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MEDICINE

Labs

## Positive Bias for Creatinine Results

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Roche Diagnostics has informed our laboratory of a positive bias for creatinine, when assayed using certain lots of reagent. Our sites used these lots of reagent between the months of November 2020 and February 2021. Currently, these lots are no longer in use at our laboratory sites.

The vendor's investigation showed the affected reagent lots demonstrated a positive bias of *up to* 0.07-0.09 mg/dL for creatinine. The vendor stated the absolute bias for all affected lots was within the product specifications; therefore, this issue introduced no risk. No patient or diagnostic test results were affected and a medical risk to patients can be excluded. The vendor is continuing to investigate the root cause.

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