



**Clinical and Translational Support Laboratory**

**Pipette: Operations and Maintenance**

SOP No./WI No.: CTSI-CRC-PL-302

Department: Processing Laboratory

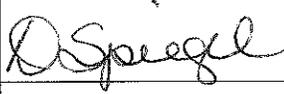
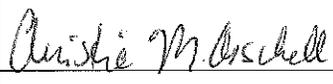
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Date	28 Dec 2016	28 Dec 2016	Dec 29, 2016

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## 1. OBJECTIVE

This procedure describes the process for how calibrated pipettes are maintained and operated in a manner which complies with all appropriate regulatory and protocol specific requirements and to ensure that all personnel are consistently using calibrated pipettes as required.

## 2. SCOPE

This Standard Operating Procedure (SOP) applies to all Clinical and Translational Support Laboratory (CTSL) staff and is intended to outline maintenance, calibration, verification and documentation procedures used within the laboratory processing procedures to ensure that variable and single volume hand-held pipettes perform with reliable precision and accuracy.

## 3. RESPONSIBILITIES

The laboratory staff is responsible for maintaining and operating pipettes used for laboratory processing and analysis procedures.

## 4. DEFINITIONS

- 4.1. **Calibration:** Procedures performed by pipette services and/or vendor to ensure that a pipette delivers the specified volume within acceptable limits as specified by the manufacturer.
- 4.2. **Relative Error (%RE):** A measure of accuracy, which may be positive, negative, or zero.  $\%RE = [(mean/theoretical) - 1] \times 100$ .
- 4.3. **Relative Standard Deviation (%RSD):** Same as % coefficient of variation (CV). RSD is a measure of precision.  $\%RSD = (standard\ deviation/mean) \times 100$ .
- 4.4. **Verification:** Procedures performed by either pipette services or laboratory personnel to verify that the pipette delivers a specified volume within acceptable limits.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	PL: Processing Laboratory
PM: Preventive Maintenance	RE: Relative Error
RSD: Relative Standard Deviation	SOP: Standard Operating Procedure

## 5. ASSOCIATED DOCUMENTS



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- 5.1. CTSI-CRC-QA-003 “Document Control and Management”
- 5.2. CTSI-CRC-CLN-030 “Handling of SOP Deviations”
- 5.3. IU EHS Policies and Procedures: <https://protect.iu.edu/environmental-health/>
- 5.4. CTSI-CRC-PL-121 “General Safety”
- 5.5. CTSI-CRC-PL-105 “Out of Specification Condition and Notification of Management”
- 5.6. CTSI-CRC-PL-123 “Contamination and Spill Clean-up Procedure”

## 6. PROCEDURE

### 6.1. Calibration, Maintenance and Repair:

- 6.1.1. CTSL staff or an approved calibration service provider will conduct preventive maintenance (PM) of hand-held laboratory pipettes on an annual basis. If the pipettes do not meet their verification standards, they are repaired, recalibrated, or discarded.
- 6.1.2. Pipette calibrations and verifications will be documented on CTSI-CRC-PL-FM509 “Pipette Maintenance, Calibration and Verification Form”.
- 6.1.3. Pipettes will be cleaned on an as needed basis and activities related to cleaning will be documented CTSI-CRC-PL-FM509 “Pipette Maintenance, Calibration and Verification Form”.
- 6.1.4. CTSL Management will review CTSI-CRC-PL-FM509 “Pipette Maintenance, Calibration and Verification Form” annually at a minimum.
- 6.1.5. If a pipette fails verification, it is repaired by the vendor or pipette services. Only when calibration and verification performance can be demonstrated within pipette service specifications can the pipette be returned to laboratory use. Repair records should be maintained as raw data according to the SOP on laboratory equipment maintenance.

### 6.2. Operations- Verification

- 6.2.1. Pipettes are verified on a routine basis, at minimum quarterly. The frequency needed will be documented per study protocol requirement.
- 6.2.2. Pipette services, vendor, or laboratory personnel can perform volume verification.
- 6.2.3. An adjustable pipette is verified at volumes at the top and bottom of the range of its intended use.
- 6.2.4. At least one channel of a multi-channel pipette must be verified.
- 6.2.5. Repeater pipettes must be verified with a minimum of single size tip at the highest and lowest settings.
- 6.2.6. Documentation of verification must contain the date of the verification, the initials of the technician performing the calibration, the serial number of the pipette being verified, the volume settings of the pipette, and the serial number of the balance used.
  - 6.2.6.1. Tare a vessel
  - 6.2.6.2. Adjust the pipette to deliver the desired volume



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- 6.2.6.3. Pipette the water into the vessel
- 6.2.6.4. Record the weight of the water dispensed
- 6.2.6.5. Repeat sets 3 and 4 at least two more times
- 6.2.6.6. Record serial number of balance used
- 6.2.6.7. Maintain verification documentation in CTSL equipment files
- 6.2.6.8. The density of water is assumed to be 1.000 g/mL
- 6.2.6.9. Acceptance/Rejection Criteria: the values of %RE must be within  $\pm 5.0\%$  of the target volume and the %RSD must be  $\leq 5.0\%$
- 6.2.6.10. If any pipette fails the acceptance criteria, initiate notification of CTSL management and proceed as follows:
  - 6.2.6.10.1. Segregate the pipette and label with Out of Service and note status on CTSI-CRC-PL-FM509 "Pipette Maintenance, Calibration and Verification Form"
  - 6.2.6.10.2. Pipettes that fail to meet the acceptance criteria must be repaired and recalibrated before they are used.
- 6.2.6.11. Pipettes that have been taken out of service due to verification failure or have past calibration expiration may be used for liquid transfer and must be labeled FOR TRANSFER USE ONLY.

**7. REFERENCES**

None

**8. APPENDICES**

None

**9. AMENDMENT HISTORY**

Date of Amendment: 22 Dec 2016

Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-010

Details of Amendment: Updated to footer file location; updated the SOPs in 5.2; removed 6.1.2 as "pipette services" is not defined and only qualified vendors are used for recertification; removed 6.1.3 as no analytical runs are performed by CTSL (C14 step reference)