
Date: 18/March/2021
To: All LifeLabs clients
From: Dr. Timothy Feltis, Medical Director, LifeLabs Ontario
Re: Creatinine Reagent Lot Positive Bias – Resolution

Background

On March 3rd 2021, LifeLabs sent a memo to all clients informing them of a positive bias on the serum creatinine assay, causing a positive shift of up to 8 umol/L in creatinine results, along with the concurrent negative shift in eGFR. The root cause was the manufacturer reagent lot bias. An interpretive comment was added to all serum creatinine results at that time, to inform clients of the shift, while LifeLabs worked on resolution.

A new reagent lot has been made available recently, and LifeLabs validation has confirmed that it corrects the previously introduced bias. This lot is implemented at all LifeLabs laboratory sites as of March 18, 2021.

A new comment is added to all creatinine results, to help with the interpretation of this change:

“Due to manufacturer reagent issue, creatinine results reported between November 12, 2020 and March 17, 2021 are up to 8 umol/L higher, with concurrent lower eGFR results, compared to the results obtained before or after this period. A new reagent lot implemented on March 18, 2021 has corrected the issue.”

What this means to you

When monitoring patient kidney function using serum creatinine and eGFR, please note the new interpretive comment on the report, and interpret results accordingly. Due to the resolution of positive bias, a downward shift in creatinine levels of an average of 8 umol/L is expected for results obtained on or after March 18, 2021, compared to the results obtained between November 12, 2020 and March 17, 2021. A concurrent shift upward is expected for eGFR. Impact to individual patients may vary.

We appreciate that the positive creatinine bias may have impacted your clinical care decisions, or referral patterns. We have done our best to implement the resolution as soon as it was available to us. We thank you for your understanding and continued trust.

If you have any further questions, please contact one of the following LifeLabs Medical Scientific staff:

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