# Stanbio hCG Tri-Level Serum Control Set, Procedure No. 1235

For Use as hCG Pregnancy Controls in Qualitative Serum hCG Pregnancy Procedures

#### **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 hCG Tri-Level Serum Control Set contains two positive controls (low and high) and a negative control (no detectable hCG) prepared in human serum with added preservatives.

#### Reagents

High Positive hCG Serum Control (Red Cap), Cat. No. 1232 @ 250 mIU/mL hCG in human serum with preservatives.

Low Positive hCG Serum Control (Yellow Cap), Cat. No. 1233 @ 25 mIU/mL hCG in human serum with preservatives.

#### Negative hCG Serum Control (Green Cap), Cat. No. 1234

Human serum containing no detectable level of hCG with added preservatives.

Precautions: For In Vitro Diagnostic Use.

This human serum has tested negative for hepatitis B surface (HBsAg) antigen and HIV.

Caution: Handle with same precautions as used for patients, since no known test can offer that products manufactured from human blood will not transmit disease.

**Reagent Preparation:** HCG Tri-Level Serum Controls are supplied ready-to-use.

**Reagent Storage and Stability:** HCG Tri-Level Serum Controls are stable until expiration dates on respective labels when properly stored at 2-30°C. Once opened, controls are stable for 90 days when properly stored at 2-30°C and kept tightly capped after each use.

DO NOT USE IF CONTAMINATION IS EVIDENT.

#### **Procedure**

 Remove hCG Tri-Level Serum Control Set from storage and allow to reach room temperature prior to use.

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#### **Procedure**

 Remove hCG Tri-Level Serum Control Set from storage and allow to reach room temperature prior to use.

- 2. Follow the test procedure located in manufacturer's package insert for performing each test.
  - Remove cap from control vial and add the same number of drops (2) to the sample well as an actual patient specimen.

#### DO NOT MIX CAPS FROM DIFFERENT VIALS!

3. After use, replace cap tightly on control vial and return to test box for storage.

#### Results

The hCG Tri-Level Serum Controls are quantitated by an EIA hCG assay and tested against each of Stanbio's hCG immunoassay products. See appropriate package insert for interpretation of test results.

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For Technical Service call: 1-800-531-5535 • (830) 249-0772

#### Index of Symbols

(i	Attention, see instructions for use	Σ	Tests per kit		Manufactured by
IVD	For in vitro diagnostic use	2	Use by	2	Do not reuse
ł	Store between temperature indicated	LOT	Lot Number	REF	Reference No.

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www.stanbio.com

**BDS** International Diagnostics GmbH Anselm-Feuerbach-Str. 12, 68723 Schwetzingen, Germany e-mail: info@bds-

EC REP

international.de

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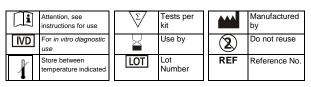
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