

Stanbio Laboratory Bi-Level TDM/ β -Hydroxybutyrate Controls, Ref. No. 2465



For Use as Controls in Quantitative Procedures for Acetaminophen, Salicylate, and β -Hydroxybutyrate

Summary and Principle

Controls, when assayed with actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision. Stanbio's TDM/ β -Hydroxybutyrate controls, Ref. No. 2465-605, contain unassayed* two levels of controls comprising low and high measured amounts of analytes such as Acetaminophen, β -Hydroxybutyrate, and Salicylate 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 the corresponding Stanbio Enzymatic Reagent Kit. The targeted values of the controls are indicated in the enclosed chart.

Reagents

Low Control, Ref. No. 2461 (5mL)

Measured amounts of Acetaminophen, β -Hydroxybutyrate, and Salicylate in a synthetic serum substitute (SeraSub™) matrix.

High Control, Ref. No. 2463 (5mL)

Measured amounts of Acetaminophen, β -Hydroxybutyrate, and Salicylate in a synthetic serum substitute (SeraSub™) matrix.

Warning and Precautions

For In Vitro Diagnostic Use.

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

Procedure

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 plug and cap and store at 2-8°C. Use only as directed.

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Expected Values










The assigned values have been obtained with Stanbio reagents using a manual procedure. These controls contain accurately measured amounts of Acetaminophen, β -Hydroxybutyrate, and Salicylate. The means and associated ranges are stated below. The controls may exhibit a matrix effect when run on automated analyzers, therefore, laboratories should assign their own range for each analyte and level.

<u>Low Control</u>	<u>Mean</u>	<u>Range*</u>
Acetaminophen	50 mg/L	45 - 55 mg/L
β -Hydroxybutyrate	0.2 mM	0.16 - 0.24 mM
Salicylate	50 mg/L	42 - 58 mg/L

High Control

Acetaminophen	250 mg/L	235 - 265 mg/L
β -Hydroxybutyrate	4 mM	3.80 - 4.20 mM
Salicylate	450 mg/L	428 - 472 mg/L

*Each laboratory should determine its own assay range.

Index of Symbols			
 Attention, see instructions for use	 Tests per kit	 Manufactured by	
 For <i>in vitro</i> diagnostic use only	 Use by	 Do not reuse	
 Store between temperature indicated	 Lot Number	 Reference No.	

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








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