

July 22, 2024

Dear Colleagues,

In May 2024 notification was received from the manufacturer that the Rubella IgG test used at BC Centre for Disease Control (BCCDC) Public Health Laboratory (PHL) was under imminent supply limitation and will be discontinued. To minimize testing disruptions, we immediately performed laboratory validation of a new Rubella IgG test.

The new test included an "Equivocal" reporting range, in contrast to the previously used test. Due to discrepant results detected in our validation, an expanded equivocal range of 5-<25 IU/mL was temporarily adopted while we further investigated. These investigations are now complete, and based on our laboratory evaluation of this test, the equivocal range of the assay has been adjusted to 5-<15 IU/mL.

## What has changed?

Please see table below for changes to reportable ranges:

Test Interpretation	Previous test (Siemens RbGII)	New test (Siemens updated RubG)
Non-reactive	< 10 IU/mL	<5 IU/mL
Equivocal	-	5 – <15 IU/mL
Reactive	≥ 10 IU/mL	≥ 15 IU/mL

## Impact to patient test results:

- Rubella IgG test results of 15 <25 IU/mL that were reported as "Equivocal" during the initial stage of test implementation will be issued an amended report and will be reported as "Reactive" to align with the new reportable range.
- Equivocal results may represent very low levels of IgG antibody many years after initial infection or vaccination. Providers should consider the patients' immunization record and previous testing history when interpreting these results.

## Guidance for serological screening:

A reminder that serological screening for Rubella virus antibodies is only recommended for pregnant people without documented laboratory evidence of rubella OR one documented dose of a rubella-containing vaccine on or after 12 months of age. Moreover, people who have been found to be serologically immune in one pregnancy do not need to be screened in subsequent pregnancies. For complete guidance please visit <a href="Pregnancy">Pregnancy</a> (bccdc.ca).

Please contact us if you have additional questions.





## **BC Centre for Disease Control**

Provincial Health Services Authority

Sincerely,

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