

Intended Use

For use as controls in quantitative procedures for Acetaminophen, Salicylate and β-hydroxybutyrate.

Summary and Principal

Controls, when assayed with actual specimens, help a laboratory evaluate whether a given procedure is performing with a acceptable accuracy and precision.

This set contains six vials of unassayed* controls, 2 of each level (5ml each), comprising low, medium and high analyte measured amounts of analytes such as Acetaminophen, Salicylate and β-hydroxybutyrate in a synthetic serum substitute (SeraSub™) matrix. The serum substitute has an advantage as it provides a matrix free of possible serum infectious agents. Each analyte in the control solution has been assayed with a corresponding enzymatic reagent kit. The targeted values of the controls are indicated in the enclosed chart.

* Each laboratory should determine its own assay range.

Warning

β-Hydroxybutyrate controls are for *in vitro* diagnostic use only. Normal precautions exercised in handling laboratory reagents should be followed.

Storage/Stability

Store unopened vials in refrigerator (2-8°C) until expiration date on label. Control solution is stable for 60 days in the refrigerator (2-8°C), after opening. Discard if turbidity or any change in appearance occurs.

Instructions for use

Gently mix the control solution by inversion. The control is ready for use and should be treated in the same manner as a test serum sample. Replace cap and store at 2-8°C. Use only as directed.

Limitations

The assigned values have been obtained with enzymatic reagent kits. The controls may exhibit a matrix effect when run on automated analyzers, therefore, laboratories should assign their own range for each analyte and level.

ANALYTE	LEVEL I	LEVEL II	LEVEL III
Acetaminophen	50 ± 5 mg/L	100 ± 6 mg/L	250 ± 15 mg/L
β-Hydroxybutyrate	0.2 ± 0.04 mM	1.0 ± 0.12mM	4.0 ± 0.2mM
Salicylate	50 ± 8 mg/L	150 ± 15 mg/L	450 ± 22 mg/L

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