TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/21/2017
Department:	Technical & QA staff	**Due Date:**	8/15/2017
		Implementation:	**8/15/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Pipette and Dilutor Calibration SGAH.QA13 v2

Note: this has been converted to a system SOP

Description of change(s):

Section 4: remove 'pipette in reserve'

Section 5: change frequency to semi-annual,
remove specific vendor,
delete reserve pipette process

Section 6: delete log

This revised SOP will be implemented on August 15, 2017

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:	

Review:		
Print Name	**Signature**	**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 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.

~~**Pipette in Reserve** – a pipette that has been calibrated within the past year but not in current use.~~

5. PROCEDURE

A. POLICY

1. Scheduled ~~quarterly~~ calibration is performed by a contacted vendor ~~Scientific Calibration, Apex, NC, 800-892-9817~~.

2. Each pipetting device must be uniquely identified.

3. Each pipetting device must be calibrated prior to first use and at least semi-annually ~~quarterly~~ 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 ~~quarterly~~ semi-annual schedule.

2. When a pipetting device is calibrated, the next due date is documented on the calibration label.

3. ~~Quarterly~~ 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. ▪ Subsequent pipette evaluations must include 4 measurements. ▪ 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. ▪ Subsequent pipette evaluations must include 4 measurements. ▪ 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 %

~~Note: Scientific Calibration meets or exceeds Quest Diagnostics Inc. limits~~

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

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- 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 ~~with a like pipette from the reserve stock~~.

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. If it is determined that the number of certain volume pipettes is greater then needed, the excess may be designated in reserve provided the following process is followed.~~
~~a. Each pipette must be successfully calibrated with all documentation complete including appropriate label on the pipette.~~
~~b. Each pipette is recorded on the Reserve Pipette log that indicates it is held in reserve.~~
~~c. Reserve pipettes and log are maintained in the supervisor's office.~~
~~d. Each pipette held in reserve must be calibrated annually.~~
~~e. When a pipette is removed from reserve and placed into service, the following must occur:~~
~~1) Log is updated to indicate date placed into service.~~
~~2) Label pipette with 'date placed into service'.~~
~~3) The pipette can only be used as calibrated for 90 days or the next calibration cycle, whichever comes first.~~

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

6. RELATED DOCUMENTS

~~Reserve Pipette Log (AG.F332)~~

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 Section 5: clarify initial requirements, add requirements for subsequent calibration failure Section 6: move log from section 9, assign form # Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman-Gholston
1	7/10/2017	Header: add other sites Section 4: remove 'pipette in reserve' Section 5: change frequency to semi-annual, remove specific vendor, delete reserve pipette process Section 6: delete log	L Barrett	C Bowman-Gholston

9. ADDENDA AND APPENDICES

None