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Tear Film Osmolarity

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I. PURPOSE/PRINCIPLE

This procedure provides direction for performing the Tear Film Osmolarity Point of Care Test for the diagnosis of Dry Eye.

The TearLab Osmolarity System is used to measure the osmolarity of human tears to aid in the diagnosis of Dry Eye Disease. Hyperosmolarity is a primary marker of tear film integrity. When either the quantity or the quality of secreted tears is compromised, the total osmolarity of the tear film is increased due to increased evaporation. As a result, basal tear equilibrium is shifted to a saltier solution, which places stress on the corneal epithelia and conjunctiva. The TearLab Osmolarity Test utilizes a temperature-corrected impedance measurement to provide an indirect assessment of osmolarity.¹ After application of a calibration curve to the steady-state electrical impedance of the tear fluid, osmolarity is calculated and displayed as a quantitative numerical value.

II. POLICY

Staff will follow the approved techniques outlined in this procedure.

Specimen:

Human tear fluid collected directly from the eyelid margin. Human tears are not considered a biohazard risk, however, personal protective equipment including gloves should be worn when collecting tears from a patient who has recently had eye surgery or where blood in tears may be present.

Reagents/Materials:

- TearLab Osmolarity System Reader
- TearLab Osmolarity System Pen
- TearLab Osmolarity Test Card
- TearLab Electronic Check Cards
- TearLab Control Solutions – Normal and High Osmolarity Control Solutions

Storage Options:

1. Store Osmolarity Test Cards at room temperature (15° - 30°C/59° - 86°F).
2. Test Cards not stored at room temperature should be at ambient temperature before use. Cold Test Cards may require several minutes to reach ambient temperature.
3. Osmolarity Test Cards are stable until the expiration date printed on the label.

Quality Control:

Internal

- Run the Electronic Check Card on each Pen before each day of patient testing to confirm that the system is within manufactured calibration specification.
- Document results in the Daily Quality Control section of the worksheet.
- Record room temperature in the Daily Quality Control section of the worksheet.

External

- Normal and High Osmolarity Control Solutions are tested monthly or once with each lot number of Test Cards or when a new shipment is received, even if it is of the same lot number as that of Test Cards received previously.
- Only TearLab Osmolarity Control Solutions should be used with the TearLab Osmolarity System.
- Control Solutions may be used as a guide in interpretation of a questionable result.
- Document the positive and negative commercial controls on the Tear Film Osmolarity worksheet when they are run.

CAUTION: The control ampoules are glass. When snapping off the top, sharp glass shards may be present around the opening of the ampoule.

Osmolarity Control Procedure

- Attach a new Test Card onto a Pen.
- Select the Normal Osmolarity Control solution and tap the neck of the ampoule to remove any fluid.
- 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.
- Invert the ampoule (the fluid won't spill out) and touch the tip of the Test Card to the Control Solution until the Pen beeps and the green light turns off.
- Locate the code on top of the Test Card.
- Dock the Pen into the Reader within 40 seconds of collecting the sample.
- Immediately press the RECALL Key below the up and down arrows to select the Test Card code.
- Press the OK Key or wait eight seconds to accept the code.
- The test result will display in a few seconds.
- Record the result on the TearLab Monthly Quality Control Procedure Log

If the Electronic Check Card and/or any of the controls do not perform as expected, do not use the test results.

Refer to the Quality Control/Troubleshooting section of this procedure or contact Technical Assistance at 1-858-455-6006 or www.tearlab.com.

III. **PROCEDURES**

NOTE: Use appropriate clinically hygienic methods when collecting tears. Dispose of used Test Cards in a biohazard container.

BEFORE EACH TEST:

- Turn the Reader On.
- Remove either Pen from the Reader. The LCD will display "Ready".
 - *NOTE: DO NOT collect tear samples if the Reader does not display "Ready".*
- 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).
- 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:

- Seat the patient with chin tilted upward and eyes directed toward the ceiling.
- Place one hand on the face for stabilization. Do not pull the eyelid down or away from the eye.
- Position the tip of the Pen just above the lower eyelid.
- Gently lower the Pen until the bottom of the tip touches the thin line of moisture between the eyelid and the eye. It is not necessary to press inward toward the eye.
- The Pen will beep and the green light will turn off after a successful tear collection.

NOTE: Sometimes when there is very little tear, the act of withdrawing the Pen breaks the surface tension of tear meniscus and allows tears to enter the microfluidic channel. In this case, the Pen will beep upon withdrawal, indicating a successful tear collection.

NOTE: Tear collection should be performed at the lateral (temporal) extend of the eyelid where the risk of inadvertent injury to the cornea can be minimized, rather than adjacent to the cornea where injury is more likely.

TO GET THE RESULT

- Dock the Pen into the Reader within 40 seconds of collecting the sample. Do NOT remove the Test Card from the Pen before docking or all data will be lost.
- Locate the code on top of the Test Card. 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.*
- Press the OK Key or wait eight seconds to accept the code.
- The test result will display in a few seconds.
- Record the date and test result in the patient chart.
- After recording test results, 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 in an appropriate manner.

EXPECTED RESULTS

Normal: Mean 310 (288 – 331 mOsm/L)

Dry Eye Disease: Mean 324 (291 - 382 mOsm/L)

- TearLab measurement range is linear from 275 mOsm/L to 400 mOsm/L. Test results outside this measurement range will be reported as either “Below Range” on the instrument, indicating a measurement below 275 mOsm/L or “Above Range” on the instrument, indicating a measurement above 400 mOsm/L. Results outside the instrument linearity should be documented in EPIC as <275 or >400 mOsm/L.
- Osmolarity may differ from left to right eye, and each eye should be tested and assessed to determine which eye represents the higher osmolarity.
- Interpretation of Results: TearLab test results are displayed on the LCD of the Reader in units of osmolarity or mOsm/L. No calculations are required. Osmotic concentration determinations are often expressed as either osmolarity (milliosmoles/liter, i.e., mOsm/L) or osmolality (milliosmoles/kilogram, i.e., mOsm/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.

REPORTING RESULTS

Staff performing test will record patient test result on the Tear Film Osmolarity Worksheet and in notes in the patient medical record. At the end of the day, the nurse will fax/deliver the worksheet to the HSC 401 Laboratory for result entry into Sunquest.

Clinic Labs: see the Computer Entry section of this procedure

PROCEDURE NOTES

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

CAUTION:

- 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 tear fluid samples from patients when eye makeup is present on the eyelid.
- Do not collect or store tear fluid samples for transport or testing at a later time.
- Do not collect tear fluid within 2 hours after ocular surface staining.
- Do not collect tear fluid after other invasive ocular diagnostic testing.
- Do not collect tear fluid within 2 hours after a slit lamp examination.
- Do not collect tear fluid from a patient who has been crying.

TROUBLESHOOTING

- Check expiration date of kit and controls.
- Recheck the Electronic Check Card.
- Recheck test using the External Quality Control Procedure.
- If the controls are still not performing as expected, open and run a new set of controls.
- If control results are still unacceptable, try a kit with a different lot number if available.
- Contact the manufacturer.

Reminder: According to the Internal Quality Control Policy, if expected QC values are not attained, patient results will not be reported until troubleshooting is complete.

For more troubleshooting information, consult the TearLab Osmolarity System User Manual, pages 12 – 13 or contact the manufacturer.

Maintenance – Routine

- The TearLab Reader can be cleaned with a damp cloth of alcohol wipe as required.
- The TearLab Pens can be cleaned with a damp cloth of alcohol wipe after each patient use.
- When cleaning it is important to keep the electronic contacts of the Pen and Reader dry.
- The electronic contacts and docking port should also be kept free of dust and dirt.
- Pen batteries cannot be replaced. If the Pen battery fails to recharge, contact your sales representative or TearLab Customer Support to purchase a replacement Pen. Cleaning fluids should never be used on the Test Cards.

REFERENCES

TearLab Osmolarity System Users Manual

Pedersen-Bjergaard K, Smidt BC. Electrolytic Conductivity, Osmotic Pressure, and Hydrogen Ion Concentration of Human Lachrymal Fluid. *Acta Derm Venereol Suppl* (Stockh). 1952;32(29):261-7.

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IV. DEFINITIONS

Osmolarity – The concentration of osmotically active particles in solution, which may be quantitatively expressed in [osmoles](#) of solute per [liter](#) of solution.

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

- TearLab Daily/Monthly Quality Control Procedure Log
- TearLab Osmolarity Worksheet

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

Computer Order and Result Entry

Tear Film Osmolarity Test
EPIC Order Code: Tear Osmolarity Lab Panel (EP 4913)
Sunquest Order Codes: RTOSM (Right Eye Tear Osmolarity)
EPIC# 4913
LTOSM (Left Eye Tear Osmolarity)
EPIC# 4914

RESULTING:

WORKSHEET:

Function MEMWorksheet TFOSM (Tear Film Osmolarity)

RESPONSE:

| <u>CODE</u> | <u>NAME</u> | <u>RESPONSE</u> |
|------------------------------|-------------------------------|--|
| LTOSM | Tear Osmolarity, Left Eye | Enter in numeric value <ul style="list-style-type: none">If numeric value is <275 or >400, computer will automatically result as <275 or > 400 respectively. The Result Interpretation will automatically append to the result. |
| RTOSM | Tear Osmolarity, Right Eye | Enter in numeric value <ul style="list-style-type: none">If numeric value is <275 or >400, computer will automatically result as <275 or > 400 respectively. The Result Interpretation will automatically append to the result. |
| Only one eye is tested | N/A | The worksheet is set to result both eyes each time. However, due to disease, one eye is not able to be tested or the patient may have only one eye. <ul style="list-style-type: none">Do not enter a resultDo NOT enter a credit code. Test will result as <275 on the TFOSM Worksheet. There are two ways you may credit this test and have it display correctly in the patient's medical record: <ul style="list-style-type: none">When you receive the test is Order Entry, credit the eye that was not tested.If you have already received the test, credit the test in Misys Gateway in the General Laboratory Option. Ensure the credit is set to REMOVE RESULT and enter NRUN (Test Not Performed). |

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