

Novel blood testing for autoimmune chronic urticaria

General

1. What is the difference between chronic urticaria and acute urticaria? Are they both a result of an autoimmune issue?

A: Acute urticaria (hives) appears suddenly and resolves within six weeks. Chronic urticaria lasts longer than six weeks. While autoimmune issues can contribute to some cases of chronic urticaria, the causes of acute urticaria are more often due to identifiable triggers to specific foods, drugs, insect venoms or infection.

2. Do guidelines recommend testing for chronic urticaria?

A: The international EAACI/GALEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis and management of urticaria states, “More advanced tests, such as basophil activation testing for CSUaiTIIb, can bring more clarity and should be guided by and based on the history, physical examination and results of basic testing.”¹

3. What is the benefit of testing a patient for chronic urticaria?

A: Similar to other allergy workups, diagnosing chronic urticaria typically involves a physical exam and medical history assessment. Testing can help determine if the cause of chronic urticaria is autoimmune related, which can help avoid treatments that may not work. Testing can also help confirm the diagnosis and rule out other conditions; assist with identifying underlying causes of the urticaria, helping a patient avoid triggers; and help predict the disease course and a patient’s response to treatment.²

4. How can chronic urticaria test results help with patient therapy management?

A: Chronic urticaria testing can help determine disease duration and activity and how a patient may respond to therapies including antihistamines, corticosteroids and/or omalizumab. Positive results in basophil activation tests have been linked to slower responses to omalizumab. The results of the basophil activation tests are significantly correlated with the time to symptom relief with omalizumab and can help set expectations for treatment.³

Method

1. What is the difference between a basophil activation test (BAT) and a basophil histamine release assay (BHRA)? Is one test more accurate than the other?

A: While both BAT and BHRA assess basophil function, BAT focuses on measuring the expression of activation markers (like CD63) on the basophil’s surface, while BHRA measures the release of histamine from these cells. BAT is generally considered to be more sensitive and accurate due to its ability to detect lower levels of basophil activation.⁴

General testing

1. Does my patient need to stop antihistamine and/or corticosteroid therapy before having the Labcorp Chronic Urticaria - Pooled Basophil Activation Test (PD-BAT) drawn?

A: Antihistamines and corticosteroids do not interfere with this test’s performance. Your patients may remain on their medications as prescribed.

2. How can Labcorp’s chronic urticaria test help me assess my patient’s responsiveness to omalizumab?

A: Positive results in basophil activation tests have been linked to slower responses and time to symptom relief with omalizumab.³ Results of chronic urticaria BAT tests may help clinicians set patients’ expectations for therapy.

3. Does Labcorp have a profile which includes other tests to work up chronic urticaria patients?

A: Labcorp has developed a Chronic Urticaria Evaluation Profile, test number 505805, which follows guidelines from the international EAACI/GALEN/EuroGuiDerm / APAAACI for the definition, classification, diagnosis and management of urticaria.¹

The profile includes the following tests:

- Chronic Urticaria PD-BAT
- Complete Blood Count (CBC) With Differential, Reflex to Peripheral Smear Review
- Sedimentation Rate, Modified Westergren
- C-Reactive Protein (CRP), Quantitative
- Alanine Aminotransferase (ALT/SGPT)
- Thyroid-stimulating Hormone (TSH)
- Thyroid Peroxidase (TPO) Antibodies

Coverage and coding**1. Is chronic urticaria testing covered by most payers?**

A: Coverage varies by state, region and payer, please consult with your local account representative for information about coverage.

2. What is the CPT code that is used for billing?

A: The Chronic Urticaria PD-BAT, test number 505800, will bill under CPT code 86849.

Comparison to CU Index®**1. What is the difference between the CU Index and Labcorp's PD-BAT for chronic urticaria?**

A: The two tests differ in methodology. These different methodologies impact test performance and the patient's ability to stay on their medications during testing.

The CU Index is a basophil histamine release assay, or BHRA, that measures the amount of histamine released. The Labcorp test is a basophil activation test, or BAT that measures the expression of the CD63 surface marker on basophils from whole blood by flow cytometry. We use a proprietary, patent-pending methodology for selecting and pooling donors which provides increased accuracy and precision over basophil histamine release assays.⁵

Antihistamines and corticosteroids do not interfere with Labcorp's test's performance. Your patients may remain on their medications as prescribed.

The CU Index indicates that patients on calcineurin inhibitors should stop their medication for 72 hours prior to testing, and patients taking prednisone should be off their medication for two weeks prior to testing.⁶

2. Will Labcorp continue to offer the CU Index as a send-out test?

A: Due to the improved clinical utility of the Chronic Urticaria PD-BAT, test number 505800, Labcorp will be discontinuing the send out of the CU Index test, test number 820022, effective May 31, 2025.

3. Does the price for the new chronic urticaria test differ from the CU Index?

A: Pricing has remained the same as the CU Index send-out test. Please contact your local Labcorp representative should you have questions.

4. How will results be displayed for the Labcorp test? How does this differ from the CU Index?

A: The Labcorp results will be displayed as a % with an index number. The following is an example comparing how the values may appear:

- Test Result Comparison CU Index: >10 - have an autoimmune basis for their disease
- Labcorp's Chronic Urticaria PD-BAT: >10.61% - have an autoimmune basis for their disease

References:

1. Zuberbiar T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022 Mar;77(3):734-766. PubMed 34536239
2. Metz M, Altrichter S, Buttgereit T, et al. The Diagnostic Workup in Chronic Spontaneous Urticaria-What to Test and Why. *J Allergy Clin Immunol Pract*. 2021;9(6):2274-2283
3. Gericke J, Metz M, Ohanyan T, et al. Serum autoreactivity predicts time to response to omalizumab therapy in chronic spontaneous urticaria. *J Allergy Clin Immunol*. 2017 Mar;139(3):1059-1061. PubMed 27838346
4. Santos AF, Alpan O, Hoffmann HJ. Basophil activation test: Mechanisms and considerations for use in clinical trials and clinical practice. *Allergy*. 2021;76:2420-2432.
5. Wills S, Chavez J, Grover A, et al. PD-BAT: A novel approach of pooling basophil donors for expansion of commercial laboratory testing of Chronic Spontaneous Urticaria. *J Immunol Methods*. 2024 Jun;529:113679.
6. CU Index specimen information. Accessed March 12, 2025. <https://eurofins-viracor/test-enu/2103-cu-index>.