Elafin serum
Test Code: 30140

Clinical and Procedure

Clinical Utility
For the quantitative measurement of Elafin. Elafin, a protein expressed by keratinocytes within the epidermis of the skin, has been shown to be elevated in medical conditions where immune dysregulation occurs causing damage of the skin.

About Graft versus Host Disease (GvHD)

Graft versus host disease (GvHD) is one of the major causes of morbidity and mortality associated with allogeneic stem cell transplants. GvHD occurs in 30 – 50% of HLA-matched sibling transplants and 60 – 90% of matched unrelated donors. GvHD often manifests in the skin, liver and/or gastrointestinal (GI) tract, and is caused by immune dysregulation that is initiated when allogeneic donor T cells recognize host tissues as foreign. GvHD may be either acute or chronic. Acute GvHD (aGvHD), which typically occurs in the first 3 months post-transplant, has an incidence of 19 – 66% and carries a poor prognosis if the disease is severe. Chronic GvHD (cGvHD) occurs 3 months to > 1 year post-transplant and has a pathophysiology that is distinct from aGvHD, although poorly understood. The overall incidence of cGvHD is 40 – 50%.

Pre-transplant conditioning regimens may damage host tissue, which in turn leads to inflammatory cytokine release (TNF-α, INF-γ, IL-1 and IL-6) directly from damaged tissues. The inflammatory cytokines stimulate antigen presenting cells which present host antigens to donor lymphocytes. In response, donor T cells proliferate, differentiate and undergo activation. Once donor T cells are activated, pro-inflammatory cytokines are produced in large quantities resulting in additional inflammation, recruitment of neutrophils to the site, and ultimately severe tissue damage. Administration of immunosuppressive agents are commonly used to treat cases of GvHD.

In skin, aGvHD frequently manifests as a maculopapular skin rash due to cellular/tissue damage. In the GI tract, aGvHD which frequently manifests as nausea, vomiting, anorexia, secretory diarrhea and in severe cases abdominal pain and at times hemorrhage, is caused by cellular damage to the mucosal epithelial barrier of the small intestines. The occurrence of aGvHD in the liver results in elevated bilirubin levels, indicative of liver damage.

Diagnosis of aGvHD has traditionally been based on the clinical presentation and ruling out other etiologies through differential diagnosis. In some cases biopsies of the liver, skin or GI tract are performed. In recent years, measurement of specific biomarkers, some of which are cytokines, has been shown to provide improved aGvHD diagnostic and prognostic approaches while utilizing in vitro methods and readily available samples such as serum. Recent research has identified several key biomarkers useful for aGvHD diagnosis and prognosis. 4

Procedure
The assay for quantification of Elafin is a sandwich ELISA performed in a microtiter plate format. Conversion of a chromogenic substrate produces a color, the intensity of which is proportional to the concentration of Elafin in the sample material. A standard curve is used to calculate the concentration of Elafin in each of the test samples. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
Specific to human Elafin.

Turnaround Time
3 business days from receipt of specimen

Specimen Information
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<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
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<td>83520</td>
<td>Yes</td>
<td>1 mL</td>
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**Special Instructions**
- Whole blood should be collected in serum tube.
- Allow to clot for 30 to 60 minutes and centrifuged to isolate the serum.
- 1 mL of serum sample should be removed to a sterile tube and frozen immediately (-70°C).

The reference range for a healthy population is less than 5-22.9 ng/mL. However, it should be noted that these ranges are obtained from a limited population of apparently healthy adults and are not diagnostic thresholds.

**Shipping**
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight© to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

**Causes for Rejection**
Invalid specimen type, inadequate volume, gross hemolysis or gross lipemia, sample not frozen upon receipt.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

**References**