1.0 Purpose

This procedure provides instruction for the calibration, verification and operation of a water activity meter and specific instruction for the operation of the AquaLab 4TE.

2.0 Scope

This procedure applies to the AquaLab 4TE water activity meter in use at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of the QC Laboratory personnel to comply with this SOP.

3.2 The QC Laboratory management is responsible for ensuring compliance with this SOP.

3.3 It is the responsibility of the QC Laboratory/Analytical Development management to keep this SOP current with the latest Ion Labs practices.

4.0 Definitions

4.1 **QC** – Quality Control

4.2 **SOP** – Standard Operating Procedure

4.3 **K** – Thousand

4.4 **M** – Million

4.5 **Full Scale Range** – A calculation of the maximum viscosity value that can be measured by a spindle and speed combination when used with the specific spring torque of the DV1 viscometer

5.0 References

5.1 AquaLab Series 4 Water activity meter Quickstart Guide

5.2 AquaLab Series 4 Water activity meter Standard Operating Procedure

5.3 D-805-F1, Form, Water Activity Measurement Ticket

6.0 Procedure

6.1 Location and Setup

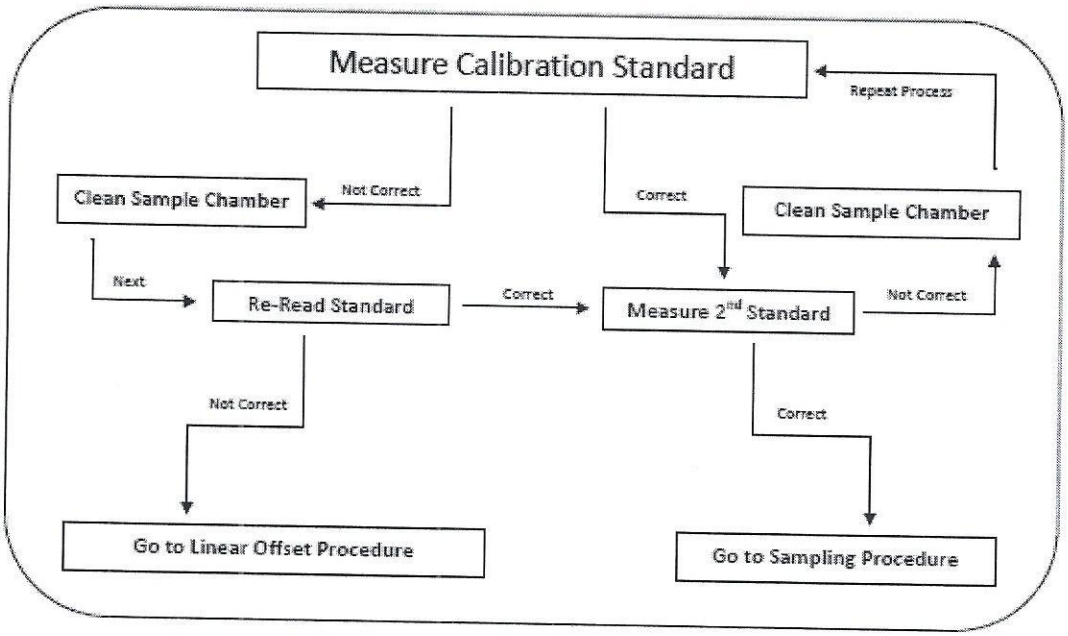
6.1.1 The water activity meter requires a clean, level surface in a temperature-stable environment for proper operation.

6.1.2 The meter is powered up by first plugging in then flipping the rocker switch on the back of the instrument. Allow the unit to warm up for 15 minutes.

6.2 Performance Verification

6.2.1 Verification should be conducted at least once per day before use or if readings become unstable.

This flowchart is a graphical representation of the directions given below for performance verification.



6.2.2 Verify the performance of the instrument with calibration standards that have known water activities:

Calibration Standard @ 25°C	Molality	Water Activity
Distilled Water		1.000 ±0.003
KCl	0.5 m	0.984 ±0.003
NaCl	6.0 m	0.760 ±0.003
LiCl	8.57 m	0.500 ±0.003
LiCl	13.41 m	0.250 ±0.003

6.2.3 Choose at least two verification standards that are on each side of the approximate samples you would like to measure.

6.2.4 Empty a vial of the calibration standard solution into a sample cup and place in the sample chamber.

6.2.5 Close lid and move the lever to the READ position.

6.2.6 The water activity reading of each standard should be within ±0.003 a_w of its specification.

6.2.7 If your first standard is not within ±0.003 a_w of its specification, it is probably due to contamination of the sample chamber. Refer to section 7.0 for cleaning instructions.

6.2.8 After cleaning, repeat verification. If reading are consistently outside of the a_w range a linear offset may have occurred and the reading of the standard should be corrected. Refer to section 6.3 for Linear offset procedure instructions.

6.2.9 If both readings are within the a_w range, proceed to section 6.4 for sample running procedure.

6.3 Linear Offset Procedure

6.3.1 When there is confidence that a linear offset has occurred, toggle to the Configuration tab by pressing the Menu icon button. Calibration is the first option highlighted in the configuration tab. Press the Enter icon button to access the calibration routine. Follow the onscreen instructions to perform the linear offset. They are listed below for convenience.

6.3.2 Press the Enter button to start the linear offset process. To return to the main menu, press the cancel button. Follow the prompt to insert a fresh standard and seal the chamber.

6.3.2.1 The same sample that triggered the need for the linear offset can be used to adjust the linear offset. Be sure that the rim and the outside of the cup are clean.

6.3.3 Close the lid and slide the lever to the READ position. Press the CHECK icon to start the test. You can cancel the linear offset program by returning the lever to the OPEN position or pressing the (X) button to cancel.

6.3.4 After the calibration standard is complete, press the up and down arrows to adjust the a_w reading to its proper value for the standard being measured.

6.3.5 When the value is correct, press the Save icon button to store the new value. To return to the main menu, press the Cancel button and no changes will be made.

6.3.6 Re-test the calibration standard in normal sampling mode (Section 6.2.5). If the standard is within the proper accepted range, continue with the second standard.

6.4 Sample Testing

6.4.1 It is important to ensure the sample should be representative of the product.

6.4.2 Be sure the completely cover the bottom of a clean, disposable sample cup.

6.4.3 To minimize the chance to contaminate the sample chamber, be sure the sample cup is not more than half full.

6.4.3.1 If testing gummy product forms, using a razor or knife, thinly slice a gummy and layer into a sample cup.

Note: Be very careful when using a razor or knife to cut gummies

6.4.4 Place sample cup, removing any lids on the sample cup, in a clean chamber and close the lid of the system.

6.4.5 Move the lever to the READ position.

6.4.6 After samples have finishing measuring, be sure to not leave samples in the chamber for extended periods of time.

6.4.7 Record the a_w of the sample on appropriate form.

6.5 Calibration Notebook and Form D-805-F1

6.5.1 This notebook will record the following information each time the water activity meter is calibrated

6.5.1.1 Analyst initials

6.5.1.2 Date

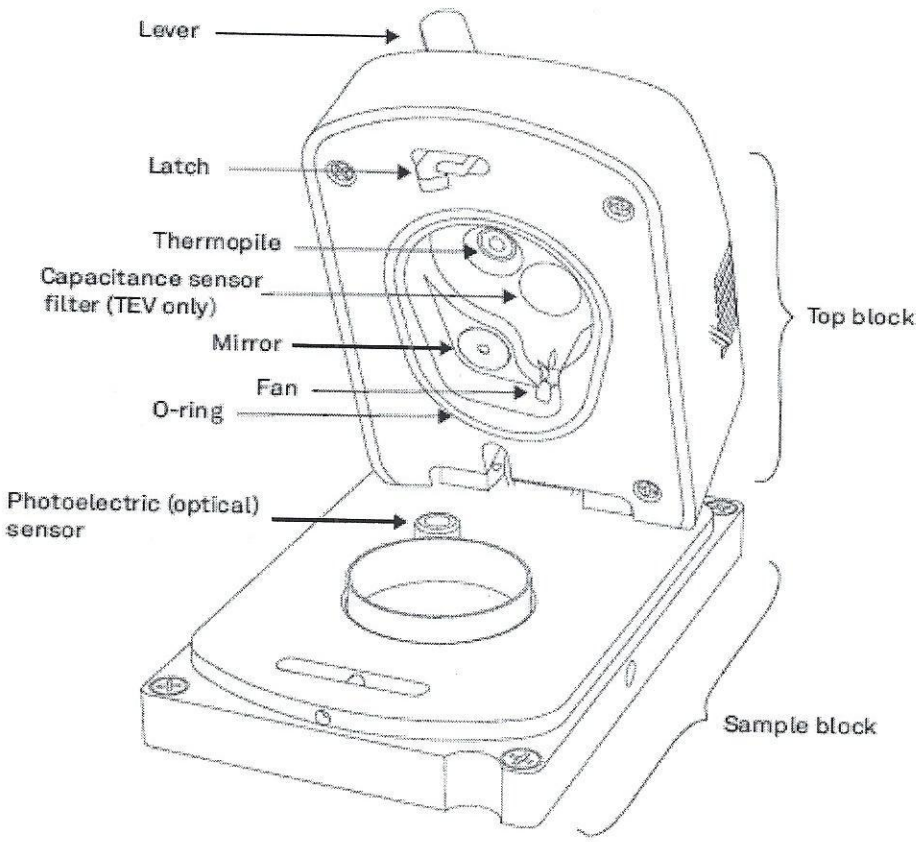
6.5.1.3 Standard theoretical value and obtained value (should be $\pm 0.003a_w$)

6.5.2 Form D-805-F1 can be used for raw material and finished product testing and should accompany the Internal Certificate of Analysis.

6.5.3 Results can also be documented in a laboratory notebook and a copy can be made to accompany the Internal Certificate of Analysis.

7.0 Cleaning

7.1 Keeping the instrument clean is vital to maintaining the accuracy of the instrument. Dust and debris from samples, oils from fingerprints on the mirror, or other sources can contaminate the chamber. The mirror must be perfectly clean for a smooth and even dew formation. A visual inspection should be performed often and at least as part of the verification process. A cleaning video is available at metergroup.com/meter_knowledgebase/aqualab-4te-certification



7.2 Be sure to wear clean gloves when cleaning the instrument.

7.3 With the instrument off, open the chamber to expose the sample chamber and sensors.

7.4 Clean the sample chamber (any area inside of the red O-ring with a closed lid) with isopropyl alcohol and Kimwipes or other appropriate cleaning solutions.

7.5 Be extremely careful around the fan blades when cleaning the chamber.

7.6 Remove any debris from the around or within the sample chamber.

7.7 You may need to wrap a moistened Kimwipe around the end of a spatula and gently clean hard to reach areas.

7.8 Repeat with deionized water and after with dry Kimwipes to remove any moisture.

7.9 After cleaning, visually inspect the chamber and sensers for any contaminant (including moisture) and let stand for at least 5 min for ensure chamber is dry.

7.10 After cleaning, be sure to perform a system verification and perform any correct for any linear offset that may have occurred.

8.0 Water Activities vs Growth of Representative Microorganisms

8.1 Per USP 1112 water activity can be used to justify reduced microbial testing.

Bacteria	Water Activity (a_w)	Molds and Yeast	Water Activity (a_w)
P. aerginosa	0.97	*R. nigricans*	0.93
B. cereus	0.95	*M. plumbeus*	0.92
C. botulinum, Type A	0.95	*R. mucilaginosa*	0.92
E. coli	0.95	*S. cerevisiae*	0.90
C. perfringens	0.95	*P. variotti*	0.84
L. viridescens	0.95	*P. chrysogenum*	0.83
S. spp.	0.95	*A. fumigatus*	0.82
E. aerogenes	0.94	*P. glabrum*	0.81
B. subtilis	0.90	*A. Flavus*	0.78
M. lysodekitcus	0.93	*A. niger*	0.77
S. aureus	0.86	*Z. rouxii*	0.62
H. halobium	0.75	*X. bisporus*	0.61

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/14/19	New.	N/A	J. Maignan
1	03/06/20	Add instructions for testing gummies	CC-20-0180	S. Sassman