Keywords: dry eye disease, osmolarity, tear, tearlab

<table>
<thead>
<tr>
<th>Table of Contents</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. ORDER</td>
<td>1</td>
</tr>
<tr>
<td>II. PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>III. PRINCIPLE</td>
<td>1</td>
</tr>
<tr>
<td>IV. SPECIMEN</td>
<td>2</td>
</tr>
<tr>
<td>V. EQUIPMENT AND MATERIALS</td>
<td>2</td>
</tr>
<tr>
<td>VI. QUALITY CONTROL</td>
<td>2</td>
</tr>
<tr>
<td>VII. PROCEDURE</td>
<td>3</td>
</tr>
<tr>
<td>VIII. REPORTING RESULTS</td>
<td>4</td>
</tr>
<tr>
<td>IX. INTERPRETATION</td>
<td>4</td>
</tr>
<tr>
<td>X. LIMITATIONS OF THE PROCEDURE</td>
<td>4</td>
</tr>
<tr>
<td>XI. REFERENCE RANGE</td>
<td>5</td>
</tr>
<tr>
<td>XII. OPERATOR TRAINING</td>
<td>5</td>
</tr>
<tr>
<td>XIII. OPERATOR COMPETENCY</td>
<td>5</td>
</tr>
<tr>
<td>XIV. TROUBLESHOOTING</td>
<td>5</td>
</tr>
<tr>
<td>XV. REFERENCES</td>
<td>5</td>
</tr>
<tr>
<td>XVI. SIGNATURES</td>
<td>6</td>
</tr>
</tbody>
</table>

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IV. SPECIMEN

The only specimen approved for testing on the TearLab® System is human tears. Because the TearLab® osmolarity test is a direct measurement, no specimen collection or handling is involved.

Collect tear fluid samples directly from the eye. Tear collection should be performed at the lateral (temporal) extent of the eyelid where the risk of inadvertent injury to the cornea can minimized, rather than adjacent to the cornea where injury is more likely.

- Do not collect tear fluid from a patient within two hours of eye drop use, use of topical medications or lotions on the face or eyes, or removal of eye makeup.
- Do not collect or store tear fluid samples for transport or testing at a later time.
- Do not collect tear fluid after ocular surface staining.
- Do not collect tear fluid after other invasive ocular diagnostic testing.
- Do not collect tear fluid within 10 minutes after a slit lamp examination.
- Do not collect tear fluid from a patient who has been crying.

Tear Lab is designed to collect samples of tear fluid from the eye, a nonsterile environment. Prevention of transmission of pathogens to the eye requires good hygienic techniques, such as handwashing and the cleanliness of the instruments touching the eye. The Test Cards are single-use, clinically hygienic and require no cleaning.

The AAO states that “human tears are not considered to contain significant amounts of blood-borne pathogens, and thus do not require OSHA’s blood-borne pathogens precautions...however, contact with tears contaminated with blood, such as in minor surgery, requires the use of blood-borne pathogen precautions.”

For Tear collection, refer to the patient testing section of this procedure.

V. EQUIPMENT AND MATERIALS

1. TearLab® Osmolarity System, consisting of the Reader, Pens and Electronic Check Cards
2. TearLab® Osmolarity System Test Cards
3. Normal and High Osmolarity Control Solutions
4. Digital Min/Max Thermometer, ordered via Cardinal Health SAP# 102529

Storage and Stability

Store the TearLab system, Test Cards and Controls at room temperature (15 – 30 degrees C/ 59 – 86 degrees F). Test cards not stored at ambient temperature before use may require several minutes to reach ambient temperature. Osmolarity Test Cards and Controls are stable until the expiration date marked on the label.

The operator will record the ambient temperature of the device area daily when performing the daily ECC Quality Control. The blank temperature log form is found in Appendix E.

VI. QUALITY CONTROL

Electronic Check Cards — Run the Electronic Check Card on each Pen before each day of patient testing to confirm that the system is within manufactured calibration specification.

1. Attach an Electronic Check Card onto a Pen. The green light on top of the Pen will illuminate and the Pen will beep. Wait approximately five seconds for the Pen to beep again or for the green light to turn off.
2. After the green light turns off, dock the Pen into the Reader. The LCD will display a code number. It is not necessary to enter a specific code for the Electronic Check Cards. Press OK to accept any code.
3. The LCD will display a test result that should fall within the expected value range indicated in the Instructions for Use provided with the Electronic Check Cards.
4. Remove the Pen and press the RECALL Key to confirm that the test result was properly stored in memory.
5. Repeat the procedure with the other Pen.
6. Record the date and Electronic Check Card test results in the Quality Control Log. The blank QC Log form can be found in Appendix A.

Normal and High Osmolarity Control Solutions — Control solutions are tested once a week with each lot number of Test Cards or when a new shipment is received even if it is of the same lot received previously. Only TearLab® Osmolarity Control Solutions should be used. In addition, controls should be run if the reader or pens are dropped or if the patient results are inconsistent with the clinical findings. If correct electronic or control solution test results are not obtained, do no test patient samples. Contact the POCT office at 5-2645 for support.

1. Attach a new Test Card onto a Pen.
2. Select the Normal Osmolarity Control Solution and tap the neck of the ampoule to remove any fluid.
3. Slide the blue rubber sleeve all the way down the neck of the ampoule. Snap off the top of the ampoule. Dispose of the ampoule top in a sharps container. Retain the blue rubber sleeve for future use.
4. Invert the ampoule and touch the tip of the Test Card to the Control Solution until the Pen beeps and the green light turns off.
5. Locate the code on top of the Test Card.
6. Dock the Pen into the Reader within 40 seconds of collecting the sample.
7. Immediately press the RECALL key below the up and down arrows to select the Test Card code.
8. Press the OK Key or wait eight seconds to accept the code.
9. The test result will display in a few seconds.
10. Confirm that the test result is within the expected value range indicated on the Control Solution Product insert. Disposed of the ampoule in a sharps container.
11. Record date and test result in the Quality Control Log.
12. With the other Pen and a new Test Card, repeat the steps with the High Osmolarity Control Solution.

VII. PROCEDURE
Patients must be positively identified using two unique identifiers such as Medical Record Number, Name or Birth date.

Before Each Test:

1. Remove either Pen from the Reader. The LCD will display “Ready”. Note: DO NOT collect tear samples if the Reader does not display “Ready.”
2. Remove a Test Card from its package and attach it onto the Pen. The Pen will beep and the green light will illuminate when the Card is attached properly. The green light will remain on until tears are collected or the Pen times out (after two minutes).
3. Remove the protective cover by holding the wings of the Test Card firmly and pulling the sheath up and off of the Test Card. Warning: A Test Card without a protective cover should be considered used. DO NOT use for patient testing.

Tear Collection Procedure

1. Seat the patient with chin tilted upward and eyes directed toward the ceiling.
2. Place one hand on the face for stabilization. Do not pull the eyelid down or away from the eye.
3. Position the tip of the Pen just above the lower eyelid.

4. Gently lower the Pen until the bottom of the tip touched the thin line of moisture between the eyelid and the eye. It is not necessary to press inward toward the eye.

5. The Pen will beep and the green light will turn off after a successful tear collection.

To Get the Result

1. Locate the code on top of the Test Card.
2. Dock the Pen into the Reader within 40 seconds of collecting the sample.
3. Immediately press the RECALL Key below the up and down arrows to select the Test Card code. IMPORTANT: if a code is not selected within eight seconds, the Reader will automatically use the default code displayed on the LCD. It is important to select the correct code to obtain an accurate osmolarity test result.
4. Press the OK Key or wait eight seconds to accept the code.
5. The test result will display in a few seconds.
6. Record the date and test result on the patient result log and in the patient chart. The blank Patient Result Log form can be found in Appendix B.
7. Remove the used Test Card from the Pen by pressing forward on top of the Test Card with your thumb. Do not pull from the wings. Dispose appropriately.

VIII. REPORTING RESULTS

After the result displays on the screen of the reader, record the date, time, operator ID and the test result in the Patient Result Log and in the patient's chart.

Results that display “Below Range” should be reported in the patient's chart and the Result log as <275. Likewise, results that display “Above Range” should be reported as >400. Osmolarities outside the stated range are very rare and should generally be confirmed with a subsequent test, as values outside the measurement range may be indicative of an error.

Results that appear to be inconsistent with patient therapy or condition should be viewed as questionable and the test should be repeated.

IX. INTERPRETATION

TearLab® test results are displayed on the LCD of the Reader in units of osmolarity (milliosmoles/liter, i.e. m/Osms/L) or osmolality (milliosmoles/kilogram, i.e., mOsms/kg). In tear fluid the difference between osmolarity and osmolality is less than 1%. It is common in the clinical literature to use the terms interchangeably, as the difference is insignificant.

Reference tear osmolarity values for Normal and Dry Eye osmolarity levels:

Normal: Mean 309.9 mOsms/L +/- 11.0

Dry Eye Disease: Mean 324.3 mOsms/L +/- 20.1

The results should be evaluated with all clinical and laboratory data available. If the results do not agree with the clinical evaluation, additional tests should be performed.

X. LIMITATIONS OF THE PROCEDURE

1. For in vitro diagnostic use only.
2. Leave the Test Card in its sealed pouch until just before use.

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3. Do not remove the protective cover until the Test Card is attached onto a Pen and immediately prior to tear collection.
4. Avoid touching the tip of the Test Card.
5. Do not use a Test Card past its expiration date.
6. Test Cards are single-use only.
7. Use only at ambient temperature of 15 – 30 degrees C/ 59 – 86 degrees F.

XI. REFERENCE RANGE
Normal range for tear osmolarity is 275 – 316 mOsm/L.

XII. OPERATOR TRAINING
Initial Training will include:

1. Overview of device and operation found in the current My Learning module and successful completion of the post-test.
2. Patient sampling in-service with the unit trainer.
3. Successfully perform and document electronic and liquid quality control

XIII. OPERATOR COMPETENCY
Operator Competency will be performed one year after the initial training and annually thereafter.

Training records will be kept in the employee’s personnel file. The POCT office will keep a copy of the training and competency records. Each operator’s competency will be assessed annually in the following areas:

A. Routine patient test performance.
B. Proper recording and reporting of test results.
C. QC and maintenance performance.
D. Assessment of problem-solving skills.

These will be assessed by successful completion of the current Tear Lab My Learning Module and completion of the current Tear Lab competency checklist with the trainer. The checklist can be found on the POCT website, https://pathology.jhu.edu/patient-care/point-of-care-testing

XIV. TROUBLESHOOTING
Refer to the troubleshooting section of the TearLab® User Manual included in Appendix E. Record error codes including “Above range” and “Below Range” errors on the error log. The blank error log form can be found in Appendix D.

XV. REFERENCES
1. TearLab® Osmolarity POL CLIA Manual — 940001 Rev C
2. TearLab® Osmolarity System User Manual — 930066 REV A, TearLab Corporation, San Diego, CA U.S. A.
### XVI. SIGNATURES

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<tr>
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<th>Date</th>
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<tr>
<td>William Clarke</td>
<td>11/17/2022</td>
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<td>Doctor of Philosophy</td>
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