



Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedures		
Title:	Calibration And Standardization Of Critical Laboratory Instruments		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

- 1.1 This procedure specifies the schedule and requirements for calibration, standardization, and maintenance of clinical Laboratory testing instruments and equipment. This procedure applies to the critical laboratory equipment used by the Laboratory

2. DEFINITONS:

- 2.1 **Calibration-** Adjustment or standardization of the accuracy of a measuring instrument, usually by comparison with a certified reference or standard.
- 2.2 **Certified Reference Material (CRM)** -A reference material whose property values are certified by a technically valid procedure and accompanied by or traceable to a certificate or documentation issued by a certifying organization.
- 2.3 **Critical Laboratory Equipment** -Analytical instrumentation and equipment affecting the accuracy or precision of a test method.
- 2.4 **Quality Control Checks** - Periodic confirmation of the reliability of equipment, and instruments.
- 2.5 **Traceability** -The linking of measurement standards and/or measuring instruments to relevant national or international standards through an unbroken chain of comparisons

3. POLICY:

- 3.1 The laboratory Quality assurance officer or his designee shall maintain an equipment inventory that shall include the following information:
 - 3.1.1 Item
 - 3.1.2 Serial number or other unique identification
 - 3.1.3 Location
- 3.2 All equipment in the equipment inventory system shall be identified uniquely (e.g., serial number).
- 3.3 All equipment shall be maintained in good operating order and according to manufacturer and/or Section maintenance requirements.
- 3.4 All critical equipment shall be calibrated or verified before use.
- 3.5 Standardization and Calibration of Thermometers every 12 months.
- 3.6 The Pipettes are inspected and checked for accuracy and/or calibration before being put in service and every six months.
- 3.7 Standardization and Calibration of Lab stop watcher, every 6 months.
- 3.8 Standardization and Calibration of Balance every 6 months. cv
- 3.9 Actions are taken in the event of unsatisfactory results

4. PROCEDURE:

- 4.1 **Thermometer**
 - 4.1.1 Categorize thermometer. Use only similar thermometers
 - 4.1.2 Label each thermometer to be calibrated.

- 4.1.2.1 To calibrate at 37 °Centigrade
 - 4.1.2.1.1 Insert the FLUKE thermometer and thermometer to be tested in a water bath.
 - 4.1.2.1.2 To calibrate at 40°C
 - 4.1.2.1.3 Fill a suitable container with an appropriate mixture of crushed ice and water.
 - 4.1.2.1.4 Make sure that the tips of all devices are at the same level and the ends of the sensors in the liquid. Stir constantly in a random motion until the desired temperature is reached.
 - 4.1.2.1.5 Record all observations on the record form provided.
 - 4.1.2.1.6 A result is acceptable if the reading on a thermometer agrees with the FLUKE thermometers (+/-) 1°C
 - 4.1.2.1.7 Calibration was done in the contract and referral accredited company, according to this method in the Policy.

4.2 Pipettes:

- 4.2.1 Operating:
 - 4.2.1.1 Attach a clean tip of the pipette
 - 4.2.1.2 Depress plunger knob to the first stop and enter tip into the sample solution.
 - 4.2.1.3 Smoothly return the plunger knob to the release position, allowing the sample to enter the tip.
 - 4.2.1.4 Do not allow the knob to snap back to release position.
 - 4.2.1.5 Withdraw the tip from the sample solution and do not wipe the tip.
 - 4.2.1.6 Place the tip against the side wall of the receiving vessel and smoothly depress the plunger knob to the first stop and depress the knob to the second and lowest position.
 - 4.2.1.7 Return the knob to the release position.
- 4.2.2 Maintenance:
 - 4.2.2.1 The maintenance schedule of the Pipette includes a scheduled task to be performed every six months. If materials are aspirated into the pipette the tip region should be cleaned as soon as possible and decontaminated with ethanol 70%.
 - 4.2.2.2 Always use the specified disposable tips.
 - 4.2.2.3 Never wash and reuse tips.
 - 4.2.2.4 Ensure that the tip is fitted firmly to the pipette
 - 4.2.2.5 Keep the pipette always clean.
 - 4.2.2.6 Always pipette in a vertical position.
 - 4.2.2.7 Return the pipette to its stand after use.
 - 4.2.2.8 Operate by a slow and smooth, consistent procedure to avoid bubbles or foaming.
- 4.2.3 Calibrating:
 - 4.2.3.1 Using the pipette that to is calibrated and aspirate distilled water and weigh the volume. Repeat the process 10 times.
 - 4.2.3.2 The mean weight of ten samplings is converted to volume in milliliters by multiplying the mean using the conversion table below.
 - 4.2.3.3 Based on the mean of volume, you can adjust the pipette as follows
 - 4.2.3.4 Place the calibration tool into the holes of the calibration adjustment lock.
 - 4.2.3.5 Turn the adjustment lock anticlockwise to decrease and clockwise to increase the volume.
 - 4.2.3.6 Repeat the method above to ensure accuracy.
- 4.2.4 Precision
 - 4.2.4.1 The pipette must meet the specifications of the manufacturer for both accuracy and precision.
 - 4.2.4.2 Using the data above establish the CV which should be not more than the figure in the table below to ensure precision.
 - 4.2.4.2.1 Calculation:
 - 4.2.4.2.2 Steps:

Mean = sum of values
 4.2.4.2.3 Number of values
 Standard Deviation = $\sqrt{\frac{\text{sum of mean} - \text{individual value}^2}{\text{Number of values} - 1}}$

Temperature (degrees centigrade)	Weight to volume conversion factor
17	1.0022
18	1.0024
19	1.0026
20	1.0028
21	1.0030
21.5	1.0031
22	1.0032
22.5	1.0033
23	1.0034
23.5	1.0036
26	1.0037

Accuracy % (A%) = $\frac{\text{mean volume} - \text{normal volume}}{\text{Nominal value}} \times 100\%$

Mean volume = $1.0031 \times \text{mean values}$
 (1.0030 = density of water @ 21°C)

The error limits in accordance with the latest version of the EN ISO 8655 standard and based on volume are contained in the following tables:

Piston pipettes, fixed volume and adjustable, single channel				
Volume/μL	Accuracy %		Precision	
1000	± 0.8 %	± 8.0 μl	± 0.3 %	± 3.0 μl
500	± 0.8 %	± 4.0 μl	± 0.3 %	± 1.5 μl
200	± 0.8 %	± 1.6 μl	± 0.3 %	± 0.6 μl
100	± 0.8 %	± 0.8 μl	± 0.3 %	± 0.3 μl
50	± 1.0 %	± 0.5 μl	± 0.4 %	± 0.2 μl
20	± 1.0 %	± 0.2 μl	± 0.5 %	± 0.1 μl

- 4.2.5 Trouble Shooting
 - 4.2.5.1 Recognizing Errors & Correction:
 - 4.2.5.1.1 Plunge is defective: Do not use & call Bio-medics.
 - 4.2.5.1.2 Not emptying well. Try to recalibrate.
 - 4.2.5.1.3 Leakage: Inspect for damages.
 - 4.2.5.1.4 Broken: Replace
 - 4.2.5.1.5 Shaft clogged: cleaning
 - 4.2.5.2 Failed accuracy and precision: use the pipette only in fluid transfer, not in any test procedure e.g. In the processing area for serum or plasma separation, urine sediment examination, staining procedures, etc.
- 4.3 **Stopwatch:**
 - 4.3.1 Acceptability Criteria:
 - 4.3.1.1 Electronic timers must be accurate to within $\pm 2\%$ (1.2 seconds/minute; 72 seconds/hour).
 - 4.3.1.2 Electric and spring timers must be accurate to within $\pm 5\%$ (2.5 seconds/minute; 180 seconds/hour).
 - 4.3.2 Procedure:
 - 4.3.2.1 Identify the timer to be tested by serial or ID number
 - 4.3.2.2 Direct Comparison Method is used for individual timers' calibration, which compares the device under testing display to a traceable time interval standard, by a reference timer.
 - 4.3.2.3 Plan the tested time interval to be corresponding to the procedure the timer is used for, check.
 - 4.3.2.4 At the minimum, midrange, and the maximum timer may be used for.
 - 4.3.2.5 Measure the uncertainty of the timer; accept at $\leq \pm 5\%$ deviation from target.
 - 4.3.2.6 TIMER QUALITY CONTROL must be completed and signed appropriately. Calibration tag is attached to the timer indicating the calibration date, expiry date, and the initials of the one who performed the calibration.
- 4.4 **Balances:**
 - 4.4.1 Setting up, leveling, preparations for weighing:
 - 4.4.1.1 The optimum location:
 - 4.4.1.1.1 The correct location makes an important contribution to the accuracy &/or the weighing results of analytical balances.
 - 4.4.1.1.2 Stable, vibration-free position & as horizontal as possible with the help of a leveling machine.
 - 4.4.1.1.3 No direct sunlight
 - 4.4.1.1.4 No excessive temperature fluctuations
 - 4.4.1.1.5 No drifts
 - 4.4.1.1.6 The best location is on a stable bench in a corner protected against air drifts, as far away as possible from doors, windows, radiators or the louvers of air conditioners.
 - 4.4.1.2 Leveling:
 - 4.4.1.2.1 Some models are equipped with a level glass and two or four leveling feet to compensate for minor irregularities in the surface on which the balance stands. The balance is exactly horizontal when the air bubble is in the middle of the level glass.
 - 4.4.1.2.2 Note: The balance should be leveled each time it is moved to a new location.
 - 4.4.1.2.3 Check the following items before weighing:
 - 4.4.1.2.4 Balance power supply is on for at least one hour.
 - 4.4.1.2.5 Balance is clean and free of dust or particulate matter.
 - 4.4.1.2.6 Balance is properly leveled as per bubble level indicator.
 - 4.4.1.2.7 Make necessary adjustments if the balance is not leveled as per operator's manual.

- 4.4.1.3 Calibration:
 - 4.4.1.3.1 The balance using in the laboratory will calibrate by company every six months. A certificate will be provided after a successful calibration and standardization.
- 4.4.1.4 Operation:
 - 4.4.1.4.1 Place weighing container on the balance (i.e. paper, beaker, etc.).
 - 4.4.1.4.2 Tare balance by depressing "zero" button.
 - 4.4.1.4.3 Place item to be weighed on center of weighing pan
- 4.4.1.5 Cleaning:
 - 4.4.1.5.1 Clean any residue particles from the balance pan and balance using a fine brush.
 - 4.4.1.5.2 Close doors, if applicable, and wait until balance reading stabilizes.
 - 4.4.1.5.3 Record weight and remove item from the balance.
 - 4.4.1.5.4 Clean bench top area around balance using a fine brush or damp cloth.

5. MATERIAL AND EQUIPMENT:

- 5.1 Analytical Balance.
- 5.2 NIST traceable weights.
- 5.3 NIST thermometer.
- 5.4 Non mercury thermometers (e.g. Alcohol thermometers).
- 5.5 Sensitive Electronic Balance with calibration facility.
- 5.6 Pipette tips, Thermometer, and Distilled water.
- 5.7 Pipette Quality checks, forms
 - 5.7.1 Form 1 for Fixed Volume Pipette.
 - 5.7.2 Form 2 for Variable Volume Pipette.

6. RESPONSIBILITIES:

- 6.1 Laboratory Quality Assurance Officer and his deputies.
- 6.2 Laboratory Director.

7. APPENDICES:



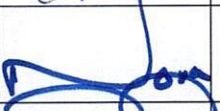



- 7.1 Inventory Equipment List

8. REFERENCES:

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- 8.10 Medley, R.J., Pockington, W.D. and Walker, R.F. 1991 Analytical quality assurance-a review, The Analyst, 116, 975-990.
- 8.11 CAP Standards (Anatomic Pathology Checklist)
- 8.12 ISO standards 15189, 2013.

9. APPROVALS:

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Appendix 7.1

INVENTORY EQUIPMENT

NO.	ITEM	SERIAL NO.	LOCATION
1	Pipette	Ym242bc0003023	HEMA
2	Pipette	187561	HEMA
3	Pipette	222902	SERO
4	Pipette	Ym242bc000	SERO
5	Pipette	Ym242bc0003022	CHEM
6	Pipette	E17y02631	B.B
7	Pipette	Cu0128078	B.B
8	Pipette	270118206	B.B
9	Stop watch	49496	SERO