Providence HEALTH CARE
How you want to be treated

Feb 26, 2021

New Nova StatStrip Glucose Meters: Explanation of glucose measurement bias as compared to laboratory plasma glucose measurements

Background:

A provincial laboratory medicine group recommended a change in hospital glucose meters from the Roche Accu-Chek® Inform II meter to the Nova StatStrip® meter for reasons of improved reliability*****.

Issue:

The Nova StatStrip meter reads on average **0.3 mmol/L less** than the corresponding plasma glucose measurement on a standard hospital laboratory plasma glucose method at concentrations between 2.0 and 11.0 mmol/L. The magnitude of this average negative bias of 0.3 mmol/L is sufficient to affect treatment decisions for neonatal hypoglycemia. This bias was noted by all laboratories in B.C. and in other provinces, where these comparisons were performed, and was independently verified by the CEQAL reference method laboratory in Vancouver.

Assessment:

Since the bias is well characterized, it is possible to program the new meters to **add 0.3 mmol/L** to each glucose result, without additional effort from the device operator. This corrective programming of the meters will allow hypoglycemia management decisions to match those that would be made if the plasma glucose test had been ordered, in all populations.

Provincial recommendations:

Each health authority point-of-care technical coordinator will program Nova StatStrip glucose meters, via the AegisPOC middleware program, to read 0.3 mmol/L higher****** than its standard calibration by utilizing a correction equation of:

Corrected Nova StatStrip glucose (mmol/L) = 1.0 * Default Nova StatStrip glucose (mmol/L) + 0.3 mmol/L

Before releasing from the supply chain warehouse to each facilities and locations, the suitability of the correction equation will be reassessed with each glucose test strip lot change by verifying with proficiency testing samples from CEQAL reference method laboratory.

Questions?

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*The Nova StatStrip meter has Health Canada approval for use in an intensive care setting, as it is specifically unaffected by variations in hematocrit or by the presence of high concentrations of galactose, N-acetylcysteine, or vitamin C. As the reliability of the Nova StatStrip meter is higher than the previous Roche Accu-Chek meter, clinicians can have more confidence in using the test results to guide clinical decisions. However, similar to any laboratory test result that does not appear to match the clinical status of the patient, independent verification of unexpected Nova StatStrip glucose results is still recommended, in this case, by measurement of laboratory plasma glucose.

**This correction improves the average bias between the Nova StatStrip and laboratory glucose measurements. Note that, as with any laboratory tests, there is also random analytical variation (imprecision) for each measurement. The 95% confidence interval for the Nova StatStrip glucose meter is ± 0.4 mmol/L or 8%. Therefore, comparison between two separate glucose measurements may often reveal a difference of 0.4 mmol/L solely due to random variation.