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Reagent Bulletin

Ammonia (NH3L) — Unstable Quality Control Results and Discrepant Patient Results

Introduction

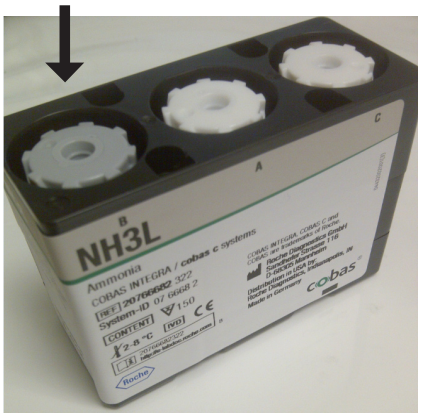
Customers have reported unstable quality control results and discrepant patient results when using the Ammonia (NH3L) assay, catalog number 20766682322 on the **cobas c** 311, 501, and 502 analyzers.

Root Cause

There is a blank increase due to ammonia (NH3) formation in the R3 reagent as a consequence of NADPH decomposition over time. This ammonia formation leads to falsely elevated test results over time.

Special Reagent Handling

A special reagent handling procedure is suggested. This procedure pre-conditions the reagent cassette before use and outside the analyzer for 24 hours at room temperature. This enables the ammonia to dissipate from the reagent cassette. The procedure follows:



1. Remove the gray colored R3 cap on the R3 bottle only using the Open/Close tool. The R3 cap is in position "B." Keep the cap in a safe clean place free from contaminants.
2. Store the reagent cassette:
   - at room temperature
   - in an environment that is free from smoke, exhaust fumes, debris of any kind, and NH3 containing cleaners
   - in a place where it will not fall over
   - in a place free from sunlight
3. After 24 hours, replace the gray colored R3 cap on the R3 bottle.
4. Load the cassette into the instrument.
5. Manually request a 2-point calibration for each NH3L cassette.
6. Manually request a blank calibration every three days for each NH3L cassette.

over...

- ☑ **cobas c** 311
- ☑ **cobas c** 501
- ☑ **cobas c** 502

Clinical Significance

Ammonia is not used as a stand-alone parameter. It is usually measured in combination with other laboratory parameters such as urea, glutamate, and amino transferases. An ammonia test result is interpreted in conjunction with the medical history and physical examination of the patient. Therefore, it is unlikely that even a more than 30% falsely elevated test result would cause an adverse event to a patient.

Questions

Please contact Roche Diagnostics Technical Support at 1-800-428-2336 if you have questions about the information contained in this Reagent Bulletin.