



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.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 25 February 2022
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, 2022**

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) | (0 to 20 000) Hz | 0.62 Hz | ANSI/ASA S3.6 |
| Audiometry Equipment (Audiometers, Optoacoustics Emissions equipment, Impedance meters, sound cameras) | (0 to 140) dB | 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 | 0.56 µS/cm 2.1 µS/cm 4.9 µS/cm 0.39 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 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 | (0 to 300) mmHg | (0.002 of reading+0.36) mmHg | DRUCK DPIN610 / GE 2200-A145, Pressure Module 2200-A145 |
| Analytical Balance ¹ Resolution: ≥0.001 mg | (0 to 100) mg | 0.002 mg | Class Weights Mass – OIML Class E2 and F1 for Balance Resolution ≥ 0,1 mg Comparison Method |
| ≥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 Resolution: ≥1 mg | (0 to 610) g | 0.021 g | Class Weights Mass – OIML Class E2, F1, M1 Comparison Method |
| ≥ 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 Resolution: ≥ 0.01 kg | (0 to 150) kg | 0.02 kg | Class Weights Mass – OIML Class F1, F2, M1, M2 Comparison Method |
| ≥ 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 | |



ANSI National Accreditation Board

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

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 | 0.6 % of indicated volume | Gravimetric Calibration Referenced to Mass Balances, ISO 8655 Family ISO8655-4 Dilutors |
| | 0.1 mL | 0.5 % of indicated volume | |
| | 0.2 mL | 0.3 % of indicated volume | |
| | 0.5 mL | 0.3 % of indicated volume | |
| | 1 mL | 0.2 % of indicated volume | |
| | 2 mL | 0.2 % of indicated volume | |
| | 5 mL | 0.2 % of indicated volume | |
| | 10 mL | 0.2 % of indicated volume | |
| | 25 mL | 0.2 % of indicated volume | |
| | 50 mL | 0.2 % of indicated volume | |
| 100 mL | 0.2 % of indicated volume | | |
| Laboratory Glassware/ Burettes | 1 mL | 0.2 % of indicated volume | Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 385 STANDARD |
| | 2 mL | 0.2 % of indicated volume | |
| | 5 mL | 0.6 % of indicated volume | |
| | 10 mL | 0.5 % of indicated volume | |
| | 25 mL | 0.26 % of indicated volume | |
| | 50 mL | 0.18 % of indicated volume | |
| 100 mL | 0.12 % of indicated volume | | |
| Laboratory Glassware/ Graduated Pipettes | 0.1 mL | 2 % of indicated volume | Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 835 STANDARD |
| | 0.2 mL | 2 % of indicated volume | |
| | 0.5 mL | 0.7 % of indicated volume | |
| | 1 mL | 0.2 % of indicated volume | |
| | 2 mL | 0.14 % of indicated volume | |
| | 5 mL | 0.07 % of indicated volume | |
| | 10 mL | 0.05 % of indicated volume | |
| | 20 mL | 0.035 % of indicated volume | |
| | 25 mL | 0.03 % of indicated volume | |
| 50 mL | 0.02 % of indicated volume | | |
| 100 mL | 0.015 % of indicated volume | | |
| Laboratory Glassware/ Single Volume Pipettes | 0.5 mL | 0.7 % of indicated volume | Gravimetric Calibration Balances: Mettler Toledo XP26PC Mettler Toledo SAG105 Mettler Toledo XS203S ISO 648 STANDARD |
| | 1 mL | 0.2 % of indicated volume | |
| | 2 mL | 0.14 % of indicated volume | |
| | 5 mL | 0.07 % of indicated volume | |
| | 10 mL | 0.05 % of indicated volume | |
| | 20 mL | 0.035 % of indicated volume | |
| | 25 mL | 0.03 % of indicated volume | |
| | 50 mL | 0.02 % of indicated volume | |
| 100 mL | 0.015 % of indicated volume | | |

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 | 10 mL 50 mL 100 mL 200 mL 250 mL 500 mL 1 000 mL | 1 % of indicated volume 0.2 % of indicated volume 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 1042 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 1042 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 |

Photometry and Radiometry

| Parameter/Equipment | Range | Expanded Uncertainty of Measurement (+/-) | Reference Standard, Method, and/or Equipment |
|--|---|--|--|
| 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 0.0025 Au 0.0025 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 $\epsilon = 0.95, \lambda = (8 \text{ to } 14) \mu\text{m}$ |
| Temperature Measure/ Incubators, Coolers/Ovens/Circulating Baths/Environmental Chambers | (-80 to 35) °C (35 to 1000) °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 | (10 to 25) RPM (25 to 100) RPM (100 to 1000) RPM (1000 to 93750) 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 Extch 461955, 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 (Electrical Simulation) | (60 to 300) BPM | 1.5 BPM | Patient simulator |

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.
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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