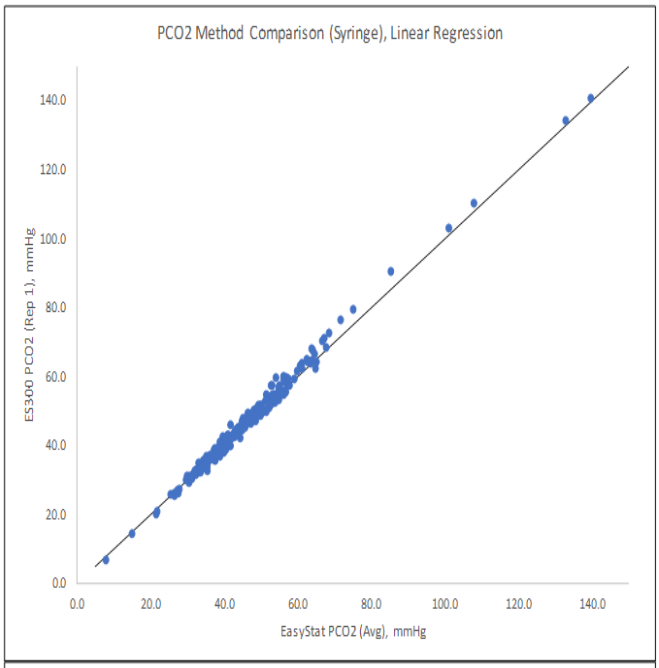


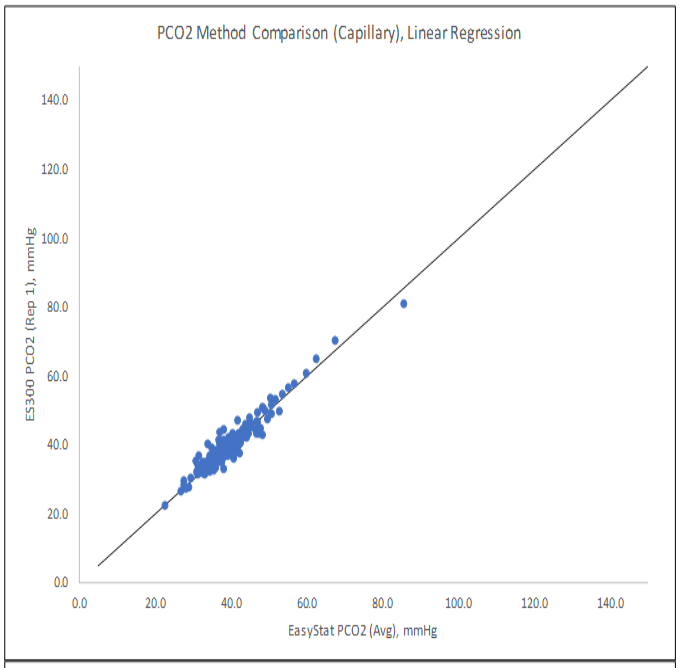


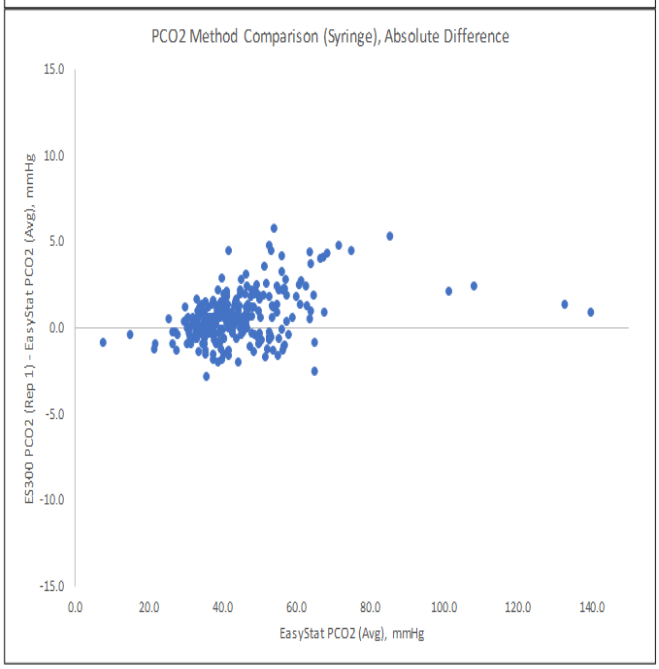
n	Slope	Intercept	R^2	Std Error
224	1.012	-1.537	0.967	14.617

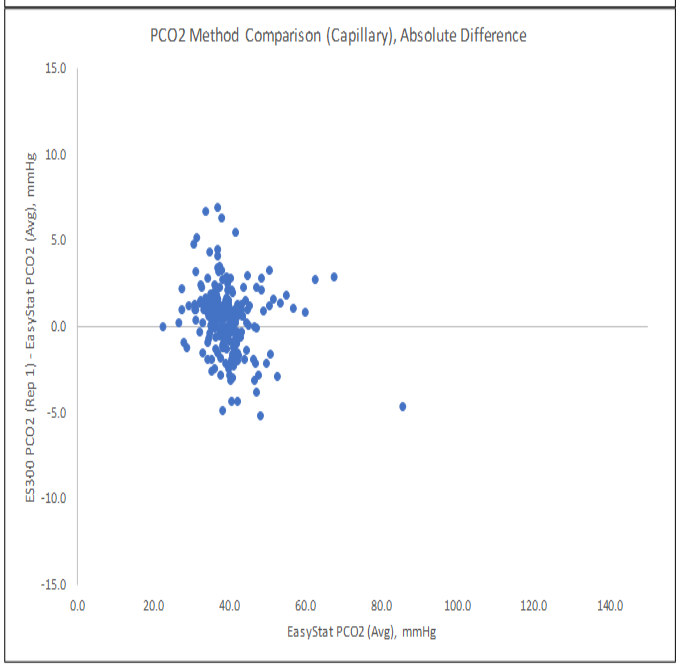
MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
30	-1.2	27	31	25	35	PASS
45	-1.0	42	46	40	50	PASS
60	-0.8	58	61	55	65	PASS

*p*CO2 Method Comparison Analysis (Syringe & Capillary Modes)









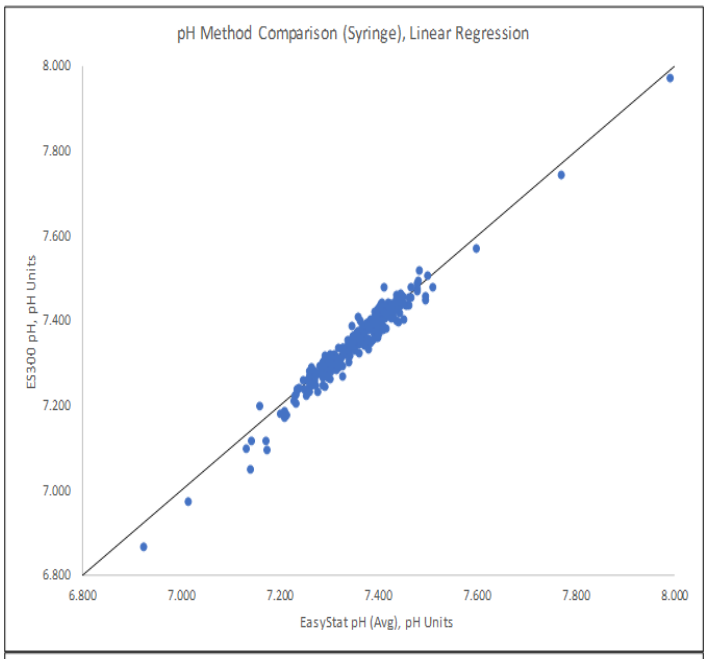
n	Slope	Intercept	R^2	Std Error
265	1.040	-1.159	0.992	1.326

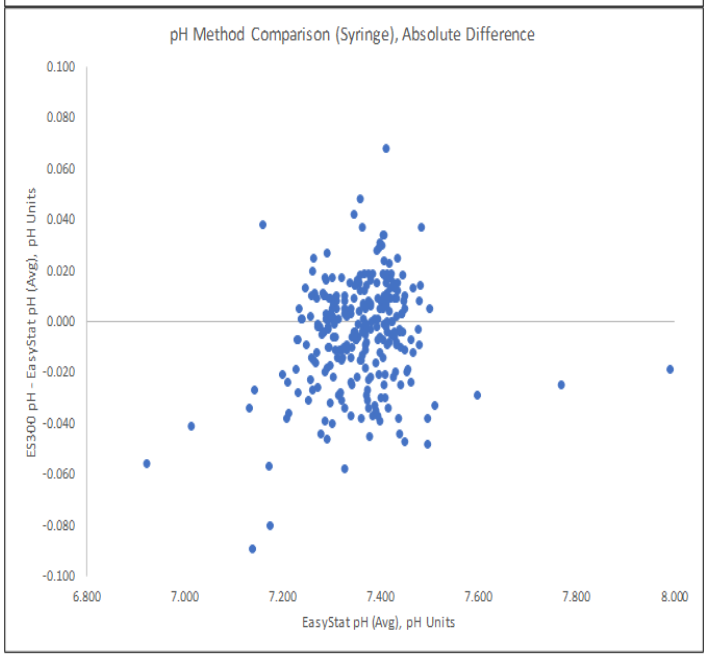
MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
5.0	-0.96	3.9	4.2	0.0	10.0	PASS
62.5	1.34	63.7	64.0	57.5	67.5	PASS
150.0	4.84	154.5	155.2	138.0	162.0	PASS

n	Slope	Intercept	R^2	Std Error
219	0.943	2.624	0.911	1.946

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
5.0	2.34	7.0	7.6	0.0	10.0	PASS
62.5	-0.94	61.3	61.8	57.5	67.5	PASS
150.0	-5.93	143.3	144.8	138.0	162.0	PASS

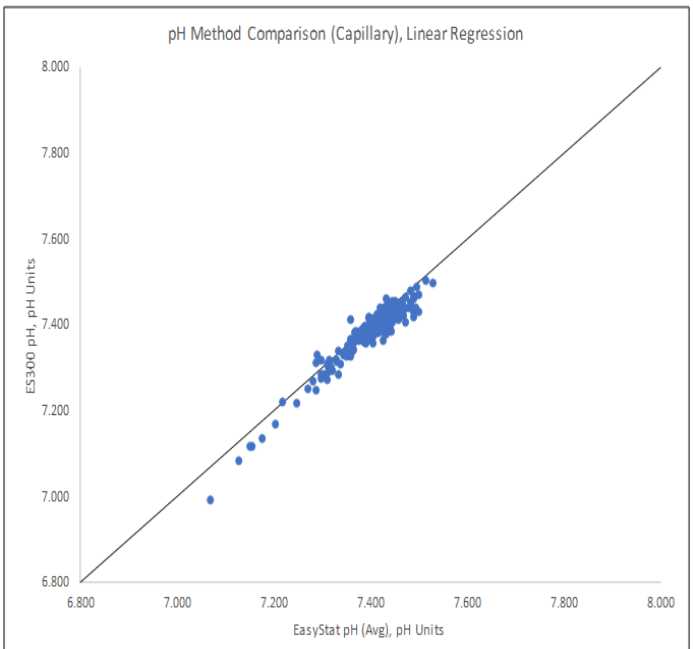
pH Method Comparison Analysis (Syringe & Capillary Modes)

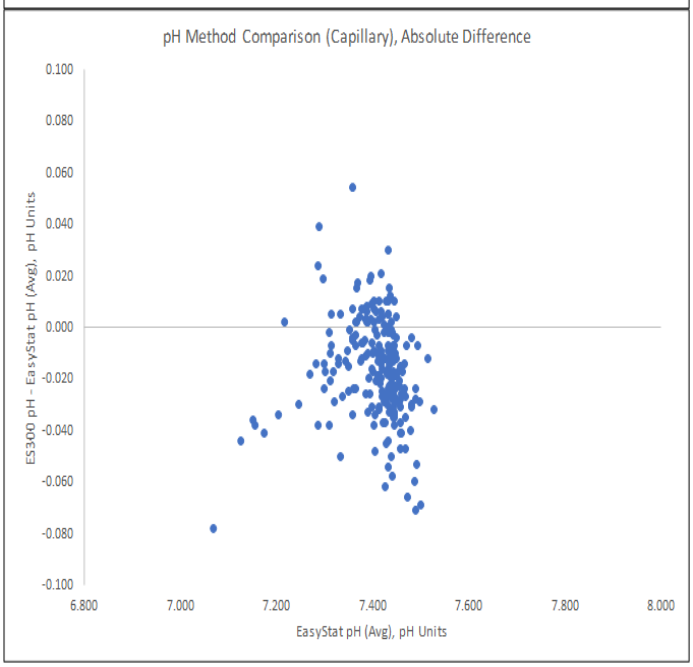




n	Slope	Intercept	R^2	Std Error
274	1.040	-0.299	0.956	0.021

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
7.300	-0.0070	7.291	7.295	7.260	7.340	PASS
7.350	-0.0050	7.343	7.347	7.310	7.390	PASS
7.450	-0.0010	7.447	7.451	7.410	7.490	PASS





n	Slope	Intercept	R^2	Std Error
224	0.977	0.153	0.918	0.020

MDL	Predicted Bias	95% Confidence Interval		100% Total Allowable Error		Status
		Min	Max	Min	Max	
7.300	-0.0149	7.283	7.287	7.260	7.340	PASS
7.350	-0.0161	7.332	7.336	7.310	7.390	PASS
7.450	-0.0184	7.430	7.433	7.410	7.490	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 analyzers covering the pH and blood gas sensors.

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

Analyte	Type of sample used	LoB	LoD	LoQ	Lowest Detection Limit (LDL)	LoQ < LDL?
*p*O2	Tonometered w. Blood	3 mmHg	4 mmHg	4 mmHg	5 mmHg	Yes
*p*CO2	Tonometered w. Blood	2.8 mmHg	4.6 mmHg	4.6 mmHg	5.0 mmHg	Yes
pH	Buffered Saline	6.140 pH units	6.498 pH units	6.498 pH units	6.800 pH units	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.

*p*O2: 5 mmHg
*p*CO2: 5.0 mmHg
pH 6.800 units

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.

	Interference	Test Level	Gas/pH Level	pO_2		pCO_2		pH	
				Change, mmHg	%Change	Change, mmHg	%Change	Change, pH Units	Conclusion
1	Acetaminophen	15.6 mg/dL	A	1.7	6.7	0.6	1.6	0.009	No Interference
			B	5.3	3.1	2.1	2.3	0.001	No Interference
2	Albumin (Protein)	60 g/L	A	-0.3	-0.55	0.4	1.2	0.029	No Interference
			B	3.3	2.1	1.0	1.1	0.027	No Interference
3	Amoxicillin	0.206 mM	A	-0.3	-1.3	0.3	0.9	-0.005	No Interference
			B	-1.7	-1.1	1.2	1.4	0.006	No Interference
4	Aprotinin	50 mg/L	A	-1.00	-1.91	-0.3	-0.7	0.007	No Interference
			B	1.3	0.8	0.2	0.3	0.003	No Interference
5	Atracurium	50 mg/L	A	0.0	0.0	-0.2	-0.7	0.016	No Interference
			B	1.3	0.8	0.4	0.4	0.001	No Interference
6	Benzalkonium chloride	5 mg/L	A	-0.3	-1.4	-0.3	-0.8	0.006	No Interference
			B	1.0	0.6	-0.2	-0.2	0.008	No Interference
7	Bilirubin	20 mg/dL	A	0.7	2.6	0.3	0.9	0.000	No Interference
			B	-1.0	-0.6	-0.6	-0.7	0.002	No Interference
8	Ceftriaxone	1.46 mM	A	0.7	2.5	0.3	0.9	-0.004	No Interference
			B	-2.0	-1.2	2.4	2.5	-0.002	No Interference
9	Ciprofloxin	30.2 µM	A	1.0	3.8	0.4	1.0	-0.002	No Interference
			B	0.3	0.2	-0.6	-0.7	0.001	No Interference
10	Epinephrine	0.5 µM	A	0.3	1.3	0.6	1.6	-0.009	No Interference
			B	-4.7	-3.2	-1.9	-2.2	0.007	No Interference
11	Ethanol	600 mg/dL	A	1.00	1.69	1.1	3.0	-0.011	No Interference
			B	0.3	0.2	0.2	0.2	0.010	No Interference
12	Gentamycin	3 mg/dL	A	0.0	0.0	0.07	0.2	0.007	No Interference
			B	4.0	2.5	0.4	0.5	0.007	No Interference
13	Halothane	4 mM	A	-1.0	-3.7	-0.2	-0.6	0.005	No Interference
			B	-1.0	-0.6	-0.5	-0.5	0.026	No Interference
14	Hematocrit	25%	A	0.7	2.7	0.6	1.7	-0.033	No Interference
			B	0.7	0.4	-1.0	-1.1	0.001	No Interference
15	Hematocrit	65%	A	1.7	5.8	-0.4	-1.02	-0.007	No Interference
			B	-1.3	-0.8	-3.5	-4.0	0.04	No Interference
16	Hemoglobin	25% (2.5 g/dL)	A	-0.3	-0.54	0.1	0.3	-0.028	No Interference
			B	-1.0	-0.6	-0.7	-0.8	-0.026	No Interference
17	Heparin	100 kU/L	A	-0.3	-1.4	0.4	1.0	0.035	No Interference
			B	4.0	2.5	3.6	3.9	0.006	No Interference
18	Lithium Chloride	3.2 mM	A	1.0	4.0	1.2	3.2	-0.007	No Interference
			B	-1.3	-0.8	0.3	0.3	-0.025	No Interference
19	Omeprazole	0.9 mg/dL	A	2	7.9	0.2	0.6	-0.011	No Interference
			B	1.3	0.9	0.7	0.8	0.005	No Interference
20	Propofol	270 µM	A	1.7	6.3	1.3	3.6	0.015	No Interference
			B	2.0	1.3	1.1	1.3	-0.009	No Interference
21	Suxamethonium	68 µM	A	1.0	3.9	-0.2	-0.5	-0.006	No Interference
			B	0.7	0.4	-0.5	-0.6	0.001	No Interference
22	Thyroxine	1.29 µM	A	2.0	7.6	0.6	1.6	-0.015	No Interference
			B	2.7	1.7	1.6	1.7	0.008	No Interference
23	Triglycerides	2%	A	0.7	2.7	1.1	3.0	0.022	No Interference
			B	-1.3	-0.8	1.3	1.4	0.027	No Interference

Note: "No Interference" If <10% change

Level A: pCO_2 5% / pO_2 3% → {pH ~7.48, PCO_2 ~37 mmHg, PO_2 ~23 mmHg}

Level B: pCO_2 12% / pO_2 20% → {pH ~7.19, PCO_2 ~90 mmHg, PO_2 ~143 mmHg}

Conclusion:

The technological and functional characteristics of the new EasyStat 300 analyzer described in the 510(k) summary are substantially equivalent to that of the predicate device EasyStat for pH, *p*CO2, and *p*O2.
The analytical study results demonstrate the EasyStat 300 is safe and effective for its intended purpose and equivalent in performance to the predicate device.