CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

PROMOCION MEDICA S.A.

Costa del Este, Parque Industrial, Calle 2da Edificio Promed
Panama

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.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 25 February 2024
Certificate Number: AC-2854

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

PROMOCION MEDICA S.A.

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CALIBRATION

Valid to: **February 25, 2024** Certificate Number: **AC-2854**

Acoustics and Vibration

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Audiometry Equipment (Audiometers, Optoacoustics Emissions equipment, Impedance meters, sound cameras)	(75 to 106) dB (10 Hz to 20 kHz)	0.47 dB	ANSI/ASA S3.6

Chemical Quantities

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Potential of Hydrogen–pH [1,3]	4 pH 7 pH 10 pH	0.014 pH 0.015 pH 0.015 pH	Certified Reference Materials - Comparison Method
Conductivity Meters [1,3]	5 µS/cm 100 µS/cm 1 413 µS/cm 100 mS/cm	0.62 µS/cm 2.1 µS/cm 4.9 µS/cm 0.37 mS/cm	Conductivity Certified Materials - Comparison Method

Electrical – DC/Low Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Energy/Defibrillator [1]	(15 to 360) J	0.017 % of reading + 0.63 J	Fluke Impulse 6000DP Defibrillator Analyzer

Electrical – DC/Low Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Electrical Simulation of pH Meters [1]	(-2 000 to 2 000) mV	0.1 mV	THERMO ELECTRIC ISOCAL 9000

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Pressure/ Blood Pressure Cuff [1]	(60 to 300) mmHg	0.002 % of reading + 0.36 mmHg	DRUCK DPIN610 / GE 2200-A145, Pressure Module 2200-A145
Analytical Balance [1]			Class Weights Mass – OIML Class E2 and F1 for Balance Resolution ≥ 0,1 mg; Comparison Method
Resolution: ≥ 0.001 mg	(0 to 100) mg	0.002 mg	
≥ 0.001 mg	(0 to 22) g	0.02 mg	
≥ 0.001 mg	(0 to 320) g	0.083 mg	
≥ 0.01 mg	(0 to 520) g	0.051 mg	
Balances / Weighing Instruments [1]			Class Weights Mass – OIML Class E2, F1, M1; Comparison Method
Resolution: ≥ 1 mg	(0 to 610) g	0.021 g	
≥ 5 mg	(0 to 64 100) g	0.011 g	
≥ 0.01 g	(0 to 4 200) g	0.019 g	
≥ 0.01 g	(0 to 10 200) g	0.13 g	
≥ 0.1 g	(0 to 32 200) g	0.26 g	
Balances / Scales Floor Scale, Weighing Instruments [1]			Class Weights Mass – OIML Class F1, F2, M1, M2; Comparison Method
Resolution: ≥ 0.01 kg	(0 to 150) kg	0.02 kg	
≥ 0.01 kg	(0 to 300) kg	0.035 kg	
≥ 0.02 kg	(0 to 600) kg	0.06 kg	
≥ 0.05 kg	(0 to 500) kg	0.045 kg	
≥ 0.05 kg	(0 to 1 000) kg	0.12 kg	
≥ 0.2 kg	(0 to 2 000) kg	0.47 kg	
≥ 0.5 kg	(0 to 3 000) kg	0.5 kg	

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Mass: OIML Classes E2, F1, F2, M1, M2 & M3	1 mg 2 mg 5 mg 10 mg 20 mg 50 mg 100 mg 200 mg 500 mg 1 g 2 g 5 g 10 g 20 g 50 g 100 g 200 g 500 g	0.002 mg 0.002 mg 0.002 mg 0.002 6 mg 0.003 3 mg 0.004 mg 0.005 3 mg 0.006 7 mg 0.008 3 mg 0.01 mg 0.013 mg 0.016 mg 0.02 mg 0.026 mg 0.033 mg 0.053 mg 0.1 mg 0.26 mg	Weight Set Class E1, E2 Mass Comparators: Mettler Toledo Model XPE56C Mettler Toledo Model XPE505C Mettler Toledo Model XPR2004SC
Mass: OIML Classes E2, F1, F2, M1, M2 & M3	1 kg 2 kg 5 kg 10 kg 20 kg 25 kg 50 kg	0.53 mg 1 mg 2.7 mg 5.3 mg 10 mg 20 mg 27 mg	Weight Set Class E1, E2 Mass Comparators: Mettler Toledo XPR10003SC Mettler Toledo XPR64003 LD5C
Piston Volume Devices [1]	1 µL 1.25 µL 2 µL 2.5 µL 5 µL 10 µL 20 µL 25 µL 30 µL 50 µL 100 µL 150 µL 200 µL 300 µL	5 % of indicated volume 2 % of indicated volume 2 % of indicated volume 2 % of indicated volume 0.8 % of indicated volume 0.6 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.2 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances: Mettler Toledo XP26PC -Mettler Toledo SAG105 -Mettler Toledo MCP105 (Movil Balance) ISO 8655 Family

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Piston Volume Devices [1]	500 µL 600 µL 1 mL 1.2 mL 2 mL 2.5 mL 5 mL 10 mL 12.5 mL 25 mL	0.2 % of indicated volume 0.2 % of indicated volume 0.1 % of indicated volume 0.2 % of indicated volume 0.1 % of indicated volume 0.3 % of indicated volume 0.1 % of indicated volume 0.1 % of indicated volume 0.1 % of indicated volume 0.1 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances: Mettler Toledo XP26PC -Mettler Toledo SAG105 -Mettler Toledo MCP105 (Movil Balance) ISO 8655 Family
Motor Driven Piston Burettes	1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL 100 mL	0.2 % of indicated volume 0.2 % of indicated volume 0.1 % of indicated volume 0.07 % of indicated volume 0.07 % of indicated volume 0.07 % of indicated volume 0.05 % of indicated volume 0.03 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances, ISO 8655 Family ISO 8655-3 Piston Burettes
Manual Piston Burettes	1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL 100 mL	0.2 % of indicated volume 0.2 % of indicated volume 0.1 % of indicated volume 0.1 % of indicated volume 0.07 % of indicated volume 0.07 % of indicated volume 0.07 % of indicated volume 0.07 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances, ISO 8655 Family ISO 8655-3 Piston Burettes
Piston Dispensers	0,01 mL 0.02 mL 0.05 mL 0.1 mL 0.2 mL 0.5 mL 1 mL 2 mL 5 mL 10 mL 25 mL 50 mL 100 mL 200 mL	0.7 % of indicated volume 0.7 % of indicated volume 0.5 % of indicated volume 0.5 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances, ISO 8655 Family ISO 8655-5 Dispensers

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Piston Dilutors	0.05 mL 0.1 mL 0.2 mL 0.5 mL 1 mL 2 mL 5 mL 10 mL 25 mL 50 mL 100 mL	0.6 % of indicated volume 0.5 % of indicated volume 0.3 % of indicated volume 0.3 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume	Gravimetric Calibration Referenced to Mass Balances, ISO 8655 Family ISO8655-4 Dilutors
Laboratory Glassware/ Burettes	1 mL 2 mL 5 mL 6 mL 10 mL 25 mL 30 mL 50 mL 100 mL	0.2 % of indicated volume 0.2 % of indicated volume 0.06 % of indicated volume 0.1 % of indicated volume 0.05 % of indicated volume 0.06 % of indicated volume 0.1 % of indicated volume 0.03 % of indicated volume 0.12 % of indicated volume	Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 385 STANDARD
Laboratory Glassware/ Graduated Pipettes	0.1 mL 0.2 mL 0.5 mL 1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL 100 mL	2 % of indicated volume 2 % of indicated volume 0.7 % of indicated volume 0.2 % of indicated volume 0.14 % of indicated volume 0.07 % of indicated volume 0.05 % of indicated volume 0.035 % of indicated volume 0.03 % of indicated volume 0.02 % of indicated volume 0.015 % of indicated volume	Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 835 STANDARD
Laboratory Glassware/ Single Volume Pipettes	0.5 mL 1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL 100 mL	0.7 % of indicated volume 0.2 % of indicated volume 0.14 % of indicated volume 0.07 % of indicated volume 0.05 % of indicated volume 0.035 % of indicated volume 0.03 % of indicated volume 0.02 % of indicated volume 0.015 % of indicated volume	Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 648 STANDARD

Mass and Mass Related

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Laboratory Glassware/ One Mark Volumetric Flasks/ Graduated Flasks	1 mL 2 mL 5 mL 10 mL 20 mL 25 mL 50 mL 100 mL 200 mL 250 mL 500 mL 700 mL 800 mL 1 000 mL 2 000 mL	1.13 % of indicated volume 1.13 % of indicated volume 0.25 % of indicated volume 0.15 % of indicated volume 0.13 % of indicated volume 0.1 % of indicated volume 0.075 % of indicated volume 0.05 % of indicated volume 0.04 % of indicated volume 0.035 % of indicated volume 0.03 % of indicated volume 0.03 % of indicated volume 0.03 % of indicated volume 0.025 % of indicated volume 0.025 % of indicated volume	Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S Mettler Toledo Model XPE505C Mettler Toledo Model XPR2004SC Mettler Toledo XPR10003SC Mettler Toledo XPR64003 LD5C ISO 1042 STANDARD
Test Tubes	5 mL 10 mL 25 mL 50 mL 100 mL 200 mL 250 mL 500 mL 1 000 mL	0.4 % of indicated volume 0.2 % of indicated volume 0.56 % of indicated volume 0.2 % of indicated volume 0.2 % of indicated volume 0.8 % of indicated volume 0.2 % of indicated volume 0.4 % of indicated volume 0.2 % of indicated volume	Gravimetric Calibration ISO 4788 STANDARD
Chemical Glasses	500 mL 600 mL 700 mL 800 mL 1 000 mL	0. 1% of indicated volume 0.08 % of indicated volume 0.07 % of indicated volume 0.06 % of indicated volume 0.07 % of indicated volume	Gravimetric Calibration ISO 1042 STANDARD
Pycnometer	25 mL 50 mL 100 mL	0.005 % of indicated volume 0.005 % of indicated volume 0.005 % of indicated volume	Gravimetric Calibration ISO 3507 STANDARD
Metallic Volumetrics	19 L 20 L	0.015 % of indicated volume 0.015 % of indicated volume	Gravimetric Calibration OIML R120

Photometry and Radiometry

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Wavelength / Spectrophotometer [1]	(279 to 637) nm	0.05 nm	Holmium Oxide Reference Material
Absorbance /Photometric Scale [1]	1 % Au 3 % Au 10 % Au 20 % Au 30 % Au 50 % Au 90 % Au	0.006 Au 0.006 Au 0.003 Au 0.003 Au 0.003 Au 0.002 5 Au 0.002 5 Au	Neutral Density Filters with Different Transmittance Percentages

Thermodynamic

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Temperature/ Digital Thermometers Direct Indication Thermometers Temperature Data Loggers Bimetallic Thermometers [1]	(-30 to 250) °C	0.05 °C	Digital Thermometer ISOTECH 935-14-95H ISOTECH T100-250-316-9 TESTO 614.024 Bath: INSCO 777; ISOTECH Orion 796 H; ISOTECH Fast Cal
Liquid-in-Glass Thermometers	(-30 to 250) °C	0.1 °C	
Infrared (IR) Thermometers	(30 to 45) °C	0.67 °C	Infrared Blackbody Temperature Calibrator $\varepsilon = 0.95$, $\lambda = (8 \text{ to } 14)$ µm
Temperature Measure/ Incubators, Coolers/Ovens/Circulating Baths/Environmental Chambers	(-80 to 35) °C (35 to 1 000) °C	0.13 °C	Testo Type K probe LMB100 Testo Type K probe LMB

Time and Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Centrifugal Speed [1,2]	(10 to 25) rpm (25 to 100) rpm (100 to 1 000) rpm (1 000 to 93 750) rpm	0.001 % of reading + 0.1 rpm 0.001 % of reading + 0.1 rpm 0.000 5 % of reading + 0.1 rpm 0.000 5 % of reading + 1 rpm	Digital Tachometer Extech 461995, Digital Tachometers Testo 465 and 470

Time and Frequency

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
Cardiac Rate/ECG Multi-parameter Monitor [1,2] (Electrical Simulation)	(60 to 300) BPM	1.5 BPM	Patient simulator MPS450
Audiometry Equipment (Audiometers, Optoacoustics Emissions equipment, Impedance meters, sound cameras)	251.2 Hz	0.62 Hz	ANSI/ASA S3.6

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. d = resolution of device under test; rpm = revolutions per minute; BPM = beats per minute.
3. The nominal values listed are approximate.
4. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-2854.

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