Performance Evaluation of the HIL Feature on the Atellica CH Analyzer

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Abstract

Background: Endogenous interferences such as hemoglobin (H) from lysis of red blood cells, turbidity of insoluble lipids, or lipemia (L), and icterus (I) from endogenous bilirubin can be a significant source of analytical error for clinical chemistry and immunassays. The Atellica® CH HIL Alert Index can notify the operator if HIL interference is present in concentrations high enough to affect assay results. HIL indices can be determined from dedicated HIL tests or from within the background of certain chemistry tests (ALT, AST, LDLP, and UN_c). This study evaluated the agreement of the Atellica CH HIL Alert Index feature with known concentrations of hemolysis, bilirubin, and Intralipid®.

Methods: Samples were prepared for each index (0–6) by adding known amounts of hemoglobin, bilirubin, and Intralipid® to normal human serum pools. Three replicates of each sample were processed on the Atellica CH Analyzer with HIL, ALT, AST, LDLP, and UN_c. The mean HIL index result from the Atellica CH Analyzer was compared to the expected index for each sample.

Results: All hemoglobin and bilirubin sample results returned the expected index. All lipemic samples produced results within ±1 of the expected index value.

Conclusions: The results demonstrate acceptable agreement of the Atellica CH HIL Alert Index feature with known concentrations of hemolysis, bilirubin, and Intralipid®.

Background

The Atellica CH HIL Alert Index for serum samples is used to flag sample results which may potentially be biased by endogenous interferences: hemoglobin (H) from lysis of red blood cells; turbidity of insoluble lipids, or lipemia (L), and icterus (I) from endogenous bilirubin. These indices specify the lowest concentration of H, I, and L that could cause bias of greater than 10%. Recommended H, I, and L indices are included in the assay test methods. The Atellica CH HIL Alert features include: AST, ALT, LDLP, and UN_c, or as a standalone HIL test.

Methods

To evaluate the performance of the HIL indices samples were prepared by adding hemoglobin, bilirubin, and Intralipid® to a normal human serum. H and L indices were assigned based on the expected concentrations, I indices were assigned using the Atellica CH TBI 2 Assay. Samples were processed in replicates of 3 with the Atellica CH with HIL, ALT, AST, LDLP, and UN_c assays. Mean HIL index results from the Atellica CH were compared to the assigned indices.

- Hemolysis (H) is measured at 571 and 596 nm, and correction is made for absorption due to lipemia.
- Icterus (I) is measured at 478 and 505 nm, and correction is made for absorption due to lipemia. An additional correction is made for absorption due to hemolysis.
- Lipemia (L) is measured at 655 and 694 nm.

Results

Table 5. Individual results for the 200 mg/dL Intralipid® sample.

Table 6. Individual results for the 600 mg/dL Intralipid® sample.

Table 7. Individual results for the 2000 mg/dL Intralipid® sample.

Table 8. HIL interference substance concentration and default HIL Alert Indices for Atellica Solution Assays.

Conclusions

- The results demonstrate acceptable agreement of the Atellica CH HIL Alert Index feature with known concentrations of hemolysis, bilirubin, and Intralipid®.
- The results of the technical report demonstrate the Atellica CH HIL Alert Index feature with known concentrations of hemolysis, bilirubin, and Intralipid®.
- All HIL output are within ±1 HIL index from the expected value.

References