

**Beaumont**

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Applicability Troy

## Pipette Calibration and Validation of Automatic Pipettes

Document Type: Procedure

### I. PURPOSE AND OBJECTIVE:

Pipette calibration is mandated by the College of American Pathologists (CAP). Periodic calibration and repair maintains the accuracy of the automatic pipettes used in the laboratory. Pipettes will be calibrated biannually. Pipettes failing the parameters of accuracy and precision will be serviced or removed from use as needed. New pipets will be deemed ready for use after verifying their precision and accuracy by performing a 5 point calibration using the Artel PCS pipette calibration system

### II. POLICY STATEMENT:

The pipettes at Troy will be calibrated by twice per year. New pipettes must be calibrated or verified prior to being placed in service.

### III. PRINCIPLE:

The Artel PCS<sup>®</sup> Pipette calibration system uses a high performance photometer and proprietary reagent to quickly and accurately measure the volume dispensed by any pipette. the Artel PCS<sup>®</sup> Pipette calibration system delivers accuracy and precision at pipette volumes between 0.1-5000µl.

### IV. REAGENTS:

- A. Artel PCS<sup>®</sup> Blank Reagent Vials.
- B. Artel PCS<sup>®</sup> Instrument Calibrator Kit.
- C. Artel PCS<sup>®</sup> Reagent kit.
- D. Sample Solutions.

## V. EQUIPMENT:

- A. Artel PCS<sup>®</sup> Pipette calibration instrument and power supply.
- B. Laptop with Artelware<sup>™</sup> Software installed.
- C. Printer for pipette labels (as needed).
- D. Pipettes to be calibrated.
- E. Proper pipette tips for the pipettes being calibrated. New pipettes may have been verified by the manufacturer and the validation data is supplied with the pipette. Save this documentation in the pipette calibration book.

## VI. SUPPLIES:

- A. Artel PCS<sup>®</sup> Kit containing:
  - 1. Blank Reagent vials.
  - 2. Sample Solutions.
  - 3. Sample Aliquot containers and transfer pipette.
  - 4. Calibrator Kit including Cal A-D vials and kit's insert.
- B. Nonabrasive cloth.
- C. Cotton Swabs
- D. Alcohol

## VII. EQUIPMENT CALIBRATION AND MAINTENANCE:

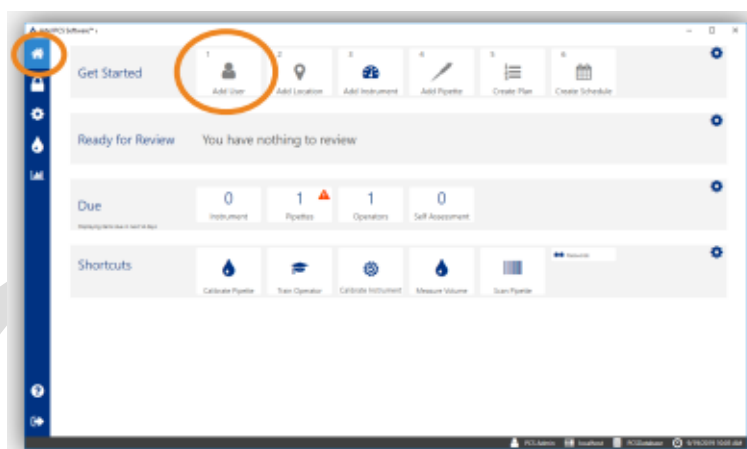
- A. Preventative maintenance
  - 1. Instrument is sent to Artel for inspection by Artel annually, or as needed.
  - 2. Storage Requirements
    - a. PCS reagents should be stored in their original box at room temperature.
      - i. Any sample solution dispensed into an aliquot container should be discarded.
      - ii. To avoid contamination, do not return reagents to their bottles after use.
    - b. The Calibrator kit should be stored at room temperature in its original box.
    - c. Avoid prolonged exposure to the light.
- B. Calibration
  - 1. A complete instrument calibration is performed monthly when in use.
  - 2. This verifies that all responses pass for Noise, Accuracy, Inaccuracy. See Operator's Manual (PCS<sup>™</sup> Procedure Guide) for procedure on performing instrument calibration.

3. The instrument housing and the vial holders are cleaned with cotton swabs dipped in alcohol and they are dried with gauze.

## VIII. PROCEDURE:

### A. Getting started:

1. Add PCS Artelware users.
  - a. Pipettes are assigned an Owner and Location to facilitate email notifications and filtering views of due items and results. At least one user and location must be created before pipettes can be added.
  - b. Add User and Add Location can be started directly from the Home screen.



- c. Click on the shortcut in the Get Started bar to launch the edit screen and then click the Home icon to return.

- d. Users need a Full Name, Email Address, an Initial Group, unique User Name, and an initial Password (users will need to set a new password on first sign-in).
      - e. Locations on require a Location Name.

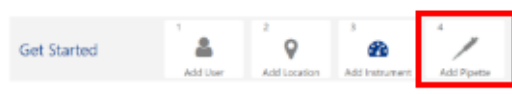
**NEW LOCATION**

**DETAILS**

Location Name:

Description:

- B. Add the pipettes to Artelware® program using the Add Pipette icon from the Get Started area of the home screen.



1. PCS Software includes a catalog of over 2000 pipette models, including manufacturer and ISO tolerances for those pipettes. Start adding a pipette into the software by browsing by Manufacturer and Model. New models can be added to the catalog through the Pipette Catalog tab on the Data Import/Export screen.
2. Enter the pipette ID.
  - a. Pipette ID is the unique identifier for the pipette for traceability through history and results. Once the pipette ID is entered and saved, it cannot be edited.
  - b. A label can be printed with the ID on it, see the PCS Quick Start Guide for instructions.
3. All pipettes in PCS Software have an assigned Location and Owner. Locations are used to filter views on due items and results. Owners are also used for filtering and can receive automatic notifications when tasks are due or completed.

C. Create a calibration plan:

1. Calibration Plans are used to describe the calibration procedures in PCS Software.
2. Each calibration requires the selection of a Calibration Plan.
3. Name the plan
  - a. Artel recommends that the name of the calibration plan reference the target volume.
4. Replicates
  - a. Enter the number of replicates or data points to be taken for the calibration, we use 10.
5. Evaluation criteria
  - a. Choose inaccuracy, imprecision, or inaccuracy and imprecision. These can be recorded as absolute or relative values.
6. Add a target volume
  - a. PCS Software will direct you to perform the pipette calibration in the same

order as the tolerances are entered.

D. Create a schedule for:

1. Pipette Calibrations
2. Operator Trainings
3. Instrument Calibrations
4. External calibration

E. Repetition Options

1. Decide how frequently the schedule needs to be completed and how date rescheduling is determined.
  - a. Due Date rescheduling stays true to the first due date.
  - b. Completion Date rescheduling adds the repetition cycle to the latest date once the schedule has been completed.

F. Scheduled Items

1. Select the pipettes, operators, or instruments which need to follow the schedule

**NEW SCHEDULE**

**DETAILS**

Name:

Description:

Type:

Repeats: Every   from ☐ Due Date ☒ Completion Date

**PIPETTES**

**CALIBRATION PLANS**

G. First Due By

1. Select the date when the schedule must first be completed.
  - a. Select OK

Pipette and Calibration Plan Selection

PIPETTES	CALIBRATION PLANS	DETAILS												
PIP123 Gilson Pipetman P20	ISO 20 µL Version 1 Approved	<table border="1"> <thead> <tr> <th>Target Volume</th> <th>Inaccuracy</th> <th>Imprecision</th> </tr> </thead> <tbody> <tr> <td>20.00 µL</td> <td>≤ 0.20 µL</td> <td>≤ 0.10 µL</td> </tr> <tr> <td>10.000 µL</td> <td>≤ 0.200 µL</td> <td>≤ 0.100 µL</td> </tr> <tr> <td>2.000 µL</td> <td>≤ 0.200 µL</td> <td>≤ 0.100 µL</td> </tr> </tbody> </table> <p>Replicates: 10 Tolerance Source: ISO Specification Evaluation Criteria: Inaccuracy and Imprecision</p>	Target Volume	Inaccuracy	Imprecision	20.00 µL	≤ 0.20 µL	≤ 0.10 µL	10.000 µL	≤ 0.200 µL	≤ 0.100 µL	2.000 µL	≤ 0.200 µL	≤ 0.100 µL
Target Volume	Inaccuracy	Imprecision												
20.00 µL	≤ 0.20 µL	≤ 0.10 µL												
10.000 µL	≤ 0.200 µL	≤ 0.100 µL												
2.000 µL	≤ 0.200 µL	≤ 0.100 µL												

First Due By: 4/10/2018

OK Cancel

## IX. BIANNUAL PIPETTE VERIFICATION:

- A. Prepare pipette for calibration by cleaning and performing any obvious maintenance procedures.
  1. The pipette to be calibrated should be cleaned and well maintained.
  2. Prepare instrument for use, according to above guidelines.
  3. From the Home screen in the Artelware™ click any Due pipettes or click Calibrate Pipette from the shortcuts menu to select a pipette which is not scheduled for calibration.

Due

0 Instrument 1 Pipettes 0 Operators

Shortcuts

Calibrate Pipette Train Operator Calibrate Instrument

4. Select the connected PCS instrument or choose to manually enter data acquired by other instruments.

Calibration using

INSTRUMENT

PCS2-100

Manual Entry  
Type in values from an external instrument or service

OK

5. Follow the on-screen instructions to complete the pipette calibration



Table 1: Artel's suggested initial tolerance limits					
Pipette Volume, $\mu\text{L}$		Relative Error		Absolute Error	
Nominal	Setting	Inaccuracy $\pm \%$	CV $\%$	Inaccuracy $\pm \mu\text{L}$	STD $\mu\text{L}$
2	2.0	2.0	1.0	0.04	0.02
	1.0	4.0	2.0		
	0.2	20.0	10.0		
2.5	2.5	2.0	1.0	0.05	0.025
	1.0	5.0	2.5		
	0.2	25.0	12.5		
10	10	2.0	1.0	0.20	0.10
	5	4.0	2.0		
	1	20.0	10.0		
20	20	2.0	1.0	0.4	0.2
	10	4.0	2.0		
	2	20.0	10.0		
50	50	2.0	1.0	1.0	0.5
	25	4.0	2.0		
	5	20.0	10.0		
100	100	2.0	1.0	2.0	1.0
	50	4.0	2.0		
	10	20.0	10.0		
200	200	2.0	1.0	4.0	2.0
	100	4.0	2.0		
	20	20.0	10.0		
500	500	2.0	1.0	10.0	5.0
	250	4.0	2.0		
	50	20.0	10.0		
1000	1000	2.0	1.0	20.0	10.0
	500	4.0	2.0		
	100	20.0	10.0		
2000	2000	2.0	1.0	40.0	20.0
	1000	4.0	2.0		
	200	20.0	10.0		
2500	2500	2.0	1.0	50.0	25.0
	1000	5.0	2.5		
	500	10.0	5.0		
5000	5000	2.0	1.0	100.0	50.0
	2500	4.0	2.0		
	500	20.0	10.0		

**ARTEL HOT LINE FOR TROUBLE SHOOTING TIPS: 888-406-3463**

## **XI. SPECIAL NOTES**

- A. The accuracy and precision of any pipette are affected by many factors. The condition in which a pipette is maintained, technique used in dispensing liquid, and type of pipette tips used are a few possible sources for discrepancy in results.



- B. Make sure the system is kept away from anything hot or cold. The pipettes, the PCS , and Reagents should be at a stable, uniform temperature.
- C. Ensure that the Reagent Kit and Instrument Calibrator Kit are at the same ambient temperature as the instrument.
- D. Keep all vials smudge free.
- E. Use the correct Sample Solution for the specific pipette volume being tested.
- F. Refer to the Artel PCS Quick Start Guide for instructions on exporting and importing data, accessory set up and other training schedules.

## XII. REFERENCES:

- A. Exhibit A: PCS 2 Instrument & Accessories Illustration, Artel PCS Pipette Calibration System Procedure Guide. Artel document #15A2135.
- B. National Committee for Clinical Laboratory Standards. Clinical Laboratory ProcedureManuals-third Edition; Approved Guideline. NCCLS document #GP2-A3.
- C. Artel PCS 2 Pipette Calibration System Procedure Guide. Artel document # 15A2135.
- D. Curtis RH. Performance verification of manual action pipettes: part 1 & 2. Am Clin Lab 1994.

### Approval Signatures

Step Description	Approver	Date
Policy and Forms Steering Committee Approval (if needed)	Masood Siddiqui: Staff Pathologist	4/25/2024
	Hassan Kanaan: OUWB Clinical Faculty	4/25/2024
	Kristin Russell: Supv, Laboratory	4/25/2024
	Elzbieta Wysteppek: Dir, Lab Operations B	4/24/2024
	Kristin Russell: Supv, Laboratory	4/24/2024

### Applicability

Troy