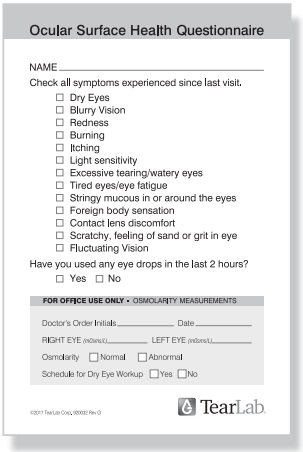
5 STEPS TO DOCUMENT A LABORATORY TEST

Medicare has several documentation requirements for point-of-care laboratory tests such as tear osmolarity, which must be noted in the patient chart or Electronic Health Record (EHR). Together with your TearLab representative, please review your EHR or paper In-Take Form to ensure that all 5 points described here are being captured correctly.

Remember, in an audit, if it is not documented properly and legibly it did not happen

1

Note the sign or symptom of disease that prompted the ordering of the test. You may use one of the standard dry eye questionnaires (DEQ-5, OSDI, or SPEED), design your own questionnaire, or utilize the Ocular Surface Health Questionnaire provided by TearLab. Dry eye signs or symptoms must be noted in the patient's record for that day. Ideally the symptom questionnaire can be added to or scanned into the EHR as further documentation. Signs or symptoms must be current complaints and not from a prior patient visit or history. A return visit to monitor therapy for an "unstable condition" would be sufficient to justify a test, but that must also be documented in the chart, and the condition that is being monitored must indicate that the disease is still active and/or unstable.


Ocular Surface Health Questionnaire

NAME _____

Check all symptoms experienced since last visit.

- ☐ Dry Eyes
- ☐ Blurry Vision
- ☐ Redness
- ☐ Burning
- ☐ Itching
- ☐ Light sensitivity
- ☐ Excessive tearing/watery eyes
- ☐ Tired eyes/eye fatigue
- ☐ Stringy mucous in or around the eyes
- ☐ Foreign body sensation
- ☐ Contact lens discomfort
- ☐ Scratchy, feeling of sand or grit in eye
- ☐ Fluctuating Vision

Have you used any eye drops in the last 2 hours?

☐ Yes ☐ No

FOR OFFICE USE ONLY - OSMOLARITY MEASUREMENTS

Doctor's Order Initials _____ Date _____

RIGHT EYE (mOsms/L)_____ LEFT EYE (mOsms/L)_____

Osmolarity ☐ Normal ☐ Abnormal

Schedule for Dry Eye Workup ☐ Yes ☐ No

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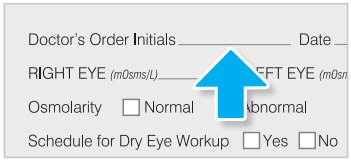
TearLab

TearLab testing can be performed anytime during the office visit if medical documentation exists showing the doctor had the intent for the test to be performed, and that intent has been authenticated by the doctor via a handwritten or electronic signature in the chart. See rules in 42 CFR 410 and Pub.100-02 chapter 15, §80.6.1.

A prior history of dry eye is not sufficient to justify a test. The patient must present with current signs or symptoms of disease, an unstable condition, or a return for the monitoring of therapy, all of which must be properly documented.

2

Specifically identify the test in the medical record by stating "tear osmolarity test was ordered". Document the name of the test, i.e. "tear osmolarity"; do not use acronyms (i.e. "TOT"). Although an order for a laboratory test is always required, Medicare regulations allow an order for an in-office laboratory test to be verbal and unsigned, as long as there is *"medical documentation (e.g. progress note) by the treating physician that he/she intended the clinical diagnostic test to be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature."*[1] (see point #5).


Doctor's Order Initials _____ Date _____

RIGHT EYE (mOsms/L)_____ LEFT EYE (mOsms/L)_____

Osmolarity ☐ Normal ☐ Abnormal

Schedule for Dry Eye Workup ☐ Yes ☐ No

Payers will not pay for the test if it is not used to manage the patient and identified by name (i.e. tear osmolarity) in the progress notes. Do not use abbreviations, i.e. "TOT".

1. Medicare Program Integrity Manual. CMS Publication 100-08, Chapter 3; para. 3.3.2.4 Exception 2.

3

Record the numerical tear osmolarity test results and indicate if the results were "normal" or "abnormal". It is not sufficient to just document the test results, you need to show that someone reviewed the test results to determine if they were "normal" or "abnormal", as per published reference values or your dry eye protocol. You must indicate that the laboratory test was used to manage the patient during that visit, and determining if the test results were normal or abnormal is critical documentation. This can be a simple check box in the chart, or a comment in the progress notes.

RIGHT EYE *(mOsms/L)*_____ LEFT EYE *(mOsms/L)*_____

Osmolarity ☐ Normal ☐ Abnormal

Schedule for Dry Eye Workup ☐ Yes ☐ No

Return visits for therapeutic monitoring must have previous test results documented for comparison to current test results and support a change in the status of the patient's condition.

4

Determine the Treatment/Management Plan, i.e. the medical action taken as a result of the tear osmolarity test, and reference the test results in the plan. This is important, as payers will not pay for a test that is not used to manage the patient, as indicated in point #3. Even if the test results are "normal" that should be indicated in the progress notes, because it has direct impact on the final diagnosis or management plan.

Laboratory tests will be covered if results are either "Normal" or "Abnormal". Either result must be used in the management of the patient, i.e. "Tear Osmolarity 'Normal', Dry Eye no longer considered, Dx Ocular Allergy"

Be sure that osmolarity testing is noted for the next follow-up appointment, if it's part of the management plan. This can be referenced for the day of the test:

"Patient returning per doctor directed orders for evaluation of the tear film, osmolarity findings, and retinal macular evaluation secondary to ocular surface disease noted at last visit 3 months ago."

5

Ensure the clinician signed the record indicating that everything in the chart that day was reviewed and confirmed as medically necessary. As discussed in point #2, a verbal order is not unusual for an in-office laboratory test, and the clinician's signature in the chart indicates the doctor's *"intent that the clinical diagnostic test be performed"*. If you are using a paper symptom questionnaire, the doctor's initials on the questionnaire provide additional documentation that the symptoms leading to the ordering of the test were properly reviewed.

FOR OFFICE USE ONLY - OSMOLARITY MEASURE

Doctor's Order Initials_____ Date____

RIGHT EYE *(mOsms/L)*_____ EFT EYE *(mOsms/L)*

Osmolarity ☐ Normal Abnormal