**TRAINING UPDATE**

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|---|---|---|---|
| **Lab Location:** | GEC, SGMC & WOMC | **Date Distributed:** | 4/26/2021 |
| **Department:** | Core Lab, Blood Bank | **Due Date:** | 5/26/2021 |

**DESCRIPTION OF PROCEDURE REVISION**

**Name of procedure:**

# Pipette and Diluter Calibration (SGAH.QA13 v3)

**Description of change(s):**

Section 3:
Added that the technical specialist or designee is responsible for coordinating the process with the contracted company and performing the first review of the reports.

Section 5:

1. Added that whenever a pipette cannot be successfully calibrated, the technical specialist or designee will:
    - Document date removed on the calibration sheet.
    - Notify the technical supervisor of the failure.
2. Added that the calibration reports are initially reviewed by the technical specialist and then forwarded to the technical supervisor for final review

This revised SOP will be implemented on April 5, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

| | | |
|---|---|---|
| **Title** | **Pipette and Dilutor Calibration** | |
| **Prepared by** | Leslie Barrett | Date: 4/1/2009 |
| **Owner** | Cynthia Bowman-Gholston | Date: 4/1/2009 |

| **Laboratory Approval** | | |
|---|---|---|
| **Print Name and Title** | **Signature** | **Date** |
| *Refer to the electronic signature page for approval and approval dates.* | | |
| Local Issue Date: | Local Effective Date: | |

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## 1. PURPOSE

To define the requirements for calibration checks of automatic and semi-automatic pipettes and dilutors used in the testing process for quantitative dispensing.

## 2. SCOPE

This procedure applies to all automatic, semi-automatic and manual pipettes, dilutors, and repipettors that perform quantitative dispensing. It does not apply to Class A volumetric pipettes.

## 3. RESPONSIBILITY

The senior QA specialist is responsible for content and review of this procedure.

The Technical Specialist or designee is responsible for coordinating the process with the contracted company and performing the first review of the reports.

The Technical Supervisor or designee is responsible for ensuring this procedure is implemented as required.

## 4. DEFINITIONS

**Accuracy -** The closeness of agreement between the stated volume of a pipetting device and the mean volume obtained during repeated, controlled deliveries or the difference between the expected result and the measured result. It is numerically expressed as inaccuracy, given as a percentage.

**Precision –** The agreement between replicate measurements or the range of values in which 95% of the replicate measurements fall. It is numerically expressed as imprecision, given as the coefficient of variation (%CV).

**Pipette** – a device to accurately and precisely dispense liquid (reagent or specimen). This device can be automated, semi-automated or manual and may have a fixed or adjustable volume.

**Dilutor** – A measuring instrument for taking up different liquids (e.g., diluent and sample) and delivering them in combination so as to comprise a predetermined ratio, or predetermined volumes, or both.

**Repipettor** – a device to repeatedly dispense an accurate volume of a liquid.

**Pipetting device** –A general term used in this procedure to include all fixed volume, adjustable volume, and multi-channel pipettes, as well as dilutors, dispensers, and automated pipetting systems.

## 5. PROCEDURE

A. POLICY

1. Scheduled calibration is performed by a contacted vendor.
2. Each pipetting device must be uniquely identified.
3. Each pipetting device must be calibrated prior to first use and at least semi-annually for the life of the device or until retired from use and after any major repair.
4. Calibration must include both accuracy and precision measurements.
5. Calibration labels must be placed on the pipettes when successfully calibrated.
6. All maintenance must be documented

B. FREQUENCY

1. Pipettes are calibrated on a semi-annual schedule.
2. When a pipetting device is calibrated, the next due date is documented on the calibration label.
3. Calibrations are due within fourteen (14) days prior to the due date up to and including the due date.

C. PROCESS

1. Uniquely identify each pipetting device.
2. For each device, identify the point(s) at which it must be calibrated.
3. A gravimetric method is utilized for calibration.

   Principle: This method determines the weight of water dispensed by the pipetting device which is directly related to the volume dispensed.

   Considerations/Limitations: This method will discriminate between imprecision of at least 0.02 mg standard deviation. It requires a well calibrated balance and experience in the proper use of an analytical balance. Room temperature must be used in the calculation to determine the volume of water dispensed.

4. Determine accuracy and precision requirements:

| Element | Description |
|---|---|
| Accuracy | ▪ The initial pipette evaluation must include 10 measurements.<br>▪ Subsequent pipette evaluations must include 4 measurements.<br>▪ The mean of the measurements is calculated. Acceptable performance for accuracy is achieved when the calculated mean falls within the acceptable range, listed in the table below, for the volume dispensed. |
| Precision | ▪ The initial pipette evaluation must be 10 measurements.<br>▪ Subsequent pipette evaluations must include 4 measurements.<br>▪ The mean, standard deviation (SD) and coefficient of variation (CV) are calculated. Acceptable performance for precision is achieved when the calculated CV falls within the acceptable range, listed in the table below, for the volume dispensed. |

| **Pipette Volume** | *Accuracy* | *Precision* |
|---|---|---|
| 1 – 10 µl | Intended Volume ± 5 % | C.V. ± 5 % |
| > 11 µl | Intended Volume ± 3 % | C.V. ± 3 % |

5. Record the readings, calculations and record judgment of acceptability (if corrective actions are taken, these must be included).
   a. Calibration records must include
      - person performing
      - date of calibration
      - the pipetting device unique identifier
      - the volume at which the pipetting device is being calibrated
      - each individual reading
      - all calculations (mean, SD, CV)
      - judgment on acceptability

b. When a pipette does not pass initial calibration:
   - Routine cleaning should be performed.
   - Recalibrate the pipette

c. When a pipette does not pass subsequent calibration, corrective action must be taken and documented (including any potential patient impact), and the device must be recalibrated and/or rechecked prior to use.

d. When a pipette cannot be successfully calibrated (initial or subsequent), it is removed from service and replaced. The technical specialist or designee will:
   - Document date removed on the calibration sheet,
   - Notify the technical supervisor of the failure.

6. When the pipette has met the acceptable criteria, the pipette must be labeled with a calibration label.
   a. The label should include the pipette ID number, the initials of the tech performing the calibration, the date of the calibration, and when the pipette is due for it's next calibration.
   b. Calibration labels may be ordered through the Purchasing Department. (Example: vendor is Seton, label number 57481).

7. The disposition of any retired pipette must be documented. All out of service pipettes are given to the supervisor for proper disposal.

8. The calibration reports are initially reviewed by the technical specialist and then forwarded to the technical supervisor for final review.

## 6. RELATED DOCUMENTS

None

## 7. REFERENCES

- *Laboratory Instrument Evaluation, Verification & Maintenance Manual*, College of American Pathologist, 5th Edition, 1999, pages 126 – 127.
- Process for Pipetting Device Calibration, Quality Assurance Best Practice, QDNQA603v2.0, 12/2007.
- Scientific Calibration Inc., Apex, NC

## 8. REVISION HISTORY

| Version | Date | Reason for Revision | Revised By | Approved By |
|---|---|---|---|---|
| | | Supersedes SOP L038.002 | | |
| 000 | 8/19/2015 | Section 3: update QA specialist title<br>Section 5: clarify initial requirements, add requirements for subsequent calibration failure<br>Section 6: move log from section 9, assign form #<br>Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13. | L Barrett | C Bowman-Gholston |

| Version | Date | Reason for Revision | Revised By | Approved By |
|---|---|---|---|---|
| 1 | 7/10/2017 | Header: add other sites<br>Section 4: remove 'pipette in reserve'<br>Section 5: change frequency to semi-annual, remove specific vendor, delete reserve pipette process<br>Section 6: delete log | L Barrett | C Bowman-Gholston |
| 2 | 4/16/2021 | Header: changed WAH to WOMC<br>Section 3: added technical specialist<br>Section 5: added details to calibration failures; added report review process | C Bowman-Gholston | C Bowman-Gholston |

## 9. ADDENDA AND APPENDICES

None