**CU Index®**

**Test Code: 2103**

**Clinical and Procedure**

**Clinical Utility**
Patients with a chronic form of urticaria who are positive (> 10) with the CU index® have an autoimmune basis for their disease. A positive result does not indicate which autoantibody (anti-IgE, anti-FceRI or anti-FceRII) is present.

**About Chronic Urticaria**

Chronic urticaria is a common skin disorder affecting 0.1 to 1% of the general population. It is characterized by recurrent, transitory, pruritic erythematous wheals present for at least 6 weeks. The impact of chronic urticaria on the quality of life can be significant. Kaplan and others have demonstrated that in 30–50% of these chronic urticaria patients there is an autoimmune etiology with autoantibodies against IgE, FcεRI or FcεRII (CD23).

It is presumed that these autoantibodies bind to the surface of mast cells and basophils and initiate a signal transduction cascade that results in secretion of histamine and other mediators. The treatment course for the autoimmune form of the disease is often different from treatment for acute and transient urticaria or idiopathic chronic urticaria. Drugs that modulate the basic immunological aspects of the disease (e.g., methotrexate, calcineurin inhibitors) may be considered if an autoimmune etiology is established.

**Procedure**

Ex-Vivo Challenge and cell culture: Donor blood cells are incubated with patient serum, a negative control and a positive control. Following the ex-vivo challenge, the cells are centrifuged and the supernatant is recovered for assay of histamine released. Histamine Analysis: Using a quantitative enzyme immunoassay, the histamine released into the supernatant is measured and compared to the total histamine in the basophils. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

**Turnaround Time**

2-5 business days from receipt of specimen

**Specimen Information**

<table>
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<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>serum</td>
<td>2103</td>
<td>86352</td>
<td>Yes</td>
<td>1 mL (min. 150 uL)</td>
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**Special Instructions**
- Collect 3-5 mL whole blood in a serum separator tube (SST).
- Centrifuge specimen within 2 hours of draw to pellet cells below the gel.
- Patients taking calcineurin inhibitors should stop their medication for 72 hours prior to draw. Patients taking Prednisone should be off their medication for 2 week prior to draw.
- Can be shipped at ambient or frozen temperature Monday through Friday.

**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.

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References

6. Platzer MH, Grattan CEH, Poulsen LK, Skov PS. Validation of basophil histamine release against the autologous serum skin test and outcome of serum-induced basophil histamine release studies in a large population of chronic urticaria patients. Allergy. 2005 Sep;60(9):1152-6.