

**Procurement for the Calibration, Verification and Re-certification of Various Laboratory Equipment of Common Services Laboratory - Alabang Testing and Quality Assurance Laboratory (CSL-ATQAL)**







TECHNICAL SPECIFICATION	
ITEM NO.	PURCHASER'S SPECIFICATION
OFF-SITE CALIBRATION/ VERIFICATION OF EQUIPMENT	
1	<p><b>Calibration of Thermometer</b>                      Liquid in Glass for Incubator                      Brand name: N/I                      Measuring range (°C): 0 to 50  <b>Test Point(°C): 20, 25, 35, 40, 44</b>                      Purpose: for verification of temperature of Incubator                      End User: Microbiology Section                      Quantity: 1                      ABC: Php 3,500.00</p>
2	<p><b>Calibration of Pipettor 50 to 250µL</b>                      Volumetric Equipment                      Brand name/Model: Eppendorf  <b>Test Points: 50µL, 100µL, 250µL</b>                      End Users: Antibiotic Section                      Quantity: 2                      ABC: Php 9,000.00</p>
3	<p><b>Calibration/Verification of Standard Weights</b>                      Masses                      Brand name/Model: Troemner S/N: 43416    <b>Test Points: OIML Class E2: (22 pcs.) 2 kg - 1pc; 1 kg- 1pc; 500 g- 1pc; 200 g - 2pcs; 100 g- 1pc; 50 g- 1pc; 20 g- 2pcs; 10 g- 1pc; 5g- 1pc; 2g- 2pcs; 1g- 1pc; 500 mg- 1pc; 200 mg- 2pcs; 100 mg- 1pc; 50 mg- 1pc; 20 mg- 2pcs and 5 mg- 1pc</b>                        End User: Antibiotic Section (1 SET)                      Quantity: 1                      ABC: Php 26,000.00  <i>*Verification is acceptable; Present proof of traceability to SI</i></p>
4	<p><b>Calibration of Hand Refractometer</b>                      Brand name/Model: Atago/N2                      Measuring range: 28 - 62%  <b>Test Points: 28 - 60%</b>                      End User: Food Section                      Quantity: 1                      ABC: Php 2,500.00    <i>Note: Does not require ISO 17025 accreditation. However, calibration should be traceable to international standards (e.g. use of reference material traceable to NIST; valid certificate of analysis of the reference material should be attached to the calibration report).(see Other Requirement no.2)</i></p>
5	<p><b>Calibration of Hand Refractometer</b>                      Brand name/Model: Erma/Tokyo No. 50045                      Measuring range: 58 - 92%  <b>Test Points: 58 - 60%</b>                      End User: Food Section                      Quantity: 1                      ABC: Php 2,500.00    <i>Note: Does not require ISO 17025 accreditation. However, calibration should be traceable to international standards (e.g. use of reference material traceable to NIST; valid certificate of analysis of the reference material should be attached to the calibration report).(see Other Requirement no.2)</i></p>

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ON-SITE CALIBRATION OF EQUIPMENT	
6	<p><b>Calibration of Furnace</b>  Testing of Temperature Controlled Enclosures  Brand name/Model/Temp. Range:  a. JP Selecta/2000366/up to 1150°C (1 unit)  b. Yamada/NF-215/up to 1100°C (1 unit)  c. Ivymen/Snol 30/1300/up to 1300°C (1 unit)  d. Naberthem Controller/B170/ up to 1100°C (1 unit)  <b>Test Points (°C): 450, 550, 600</b>  End Users: Food Section (2 units); Toxicology Section (1); Drug Section (1 unit)  Quantity: 4  ABC: Php 20,000.00</p>
7	<p><b>Calibration of Autoclave</b>  Temperature Controlled Enclosure  Brand name/Model:  a. Hirayama HE-3D (1 unit)  b. Hirayama HV-50 (1 unit)  <b>Test points: Temp 121 °C</b>  <b>Time 15 &amp; 30 mins</b>  <b>Pressure 15 psi</b>  End User: EAH Section (2 units)  Scope of Work must include the following, at a minimum:  - Calibration of autoclave (temperature, time and pressure)  Quantity: 2  ABC: Php 15,000.00  <i>Note: Does not require ISO 17025 accreditation. However, calibration should be traceable to international standards (e.g. use of reference material traceable to NIST; valid certificate of analysis of the reference material should be attached to the calibration report).(see Other Requirement no.2)</i></p>
8	<p><b>Calibration of Dry Block Heater</b>  Testing of Temperature  Brand name/Model/Temp. Range:  a. ThermoScientific/ReactiTherm 18822/from 10 to 200°C;  <b>Test Points(°C): 40, 50, 70</b>  b. IKA/Dry Block Heater 4/from 5 to 120°C  <b>Test Points(°C): 30, 60, 90</b>  End Users: Food Section (2 units); Cosmetic Section (1 unit)  Quantity: 3  ABC: Php 15,000.00  <i>Note: Does not require ISO 17025 accreditation. However, calibration should be traceable to international standards (e.g. use of reference material traceable to NIST; valid certificate of analysis of the reference material should be attached to the calibration report).(see Other Requirement no.2)</i></p>



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<b>ON-SITE RE-CERTIFICATION OF EQUIPMENT</b>			
9	<p><b>Re-certification of Biosafety Cabinet</b>            ThermoScientific Forma Class II            Brand name Name/Model:            a. Baker SG403TX            b. Dalton 3-BSCI30011BS            c. ThermoScientific/Forma Class II, A2            d. Halton 82071107 and Halton 82071109</p> <p>End Users: Food Section (1 unit), Antibiotic Section (2 units) Microbiology Section (2 units)</p> <p><b>Scope of Work must include the following, at a minimum:</b>            1. Inflow Velocity Test            2. Down Flow Velocity Test            3. Filter Leak Test            4. Site Installation, Alarms Verification Test            5. Smoke Pattern Test            6. UV Light Radiation Test            7. Light Intensity Test            8. Noise Level Test            9. Vibration Test            Quantity: 5            ABC: Php 175,000.00</p> <p><b>Note:</b>            a. Service Provider must be NSF Certified or equivalent. Relevant documents must be submitted to substantiate NSF or equivalent Certification.            b. Sub-contracting for this service is allowed provided that it met the applicable requirements stated in the Other Requirements and Schedule of Requirements</p>		
10	<p><b>Re-certification of Fume Hood</b>            Brand Name/Model:            a. LabConco            b. Protector Xstream            c. Esco</p> <p>End Users: Antibiotic Section (1 unit), ARS (1 unit), Cosmetic Section (1 unit), Drug Section (1 unit), Food Section (2 units) and Toxicology Section (1 unit)</p> <p><b>Scope of Work must include the following, at a minimum:</b>            1. Face Velocity Test            2. Smoke Visualization Test            3. Local Visualization Challenge            4. Large Volume Visualization Challenge            5. Noise Level Test            6. Light Intensity Test            Quantity: 7            ABC: Php 175,000.00</p> <p><b>Note:</b> Service Provider must be NSF Certified or equivalent. Relevant documents must be submitted to substantiate NSF or equivalent Certification.</p>		
<table border="0"> <tr> <td> <p>Requested by:</p> <p>Signature: </p> <p>Printed Name: <b>MARIA VICTORIA P. CALUB, RPh., MPA</b></p> <p>Designation: FDRO V, Common Services Laboratory</p> </td> <td> <p>Approved by:</p> <p></p> <p><b>JOCELYN E. BALDERRAMA, RPh., MBA</b></p> <p>Director II, Common Services Laboratory</p> </td> </tr> </table>		<p>Requested by:</p> <p>Signature: </p> <p>Printed Name: <b>MARIA VICTORIA P. CALUB, RPh., MPA</b></p> <p>Designation: FDRO V, Common Services Laboratory</p>	<p>Approved by:</p> <p></p> <p><b>JOCELYN E. BALDERRAMA, RPh., MBA</b></p> <p>Director II, Common Services Laboratory</p>
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DTN: 20210920073933

## OTHER REQUIREMENTS

### PURCHASER'S REQUIREMENTS

1. Calibration service must be a National Metrology Laboratory (NML) or an ISO 17025 accredited calibration laboratory, unless otherwise specified in each line item. A copy of the scope of accreditation (indicating the specific calibration service) and list of approved signatories shall be provided, whenever applicable.
2. If not an ISO 17025 accredited calibration laboratory and/or if the offered service is not included in the list of ISO 17025 accredited scopes, the calibration service provider must demonstrate traceability of measurement to the International Systems of Units (SI) (e.g. use of reference material traceable to NIST). A documentary evidence must be submitted (e.g. Certificate of Analysis indicating information on traceability to International Systems of Units)
3. Calibrators must submit proof of competency specific to the scope of test/s to be provided (e.g., Training certificate) or as approved signatory.
4. Information reflected in the calibration certificate shall include, but not be limited to the following:
  - a. The FDA and service provider name, address and contact information
  - b. The equipment name, including all its components, and its unique identification (e.g. equipment code, serial number, etc.)
  - c. Description on the condition of equipment
  - d. Description on the environmental condition which may have an effect on result of calibration
  - e. Method of measurement and/or calibration procedure
  - f. Calibration date and issuance date of the certificate
  - g. Test results with corresponding units of measurement
  - h. Metrological traceability of the all-reference standards and/or calibration standards used for the calibration
  - i. Uncertainty of measurement and/or statement of compliance with identified metrological specification
  - j. Measuring conditions
  - k. Logo of the accreditation body, if applicable
  - l. Identity of the personnel authorizing the certificate
  - m. If adjustment/s is done during calibration, results before and after adjustment shall be reflected
- Note:** Calibration certificate shall not contain information on next due date of calibration or any recommendation on calibration interval, unless otherwise, requested by FDA
5. Appropriate Report shall be issued to any equipment found to be defective during calibration
6. For off-site calibration, the unit shall be picked-up at the Common Services Laboratory-Alabang Testing and Quality Assurance Laboratory of the Food and Drug Administration, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa at no cost to the end-user and shall be returned at least three (3) days after the conduct of the testing. Schedule of pick-up shall be properly coordinated with the FDA.
7. For on-site calibration and re-certification, the transportation and meal allowance of the calibrator/s shall be shouldered by the supplier. Schedule of service/s shall be properly coordinated with FDA and shall be agreed upon by both parties.
8. All service provider personnel for On-site calibration shall accomplish the Confidentiality Agreement, Contact Tracing and Medical/Health History Form prior entry to the FDA facility and shall observe the minimum safety protocol to prevent the spread of Covid-19 virus. Likewise, each personnel should have his own personal protective equipment (e.g. laboratory gown, gloves, face mask and face shield). Laboratory gown is required to be worn whenever inside the laboratory premises.

## SCHEDULE OF REQUIREMENTS

### PURCHASER'S SPECIFICATION

The delivery schedule expressed as weeks/months stipulates hereafter a delivery date which is the date of delivery to the project site.

#### **1. For All Equipment requiring Off-site Calibration**

**Pick-up:** Pick up schedule shall be done in a maximum of two (2) batches. The first batch shall be within ten (10) working days from receipt of the approved Purchase Order. The second batch shall be within five (5) working days from return of the first batch.

**Return of calibrated equipment:** Equipment shall be returned within ten (10) working days from its picked-up date.

All calibration reports must be provided together with the equipment upon its return

#### **2. For All Equipment requiring On-site Calibration/Re-certification**

All equipment shall be calibrated/ re-certified within ten (10) working days upon receipt of the approved PO. All reports (e.g., Calibration report, re-certification report, etc.) must be provided within three (3) working days from conduct of calibration or certification activity