

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



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 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, 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.

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.

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



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 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, 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.

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.

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



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 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, 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.

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

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.

Low Control	Mean	Range*
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

Medium Control










Acetaminophen	100 mg/L	94 - 106 mg/L
β -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
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.

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>
 RBR.2460CE.08 • Last Revision: 06/2015 • Procedure No. 2460

STANBIO LABORATORY DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES OF THE MERCHANTABILITY AND FITNESS PERTAINING TO THIS PRODUCT WHICH ARE NOT EXPRESSLY DETAILED IN THIS PACKAGING INFORMATION OR A WRITTEN AGREEMENT BETWEEN THE BUYER AND SELLER OF THIS PRODUCT. STANBIO LABORATORY MAINTAINS THAT THIS PRODUCT CONFORMS TO THE INFORMATION CONTAINED IN THIS INSERT. PURCHASER MUST DETERMINE THE SUITABILITY OF THE PRODUCT FOR THEIR PARTICULAR USE. USE ONLY IN ACCORDANCE WITH LABELING INSTRUCTIONS.



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.

Low Control	Mean	Range*
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

Medium Control










Acetaminophen	100 mg/L	94 - 106 mg/L
β -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
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.

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>
 RBR.2460CE.08 • Last Revision: 06/2015 • Procedure No. 2460

STANBIO LABORATORY DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES OF THE MERCHANTABILITY AND FITNESS PERTAINING TO THIS PRODUCT WHICH ARE NOT EXPRESSLY DETAILED IN THIS PACKAGING INFORMATION OR A WRITTEN AGREEMENT BETWEEN THE BUYER AND SELLER OF THIS PRODUCT. STANBIO LABORATORY MAINTAINS THAT THIS PRODUCT CONFORMS TO THE INFORMATION CONTAINED IN THIS INSERT. PURCHASER MUST DETERMINE THE SUITABILITY OF THE PRODUCT FOR THEIR PARTICULAR USE. USE ONLY IN ACCORDANCE WITH LABELING INSTRUCTIONS.



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.

Low Control	Mean	Range*
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

Medium Control










Acetaminophen	100 mg/L	94 - 106 mg/L
β -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
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.

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>
 RBR.2460CE.08 • Last Revision: 06/2015 • Procedure No. 2460

STANBIO LABORATORY DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES OF THE MERCHANTABILITY AND FITNESS PERTAINING TO THIS PRODUCT WHICH ARE NOT EXPRESSLY DETAILED IN THIS PACKAGING INFORMATION OR A WRITTEN AGREEMENT BETWEEN THE BUYER AND SELLER OF THIS PRODUCT. STANBIO LABORATORY MAINTAINS THAT THIS PRODUCT CONFORMS TO THE INFORMATION CONTAINED IN THIS INSERT. PURCHASER MUST DETERMINE THE SUITABILITY OF THE PRODUCT FOR THEIR PARTICULAR USE. USE ONLY IN ACCORDANCE WITH LABELING INSTRUCTIONS.

