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inside Diagnostics

THE NEWSLETTER FOR HEALTHCARE PROVIDERS

LifeLabs® EMPOWERING HEALTHIER CANADIANS FOR OVER 60 YEARS

Beyond TSH and Free T4

The Clinical Utility of Thyroid Receptor Antibodies (TRAb) Testing

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Thyroid receptor antibodies (TRAbs) are a series of autoantibodies that bind to thyrotropin (TSH) receptors on the thyroid gland. These antibodies can be classified into distinct subtypes including (a) stimulating antibodies (increasing the production of T4 and T3), (b) inhibitory antibodies (reducing the production of T4 and T3) or (c) neutral or cleavage antibodies (do not significantly affect T4 or T3 production by the thyroid gland).

There is some confusion regarding the terminology for these thyroid binding antibodies. They have been called different things over the years, such as (a) TRAbs, (b) long-acting thyroid stimulator (LATS) and (c) thyroid binding inhibitory immunoglobulins (TBIIs). Briefly, both LATS and TBIIs appear to be subsets of TRAbs, with LATS being a thyroid stimulating antibody and TBIIs being inhibitory in the sense that they inhibit TSH binding to thyroid receptors but do not necessarily inhibit thyroid function. Currently we group all of these thyroid binding antibodies into the group called TRAbs and determine their clinical effect on the thyroid by measuring the typical thyroid markers such as TSH, free-T4 and free-T3.

Graves Disease (GD) results from unregulated thyroid stimulation by stimulating TRABs. GD is the most frequent cause of hyperthyroidism, affecting far more women than men (about 5-10:1). Patients with GD most often present with excessive sweating, heart palpitation, heat intolerance, weight loss, tremors, insomnia, anxiety, and other classic symptoms of thyrotoxicosis. Symptoms can also include amenorrhea, a palpable thyroid (goitre), pretibial myxoedema and typical Graves' ophthalmopathy.

Diagnosis of GD utilizes typical thyroid function tests (free-T4, free-T3, TSH), radioactive iodine uptake scans, thyroid ultrasound and TRAb. It is recommended that TRAb be measured in cases of thyrotoxicosis to confirm a diagnosis of GD, given its specificity for GD. Subsequently, TRAb levels can be used to choose the optimal treatment for GD and help avoid progression of ophthalmic disease.

Treatments for GD include thioamides, methimazole, carbimazole and propylthiouracil, with non-responders necessitating thyroid ablation with either radioactive iodine or thyroidectomy. Recurrence of GD following treatment is fairly common, and measurement of TRAb can predict recurrence and assist in determining further treatment options to avoid ophthalmic and other damage to the extent possible.

TRAb can be used to monitor the progression (or lack thereof) of ophthalmopathy. It is now known that TRAbs readily cross the placental barrier and their levels should therefore be measured regularly in patients with gestational GD to guide treatment and avoid thyrotoxicosis or hypothyroidism in the fetus. Pediatric GD should also be monitored with TRAb to assist in controlling progression of pediatric ophthalmopathy.

At this time, TRAB is not a benefit of OHIP, and patients are required to pay for the test. When TRAB is ordered, LifeLabs performs the test in-house with maximum 5-day turnaround time. In addition, the TRAB result will be supported by an interpretive algorithm that looks at all thyroid results performed for that patient at LifeLabs over the previous 6-month period. The ensuing pathologist-reviewed report will assist health care professionals in interpreting the test results and can be useful in determining the next steps in the care of the patient. Please note there is no additional charge to patients or clients for this interpretive report.

We trust you will find the TRAB test result and its accompanying professional interpretation useful in guiding the treatment of your patients.

For more information, including pricing, please contact our Ontario Customer Care Centre at: **1-877-849-3637.**

EUROIMMUN Workstation

Enhancing Diagnostic Confidence and Clinical Efficiency

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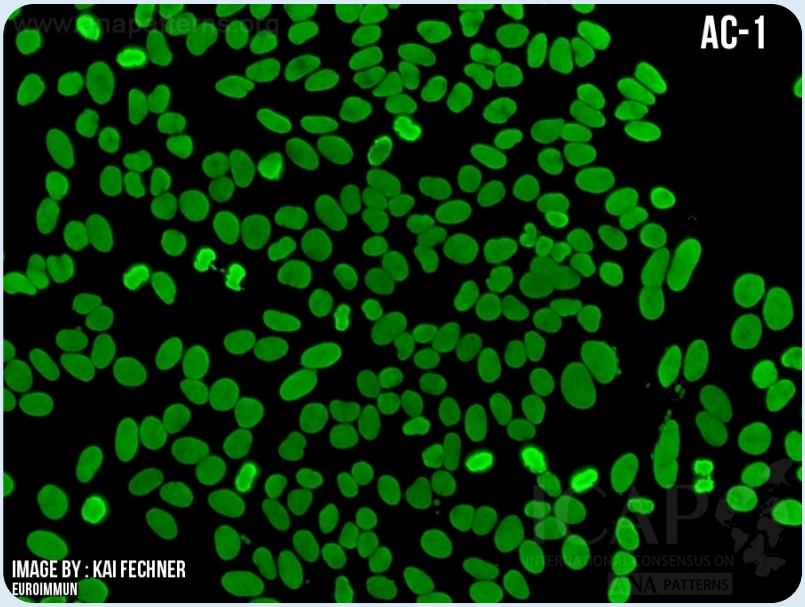

Immunofluorescence assay (IFA) methodology plays a critical role in the diagnosis of autoimmune rheumatologic diseases. IFA detects circulating autoantibodies directed against specific cellular (nuclear and cytoplasmic) or tissue antigens, often serving as an early indicator of disease.

One commonly used method is indirect immunofluorescence where a special "detection" antibody is added to the sample. This antibody is designed to attach to another antibody that has already bound to a specific target (antigen) in the sample. After this step, the sample is viewed under a fluorescence microscope. If the target is present, the detection antibody binds and produces a glowing (fluorescent) signal.

The pattern and location of this fluorescence are then carefully interpreted. Different patterns are associated with different conditions and the characteristic fluorescence patterns help narrow differential diagnoses and guide follow-up testing. IFA provides high diagnostic sensitivity to allow detection of low-titre antibodies which may be missed by some solid-phase assays.

Maintaining up-to-date, advanced technology is essential to support clinicians in accurate diagnosis and patient monitoring. In November 2025, LifeLabs implemented the EUROIMMUN Workstation, a new fully automated indirect immunofluorescence platform. The new EUROIMMUN platform represents a significant advancement over our previous system, and this article outlines some key benefits.

Improved Diagnostic Reliability

The EUROIMMUN workstation strengthens result consistency through enhanced sample identification and tracking, ensuring that every specimen is verified throughout its entire analytical pathway. This reduces the risk of pre-analytical and analytical errors and supports greater confidence in result interpretation.

Shorter, More Predictable Turnaround Times

The platform is built to handle high testing volumes efficiently, enabling a faster progression from sample receipt to finalized result. By reducing turnaround time, physicians can advance diagnostic workups, and initiate treatments sooner.

Clearer, More Standardized Reporting

Concurrently with implementation of the new EUROIMMUN workstation, LifeLabs updated its reported ANA patterns to align with the International Consensus on ANA Patterns (ICAP). Previously, when mixed antinuclear antibody (ANA) patterns were identified, only a single titre was reported. Reporting a single titre could obscure the presence of a lower- or higher-intensity pattern that may be diagnostically or prognostically significant.

To enhance the clinical value and clarity of ANA test reporting, a separate titre and an interpretive comment will now be reported for each identified pattern when mixed patterns are present. Reporting individual titres for each pattern supports improved interpretation in several ways. First, it helps distinguish dominant from secondary patterns, which may guide follow-up testing. Secondly, it reduces the risk of misinterpretation that may arise when clinically significant patterns are masked by weaker or unrelated ones. This change provides a more complete and transparent representation of the findings, allowing clinicians to better appreciate the relative strength of each pattern and correlate them more accurately with the patient's clinical presentation.

Furthermore, interpretive comments have been added to the anti-Endomysial antibody (EMA), anti-mitochondrial antibody (AMA), anti-parietal cell antibody (APCA), and anti-smooth muscle antibody (ASMA) test reports to support clearer and more consistent result interpretation. These comments are intended to enhance clinical clarity and aid report understanding for both physicians and patients. Notably, the interpretive comments for anti-EMA are newly introduced, as they were not previously available. See the table below for anti-EMA, AMA, APCA, and ASMA comments.

Table: Interpretive comments for anti-EMA, AMA, APCA and ASMA

Test	Positive Test Result	Negative Test Result
Anti-EMA	**POSITIVE** Endomysial IgA antibodies were detected. Endomysial IgA antibodies are antibodies created in gluten-sensitive individuals in response to gluten exposure. A positive endomysial IgA antibody test suggests the possibility of celiac disease. It does not confirm diagnosis. If not already tested, anti-tissue transglutaminase IgA antibody testing is recommended to support celiac disease diagnosis.	**NEGATIVE** Endomysial IgA antibodies were not detected. Endomysial IgA antibodies are antibodies created in gluten-sensitive individuals in response to gluten exposure. A negative result suggests decreased likelihood of celiac disease. False negative results may occur with a gluten-restricted diet or IgA deficiency. If there is a clinical suspicion of celiac disease, a total IgA test should be ordered to rule out IgA deficiency. If IgA deficiency is confirmed, anti-deamidated gliadin peptide IgG test can be ordered to support celiac disease diagnosis.
AMA	The presence of a cytoplasmic reticular pattern is highly suggestive of primary biliary cholangitis (PBC). This pattern may also be observed in systemic sclerosis (SSc), and in overlap syndromes such as PBC-SSc and PBC-Sjögren's syndrome.	
APCA	Anti-parietal cell antibodies are commonly found in cases of pernicious anemia and autoimmune atrophic gastritis.	
ASMA	Anti-smooth muscle antibodies are commonly found in autoimmune hepatitis but may also be observed in other hepatic disorders, viral infections and some malignancies.	

Supporting the Evolving Needs of Modern Clinical Practice

With rising test volumes and growing demand for specialty diagnostics, the EUROIMMUN system is engineered to meet today's clinical complexity. By reducing manual steps, increasing efficiency, and reinforcing analytical integrity, the platform allows our laboratory staff to prioritize quality oversight, strengthening the overall clinical value delivered to you and your patients.

Of the tests listed above, only anti-EMA testing is uninsured. All other tests are covered by OHIP.

References:

1. Chan, E.K.L., et al., Report of the First International Consensus on Standardized Nomenclature of Antinuclear Antibody HEp-2 Cell Patterns 2014-2015. Front Immunol, 2015. 6: p. 412.
2. Chan EKL, von Mühlen CA, Fritzler MJ, Damoiseaux J, Infantino M, Klotz W, Satoh M, Musset L, Torre IG, Carballo OG, Herold M, Cruvinel WM, Mimori T, Conrad K, Andrade LEC; ICAP Committee. Correction to: The International Consensus on ANA Patterns (ICAP) in 2021-the 6th Workshop and Current Perspectives. J Appl Lab Med. 2023 Mar 6;8(2):419. doi: 10.1093/jalm/jfac013.

New Collection Procedure and Analytical Platform for H. Pylori Diagnosis & Follow Up

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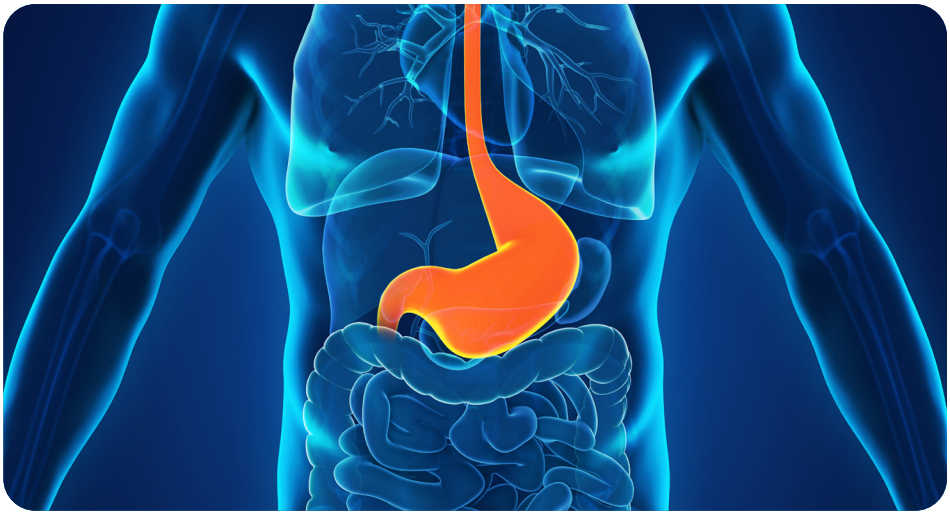
In May, 2026, LifeLabs introduced the Gulf Coast PyloPlus+ platform and collection system for *H. pylori* breath testing. This platform better supports a streamlined and patient-friendly testing experience, while maintaining accuracy and reliability using more robust technology. The Gulf Coast Pylo Plus+ test replaces our previous *H. pylori* Urea Breath test offering.

What is Changing?

The new platform introduces an **air-bag-based** collection system, offering key advantages for your patients including shorter fasting requirements and a quicker collection process. The new collection method also offers improved quality assurance in the collection process.



During this test, the patient drinks a urea and citric solution labeled with carbon. If *H. pylori* are present, the bacteria break down the urea, releasing carbon that is absorbed into the bloodstream and exhaled in the breath. The patient then blows into an airbag-based collection system, after which the amount of carbon released is measured to detect infection.[1,2] This non-invasive test is suitable for adults and children over three years old who can follow instructions.

Please refer to the summary of changes below:

H. pylori Breath Test: Transition to Gulf Coast PyloPlus+

Current (until May 4)	New (effective May 4)
Patient must not eat or smoke/vape **for 4 hours** before the test. Clear fluids (i.e. water) are acceptable, until one hour before the test.	Patient **must fast for 1 hour** before collection (no eating, drinking, smoking/vaping or chewing gum)
This test cannot be performed if the patient is allergic to citric acid.	This test cannot be performed on a patient who is allergic to citric acid. There is insufficient data to recommend this test for patients who are pregnant or lactating. Please consider ordering the H. pylori stool antigen test to determine active infection of H. pylori in pregnant and lactating women, or if the patient is allergic to citric acid.
Sample Collection: Patient provides baseline breath sample by: • Taking a deep breath • **Exhaling for 4-8 seconds** into a **collection tube** using a straw • Patient drinks a urea and citric acid solution • Patient collects a second sample **30 minutes** after the baseline collection	**Sample Collection:** Patient provides baseline breath sample by: • Taking a deep breath and **holding for 10 seconds** • Partially exhaling into the room to release air from mouth and throat and then fully exhaling remaining breath into mouthpiece of a **collection bag** • Patient drinks a urea and citric acid solution. • Patient collects a second sample **15 minutes** after completing the drink.

There are no changes to test ordering, reporting or pricing as a result of this change. The test is uninsured. For more information including how to order both the H. Pylori Stool Antigen and Urea Breath tests, click here.

A Reminder on Retesting

Best practice indicates testing once for diagnosis, and a second test 4 - 8 weeks after treatment to confirm eradication[1,2,3]. It is important to note that **serological** antibody testing for H. Pylori should **not** be used to detect active infections or monitor treatment, as it is unable to differentiate between current and past infections[4]. Instead of serological antibody testing, repeat testing with the Urea Breath or Stool Antigen test, 4 - 8 weeks after treatment to ensure the patient is free of infection.

References:

1. Lopes AI, Vale FF, Oleastro M. Helicobacter pylori infection - recent developments in diagnosis. World J Gastroenterol. 2014 Jul 28;20(28):9299-313.
2. Sankararaman S, Moosavi L. Urea Breath Test. [Updated 2024 Feb 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK542286/
3. Weldeamanuel MT, Berhe R, Belachew H, Azibte GT, Ayalew ZS, Mohammed AA, Shewangizaw YK. Declining eradication rates of Helicobacter pylori with standard triple therapy in Addis Ababa, Ethiopia. World J Gastroenterol. 2025 Feb 21;31(7):97401
4. Omar M, Abu-Salah R, Agbareia R, Sharif Y, Levin R, Lahat A, Sharif K. A comparative systematic review and meta-analysis on the diagnostic accuracy of non-invasive tests for Helicobacter pylori detection in elderly patients. Front Med (Lausanne). 2023 Dec 8;10:1323113

Cystatin C in the KDIGO (Kidney Disease: Improving Global Outcomes) Guidelines

A Key Populations Overview

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Accurate estimation of kidney function is essential for diagnosing chronic kidney disease (CKD), guiding treatment decisions, and assessing CKD-associated cardiovascular risk.

While serum creatinine remains the standard initial test, it measures muscle metabolism rather than kidney function directly, which can limit its accuracy in estimating glomerular filtration rate (eGFR). This is particularly relevant for individuals with atypical muscle mass (very low or very high), high meat intake, or use of creatine supplements, among other factors.

Cystatin C is a low molecular weight protein produced by all nucleated cells at a relatively constant rate. It is far less affected by muscle mass or diet and therefore **provides a more accurate estimate of eGFR in specific patient populations.**

Cystatin C offers a complementary solution, helping clinicians refine kidney assessment in situations where creatinine alone may be inadequate.

KDIGO (Kidney Disease: Improving Global Outcomes) 2024 Guidelines Highlighting the Utility of Cystatin C:

1.2.2.3: Understand the value and limitations in both eGFR and measured glomerular filtration rate (mGFR) as well as the variability and factors that influence SCr (serum creatinine) and cystatin C measurements.

1.2.2.6: Consider the use of cystatin C–based estimated glomerular filtration rate (eGFRcys) in some specific circumstances.

Patient Types Where Cystatin C Should Be Considered

1. **Patients with High or Low Muscle Mass and Atypical Protein Consumption**

- In highly muscular individuals, especially those who supplement with creatine, or in individuals with a high protein diet like keto, creatinine-based eGFR can indicate CKD where there is none.
- In patients with low muscle mass, such as those with sarcopenia, frailty, cachexia, or vegetarian or low protein diet, creatinine production is reduced, leading to underestimation of CKD if serum creatinine is measured exclusively.

2. **When creatinine-based eGFR is 45–59 mL/min/1.73m^2 with no albuminuria: Stage 3A CKD**

Stage 3a CKD is often the first stage where patients are diagnosed with CKD. In this range, serum creatinine may over diagnose CKD, and differentiation between age-related decline vs. CKD must be examined. The 2024 KDIGO guidelines recommend Cystatin C as a key tool for addressing diagnostic uncertainty, in addition to repeat testing.

3. **Patients with Chronic Illness and Altered Body Habitus**

The KDIGO guidelines note that equations combining serum creatinine and cystatin C are more accurate for patients living with:

- Cancer
- Obesity
- Cirrhosis
- Heart failure
- Catabolic states or muscle-wasting diseases
- Limb amputation
- Spinal cord injury resulting in para or quadriplegia

Cystatin C for Better Prediction of CVD Risk in Patients with CKD

Cardiovascular morbidity and mortality disproportionately affect people with CKD. Risk prediction tools developed in the general (non-CKD) population may underestimate the risk of atherosclerotic cardiovascular disease (CVD) or heart failure in CKD populations leading to suboptimal treatment. Incorporating cystatin C to calculate a more accurate eGFR, allows for more appropriate CGA staging.

CGA staging classifies kidney disease based on disease cause (C), GFR category (G), and albuminuria (A). It was first proposed in the KDIGO 2012 CKD guidelines and research has since confirmed that higher specific CGA staging, characterized by level of GFR and albuminuria independently, portend greater relative risk for adverse outcomes. These include, but are not limited to, CKD progression, CVD, mortality (all-cause and cardiovascular), kidney failure, and acute kidney injury (AKI).

Summary

Cystatin C is incorporated into clinical guidelines and recommended as part of clinical decision-making processes in CKD assessment for patients with altered body habitus, high or low muscle mass and diets with non-standard protein intake. Additionally, the 2021 CKD-EPI equation combining serum creatinine and cystatin C has been validated, with eGFR outputs especially beneficial in patients where serum creatinine alone is borderline or inaccurate.

How To Order

1. Write Cystatin C in the Other Tests section of a standard Ontario Ministry of Health requisition.
2. Ask your patient to visit a LifeLabs Patient Service Centre (PSC) for their blood draw.
3. At the PSC, patients must present the Cystatin C requisition signed by a healthcare provider.

Testing is not covered by Ontario healthcare programs, and the patient will be required to pay for the test. For more information, including pricing, please contact our Ontario Customer Care Centre at: **1-877-849-3637.**

References:

1. KDIGO Guidelines: https://kdigo.org/wp-content/uploads/2024/03/KDIGO-2024-CKD-Guideline.pdf
2. National Kidney Foundation web page: https://www.kidney.org/kidney-topics/stage-3a-chronic-kidney-disease-ckd#:~:text=Disease%20Main%20Page-,About%20Stage%203a%20CKD,with%20CKD%20are%20first%20diagnosed.
3. National Kidney Foundation web page on CGA classification: https://www.kidney.org/how-to-classify-ckd

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