



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Sistagrosa S.A.
Cdla Guayaquil, Av. Victor H. Sicuret P. Mz11,
S4; Entre Emilio Soro Lenti y Enma E. Ortiz Bermeo
Guayaquil, Ecuador

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

CALIBRATION

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 02 October 2026
Certificate Number: AC-2622



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

SISTAGROSA S.A.

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CALIBRATION

Valid to: **October 2, 2026**

Certificate Number: **AC-2622**

Acoustics and Vibration

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Sound Pressure Level/Audiometer (Air conduction) Reference (70 dB) ^{1,2}	(125 to 8 000) Hz (77 to 83) dB HL (83 to 115) dB HL	(2.3 - 0.017X) dB (1.1 - 0.002 4X) dB	Internal Procedure PEC.SIS.17; Larson Davis 824 Precision Sound Level Meter
Sound Pressure Level/Audiometer (Air conduction) Reference (0 dB) ^{1,2}	(125 to 8 000) Hz (7 to 13) dB HL (13 to 45) dB HL	(1.3 - 0.027X) dB (0.99 - 0.004 3X) dB	Internal Procedure PEC.SIS.17; Larson Davis 824 Precision Sound Level Meter
Sound Pressure Level/Audiometer (Bone conduction) Reference (20 dB and 40 dB) ^{1,2}	(51 to 88) dB HL (250 to 8 000) Hz	(0.8 + 0.000 2X) dB	Internal Procedure PEC.SIS.17; Larson Davis 824 Precision Sound Level Meter

Chemical Quantities

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Breathalyzer – Breath Alcohol Mass Concentrations (Mass per Volume of Vapor) @ 34 °C ^{1,2}	0.12 mg/L 0.3 mg/L 0.61 mg/L	0.009 mg/L 0.009 mg/L 0.011 mg/L	Internal Procedure PEC.SIS.50; Alcohol Reference Solutions (CRMs)

Electrical – DC/Low Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Energy/Monophasic Defibrillator ^{1,2}	(15 to 360) J	$(0.15 + 0.012X)$ J	Internal Procedure PEC.SIS.03; Fluke Impulse 7000DP Defibrillator Analyser and Pacemaker Tester
Energy/Biphasic Defibrillator ^{1,2}	(15 to 175) J	$(0.35 + 0.019X)$ J	Internal Procedure PEC.SIS.03; Fluke Impulse 7000DP Defibrillator Analyser and Pacemaker Tester
Power/Electrosurgical Equipment ^{1,2}	(5 to 300) W at 200 Ω at 300 Ω at 400 Ω at 500 Ω	$(1.2 + 0.053X)$ W $(1.2 + 0.059X)$ W $(1.2 + 0.063X)$ W $(1.2 + 0.063X)$ W	Internal Procedure PEC.SIS.05; Fluke QA ES II Electrosurgery Analyser
Resistance/Electrosurgical Analysers ^{1,2}	(50 to 5 200) Ω	$(1.3 + 0.001\ 4X)$ Ω	Internal Procedure PEC.SIS.30; Agilent U3402A 5.5 Digit Multimeter
Low Frequency Power / Electrosurgical Analysers ^{1,2}	(5 to 490) W at 200 Ω at 300 Ω at 500 Ω	$(0.055X - 0.008\ 7)$ W $(0.062X - 0.073)$ W $(0.19 + 0.49X)$ W	Internal Procedure PEC.SIS.30; Agilent 3458A 8.5 Digit Multimeter, Power Source
Energy/Defibrillator Analysers ²	(2 to 360) J	$(0.21 + 0.017X)$ J	Internal Procedure PEC.SIS.22; Agilent U3402A 5.5 Digit Multimeter, Uni-T UTD2202CE Oscilloscope

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Volume Liquid Flow Rate/Infusion Pump ^{1,2}	(16 to 200) ml/h	$(0.083 + 0.012X)$ ml/h	Internal Procedure PEC.SIS.01; IDA 5 Infusion Pump Analyser
Volume Liquid Flow Rate/Infusion Pump Analyser ^{1,2}	(10 to 50) ml/h at 3 ml (100 to 200) ml/h at 10 ml (400 to 500) ml/hr at 20 ml	$(0.01 + 0.003X)$ ml/h $(0.093 - 0.002 \ 2X)$ ml/h $(0.059 - 0.002 \ 2X)$ ml/h	Internal Procedure PEC.SIS.33, Gravimetric Method; Sartorius Analytical Scale, Timer
Pneumatic Pressure Gauges ^{1,2}	Up to 3 500 psi	$(0.29 + 0.001 \ 3X)$ psi	Internal Procedure PEC.SIS.42; HSIN685 Digital Pressure Gauge
Pneumatic Pressure/ Blood Pressure Cuff ^{1,2}	Up to 300 mmHg	$(0.65 + 0.002 \ 2X)$ mmHg	Internal Procedure PEC.SIS.20; Additel ADT681-02-GP5-PSI-N Digital Pressure Gauge
Non-Invasive Blood Pressure /Multi-parameter Patient Monitor (Electrical Simulation) ^{1,2}	(30 to 150) mmHg	$(0.5 + 0.007 \ 4X)$ mmHg	Internal Procedure PEC.SIS.21; Fluke PROSIM 8 Vital Signs Patient Simulator
Invasive Blood Pressure / Multi-parameter Patient Monitor (Electrical Simulation) ^{1,2}	Up to 120 mmHg	$(1.2 + 0.011X)$ mmHg	Internal Procedure PEC.SIS.13; Fluke PROSIM 8 Vital Signs Patient Simulator
Non-invasive Pressure Simulator ^{1,2}	Systolic (60 to 100) mmHg (120 to 150) mmHg Diastolic (30 to 70) mmHg (80 to 110) mmHg	$(0.095 + 0.000 \ 08X)$ mmHg $(0.086 + 0.000 \ 1X)$ mmHg $(0.092 + 0.000 \ 1X)$ mmHg $(0.097 + 0.000 \ 06X)$ mmHg	Internal Procedure PEC.SIS.28; JUMO LOGOSCREEN Recorder
	Pressure Meter Up to 290 mmHg	0.011 mmHg	Internal Procedure PEC.SIS.28; Additel ADT681-02-GP5-PSI-N Digital Pressure Gauge

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Airway Pneumatic Pressure/Lung Ventilator ^{1,2}	(-100 to 100) cmH ₂ O	(0.083 + 0.006 3X) cmH ₂ O	Internal Procedure PEC.SIS.18; Fluke VT900 Gas Flow Analyser
Airway Volume Flow/ Lung Ventilator ^{1,2}	(1 to 100) slpm	(0.019 + 0.005X) slpm	Internal Procedure PEC.SIS.18; Fluke VT900 Gas Flow Analyser; Flow Conditions: 21 °C, 760 mmHg
Volume/Airway Spirometer ^{1,2}	(1 to 3) l	(0.025 + 0.005X) l	Internal Procedure PEC.SIS.07; Hans Rudolph 3 liter Calibration Syringe
Balances and Scales; Medical (platform) Adult and Pediatric ^{1,3}	(100 to 220) g (220 to 5 000) g (5 to 20) kg (20 to 260) kg	0.3 % of reading + 0.8 mg 0.4 % of reading + 7.3 mg 1.5 % of reading + 8.9 mg 5.9 % of reading + 18 mg	OIML Class F1 weights, OIML Class M1 weights, and Internal Procedure PEC.SIS.31 utilized in the calibration of the weighing system.

Thermodynamic

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Temperature/ Infant Incubator ¹	(25 to 40) °C	0.77 °C	Internal Procedure PEC.SIS.14; Fluke INCU Incubator Analyser
Temperature/ Temperature Chambers ^{1,2}	(-80 to -20) °C (-20 to 0) °C	0.59 °C 0.59 °C	Internal Procedure PEC.SIS.40; Temperature Data Loggers, Digital Thermometer
Temperature/ Temperature Data Loggers ^{1,2}	(-80 to -20) °C (-20 to 0) °C (0 to 40) °C	(0.72 - 0.000 2X) °C (0.72 + 0.000 1X) °C (0.72 - 0.000 6X) °C	Internal Procedure PEC.SIS.44; Fluke 1502A Thermometer Readout, Dry Block Calibrator

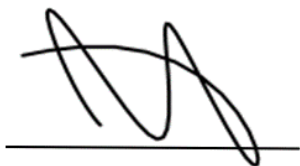
Time and Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Cardiac Rate ECG/ Multi-parameter Monitor (Electrical Simulation) ^{1,2}	(40 to 300) BPM	(0.022 + 0.011X) BPM	Internal Procedure PEC.SIS.11; Fluke PROSIM 8 Vital Signs Patient Simulator
Cardiac Rate/ Electrocardiogram (Electrical Simulation) ^{1,2}	(40 to 300) BPM	0.000 02 * X ² BPM	Internal Procedure PEC.SIS.06; Digital Caliper, Fluke PROSIM 8 Vital Signs Patient Simulator
Cardiac Rate/Fetal Doppler (Electrical Simulation) ^{1,2}	(90 to 180) BPM	(0.6 + 0.008 9X) BPM	Internal Procedure PEC.SIS.10; Fluke PS 320 Fetal Simulator
Respiration Rate/ Multi-Parameter Monitor (Electrical Simulation) ^{1,2}	(20 to 60) BrPM	(0.033 + 0.06X) BrPM	Internal Procedure PEC.SIS.23; Fluke PROSIM 8 Vital Signs Patient Simulator
Simulation of Heart Rate ^{1,2} (40 to 300) BPM	(0.6 to 5) Hz	(0.000 5 + 0.000 6X) Hz	Internal Procedure PEC.SIS.25; Agilent 53131A Universal Counter
Rotational Speed/ Centrifuge ^{1,2}	(300 to 590) rpm (600 to 5 000) rpm	1.2 rpm 0.009 % of reading + 0.55 rpm	Internal Procedure PEC.SIS.37; Digital Tachometer

Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and reference standard, method, and/or equipment. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 ($k=2$), corresponding to a confidence level of approximately 95%.

Notes:

1. On-site calibration service is available for this parameter, since on-site conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected on-site than what is reported on the accredited scope.
2. X = reading of the unit under test in said unit; BPM = beats per minute; BrPM = breaths per minute; rpm = revolutions per minute.
3. The CMC for scales and balances is highly dependent upon the resolution of the unit under test. The CMC presented here does not include the resolution of the unit under test. The resolution will be included in the reported measurement uncertainty at the time of calibration.
4. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-2622.
5. Accreditation Suspended from 12/03/2024 through 12/19/2024



Jason Stine, Vice President

