

Provincial Laboratory Bulletin

March 3, 2021

We have determined that serum (but not plasma) creatinine results determined using Roche chemistry analyzers and specific lots of enzymatic creatinine reagent have resulted in serum creatinine levels being higher than expected and eGFR values being lower than expected. This problem started in early November, 2020, and impacted results from LifeLabs, Valley Medical Laboratories and some collections from Northern Health laboratories.

According to analysis of affected results by Provincial Lab Medicine Service, we have determined that the serum creatinine values may be higher by 9 $\mu\text{mol/L}$ on average (confidence limits – 7 $\mu\text{mol/L}$ to + 26 $\mu\text{mol/L}$, for a given patient). This will also impact eGFR calculations, causing a drop of on average 8 $\text{mL/min}/1.73\text{m}^2$ (confidence limits of -3 to 23 $\text{mL/min}/1.73\text{m}^2$).

This problem has been reported in other jurisdictions internationally, and appears to be solved by changing the reagent batch used to run the serum creatinine on the analyzers; we are in the process of switching over, with assistance from the manufacturer.

We appreciate that this may have impacted your clinical care decisions, or referral patterns. We are working to rectify the issue and will be in touch as soon as we know when it has been resolved.

Sent on behalf of Dr. Blake Gilks, Chief Medical Lab Officer, Provincial Lab Medicine Services