

Overview of ATD's Diagnostic Tear Tests



Two assay tests can be done with the ATD TearScan™, Lactoferrin and IgE.

Ocular Lactoferrin is a protein marker that indicates the secretory function of the Lacrimal Gland and aids in determining if the patient has Aqueous Deficient Dry Eye or Evaporative Dry Eye. As a result of its iron binding properties, Lactoferrin exhibits a unique combination of antimicrobial, antiviral and anti-inflammatory properties. Lactoferrin is one of the eye's main immunological defense mechanisms and plays an important role in the maintenance of ocular health. Low lactoferrin levels directly indicate a depressed ocular immune system, thus, may represent an elevated surgical risk factor for both IOL and LASIK surgery.

The system also tests *Ocular IgE* allergy levels. These allergies can often "mask" as Dry Eye. IgE can be asymptomatic and is a contraindication for LASIK. Because total IgE in tear fluid increases with the severity of allergic response, determination of total tear IgE level is useful not only for making a clinical diagnosis of allergic conjunctivitis but also for the assessment of severity. The presence of an allergen often mimics the signs and symptoms of dry eye disease; thus, it is important to assess the presence of an allergen during an initial dry eye evaluation.

Doctors using the TearScan™ system have noted that both low and high Lactoferrin levels as well as high IgE levels appear to lead to discomfort for contact lens wearers. Also low Lactoferrin levels seem to be boosted by the use of Lactoferrin supplements that are readily available in the marketplace. These claims still need to be proven by clinical research and are only interesting antidotal evidence at this point in time.

The TearScan™ test strips are \$10.50 per eye, per test. The tests are both CMS and Private Insurance reimbursable and require a CLIA Class 2 moderate complexity certification. ATD will assist with the CLIA application and provide training and schedules so a clinic can easily maintain CLIA compliance.

The CPT Code for Lactoferrin is 83520 and the IgE code is 82785. The gross reimbursement for both tests is slightly over \$80.00 with a net profit of just under \$40.00. The tests can be repeated as needed, but generally are repeated within 6 weeks from the initial test. Since this is a point-of-care lab test, patient deductibles or co-pays do not apply on government related CMS reimbursement nor do they apply to most private payer plans.



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How are the ATD tests performed?

The test materials consist of the following;

- IgE or Lactoferrin test strip
- Micropipette
- Chase fluid
- TearScan reader

Both the IgE and Lactoferrin (LF) test require 0.5 micro liter of tears from each eye. Tears are harvested from the lower lid margin using the micropipette. This provides basal tears and not reflex tears. The tears are dropped into the OD/OS wells on the test strip followed by 5 drops of chase fluid. The IgE test takes approximately 3 minutes while the Lactoferrin test is around 90 seconds. The TearScan™ reader will scan the strip, 5 seconds, and display the amount of IgE or LF that is contained in the patient tear sample. The results of the test can be wirelessly sent to a printer for a copy of the patient lab results or linked to your EMR system.

Benefits of ATD's Diagnostic Tear Tests

Improved Patient Care: Quantitative tests identify the cause of dry eye type symptoms, allow for the grading of severity and management of treatment efficacy

Diagnostic Accuracy: Specificity of all ATD tests exceeds 96% - tests are simple, accurate and reproducible

Productive: Doctor's chair times is shifted to technicians with POC test results available to the doctor before they see the patient

Profitable: Tests are reimbursable under CPT codes authorized by the American Medical Association and the American College of Pathology - average net return is just under \$40 per patient tested



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