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St. Paul's Hospital &
Mount Saint Joseph Hospital

Laboratory Medicine Bulletin

Infliximab Therapeutic Drug Monitoring Provincial Program

Effective date August 12, 2019

Change All MSP-funded testing for infliximab (IFX), with reflexive testing for antibodies-to-IFX, will be performed at St. Paul's Hospital in Vancouver. There will be a change in testing methodology from previous testing performed in Alberta and, correspondingly, a change in interpretive values.

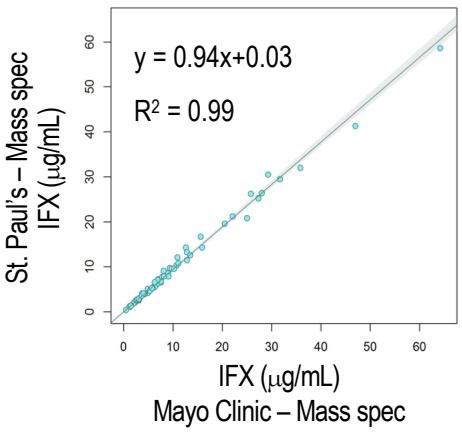
There are NO changes to the test requisition/approval process, or sample collection and processing.

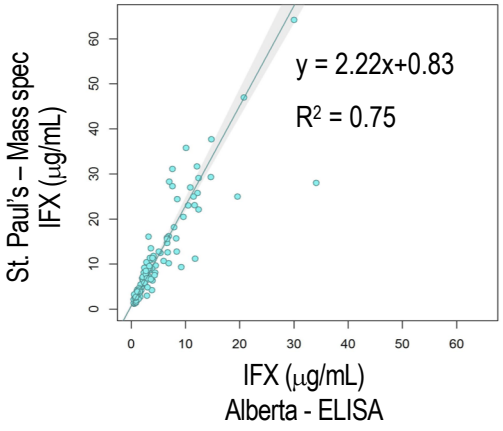
Key benefits Expedited turn-around-times for results and improved testing accuracy.

NEW IFX method Quantitative analysis performed by a laboratory-developed mass spectrometry assay at St. Paul's Hospital.

As the mass spec method is calibrated against actual drug concentrations, there will be an increase in absolute IFX concentrations compared to the ELISA method in Alberta. Details of the new methodology can be found here: https://doi.org/10.1016/j.clinms.2019.01.003

Method comparisons and correlations:





IFX (µg/ml)*	
Alberta	St. Paul's
3	7.5
5	12
8	19
15	34
20	45

*Approximate correlated concentrations based on linear regression.

Reflexive testing

All specimens with **IFX ≤ 5 µg/mL** will be automatically reflexed for testing for antibodies-to-IFX.

NEW antibodies-to-IFX method

Analysis performed at St. Paul's Hospital by a Health Canada licensed semi-quantitative ELISA (Immunodiagnostik/ALPCO), which measures total antibodies-to-IFX.

Result	Interpretation
Not detected	Antibodies to infliximab not detected.
1+	Antibodies to infliximab detected, clinical significance uncertain.
2+	**Antibodies to infliximab detected at significant concentrations.**
3+	**Antibodies to infliximab detected at significant concentrations.**

Interpretive thresholds were established by correlation with two other assays, whereby results ≥ 2+ corresponds to the presence of a clinically significant amount of antibodies-to-IFX. This cut-point at 2+ generally corresponds to the following interpretation in the comparative assays/labs:

- Mayo Clinic result of "Abnormally high (> 50 U/mL)"
- Alberta result >8 µg/mL "Consider AZA, 6MP, MTX, OR switch in class"

Increased sensitivity: The new assay is more sensitive than the Alberta assay. It is therefore anticipated that a proportion of specimens with undetectable antibodies-to-IFX by analysis in Alberta would be in the detectable range using the assay at St. Paul's Hospital.

Further info

Methodological information, interpretive guidance, as well as test requisitions and related information can be found in the Providence Laboratory Test Catalogue: http://www.providencelaboratory.com/test_catalog.php?ID=441

Questions?

Please contact:
Dr. Mari DeMarco, PhD DABCC FCACB
Clinical Chemist, Providence Health Care
Department of Pathology & Laboratory Medicine
mdemarco@providencehealth.bc.ca
Tel. 604.806.8470