



CLIENT NOTICE:

CHANGE TO H. PYLORI SERUM IGG ASSAY

October 12, 2017

LifeLabs Ontario will be introducing standardized methodology for the determination of H.Pylori IgG in serum. Since the integration of CML and LifeLabs in 2014 we have maintained two different pathways for H.Pylori testing, one in-house and one a referred-out pathway. This has led to some challenges for our patient service centers, patients and physicians.

On November 6. 2017 LifeLabs ON will introduce a single testing pathway for H.Pylori IgG in serum. The method currently used in-house (Siemens Immulite) will be changed to a new method (DiaSorin Liaison). The DiaSorin Liaison method is used at the referral laboratory, so for clients whose samples travel this pathway there will be no noticeable change. For our other clients there will be a change in the reporting style as shown in the table below.

| Current Method (Siemens Immulite) | U/mL | New Method (DiaSorin Liaison) | Index Value (RLU) |
|--------------------------------------|-------------|----------------------------------|-------------------|
| Negative | <0.90 | Negative | <0.80 |
| Indeterminate | 0.90 - 1.09 | Equivocal | ≥ 0.80 - < 0.90 |
| Positive | >1.09 | Positive | ≥ 0.90 |

LifeLabs has done a full validation of the new methodology. This includes a patient correlation study which has shown acceptable concordance between the two methods.

There will be a change to the ordering process for those clients who have been using the Public Health Laboratory requisition. From September 11. 2017 a regular LifeLabs or OHIP requisition has been acceptable at all Patient Service Centers.

For all inquiries please contact LifeLabs Customer Care at 1-877-849-3637.

Sincerely,

Dr. Andrew Don-Wauchope M.D., FRCPE, FRCPath

Chemical Pathologist

October 2017 1/1