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Date: 03/March/2021  
To: All LifeLabs clients  
From: Dr. Timothy Feltis, Medical Director, LifeLabs Ontario  
Re: Creatinine Reagent Lot Positive Bias

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## *Background*

LifeLabs has recently become aware of a positive bias on the serum creatinine assay, which may contribute to a positive shift of up to 8 umol/L in creatinine results. A concurrent negative shift in eGFR may be present.

Our investigation, both internally and with the test manufacturer, determined that the bias started with the creatinine reagent lot implemented across LifeLabs laboratory sites in the second half of November 2020. A manufacturer production error affected multiple laboratories internationally. Due to unavailability of another reagent lot that could correct the bias, LifeLabs implemented the following comment on all patient results to alert the health care providers of this issue:

“Manufacturer reagent lot bias noted since mid-November 2020. This may lead to positive shift of up to 8 umol/L in creatinine results when patient is serially monitored. A concurrent negative shift in eGFR may be present. Interpret with caution and correlate clinically.”

## *What this means to you*

When monitoring patient kidney function using serum creatinine and eGFR, please note the interpretive comment on the report, and interpret results accordingly. The constant nature of the bias indicates that the highest impact will be seen in patients with normal or near normal creatinine values (i.e. up to 150 umol/L), however it is also sample matrix-specific, suggesting impact to individual patients may vary. Please note that the urine creatinine results are not affected.

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. For future updates, please check:

<https://www.lifelabs.com/news/notifications-alerts/?myProvince=on>

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

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