Stanbio Laboratory Tri-Level TDM/ß-Hydroxybutyrate Controls, Ref. No. 2460

For Use as Controls in Quantitative Procedures for Acetaminophen, Salicylate, and ß-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 controls, Ref. No. 2460-605, contain three sets of vials (5 mL each) containing unassayed* tri-level controls comprising low, medium, and high analyte measured amounts of analytes such as Acetaminophen, ß-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, ß-Hydroxybutyrate, and Salicylate in a synthetic serum substitute (SeraSub™) matrix.

Medium Control, Ref. No. 2462 (5mL)

Measured amounts of Acetaminophen, ß-Hydroxybutyrate, and Salicylate in a synthetic serum substitute (SeraSubTM) matrix.

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

Measured amounts of Acetaminophen, ß-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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Reagents

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Medium Control, Ref. No. 2462 (5mL)

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

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Reagents

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

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

Medium Control, Ref. No. 2462 (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.

Expected Values

Salicylate

The assigned values have been obtained with Stanbio reagents using a manual procedure. These controls contain accurately measured amounts of Acetaminophen, ß-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.

Low Control	Mean	Range*	
Acetaminophen	50 mg/L	45 - 55 mg/L	
ß-Hydroxybutyrate	0.2 mM	0.16 - 0.24 mM	
Salicylate	50 mg/L	42 - 58 mg/L	
Medium Control			
Acetaminophen	100 mg/L	94 - 106 mg/L	
ß-Hydroxybutyrate	1 mM	0.88 - 1.12 mM	
Salicylate	150 mg/L	135 - 165 mg/L	
High Control			
Acetaminophen	250 mg/L	235 - 265 mg/L	
ß-Hydroxybutyrate	4 mM	3.80 - 4.20 mM	

*Each laboratory should determine its own assay range.

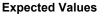
450 mg/L

		Index of	Symbols [Variable]		
ĺ	Attention, see instructions for use	Σ Σ	Tests per kit		Manufactured by
IVD	For <i>in vitro</i> diagnostic use only	2	Use by	2	Do not reuse
ł	Store between temperature indicated	LOT	Lot Number	REF	Reference No.

Stanbio Laboratory • 1261 North Main Street • Boerne, Texas 78006 USA For Technical Service call: 1-800-531-5535 • (830) 249-0772 Fax (830) 249-0851 • e-mail: stanbio@stanbio.com http://www.stanbio.com IFU.00015.00 • Procedure No. 2460

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High Control			
Acetaminophen	250 mg/L 235 - 265 m		
ß-Hydroxybutyrate	4 mM	3.80 - 4.20 mM	

Salicylate 450 ma/L 428 - 472 ma/L

*Each laboratory should determine its own assay range.

		Index of	Symbols		
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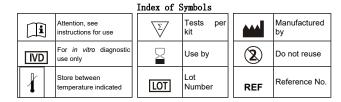
STANBIO SUITABILITY OF THE PRODUCT FOR THEIR PARTICULAR USE. USE ONLY IN LABORATORY

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Salicylate	150 mg/L	135 - 165 mg/L
High Control		
Acetaminophen	250 mg/L	235 - 265 mg/L
ß-Hydroxybutyrate	4 mM	3.80 - 4.20 mM
Salicylate	450 mg/L	428 - 472 mg/L

*Each laboratory should determine its own assay range.



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