Serum hCG Control Set

(Negative, Low Positive and High Positive)

Instructions for Professional Use
For *In Vitro* Diagnostic Use

INTENDED USE

The Serum hCG Control Set is intended for use with QuickVue® One-Step hCG Combo and QuickVue+® One-Step hCG Combo. These controls provide an aid in the interpretation of positive and negative test results and verify proper test performance.

SUMMARY AND EXPLANATION

The Positive Controls contain purified human chorionic gonadotropin (hCG) in human serum. The Negative Control contains no detectable hCG.

The appearance of hCG shortly after conception and its continual increase during the early stages of gestation make hCG an excellent indicator for the detection of early pregnancy.

When used as qualitative controls in place of a patient specimen in the QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo, the results may aid in the interpretation of positive and negative test results and verify test performance.

PRINCIPLE OF THE TEST

The Serum hCG Control Set is designed to be used as qualitative control samples in accordance with the QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo package insert procedures.

REAGENTS AND MATERIALS SUPPLIED

- One (1) vial (5 mL) Serum hCG Negative Control: Contains human serum, negative for hCG with 0.1% sodium azide as a preservative. Lyophilized.
- One (1) vial (5 mL) Serum hCG Low Positive Control: Contains human serum, with approximately 30 mIU/mL hCG with 0.1% sodium azide as a preservative. Lyophilized.
- One (1) vial (5 mL) Serum hCG High Positive Control: Contains human serum, with approximately 250 mIU/mL hCG with 0.1% sodium azide as a preservative. Lyophilized.

PREPARATION OF CONTROLS

When ready to use, reconstitute with 5 mL deionized water using a serological or volumetric pipette, and wait thirty (30) minutes prior to use. Write the date of reconstitution on the vial label. Controls can be used for 2 weeks after reconstitution. Store refrigerated.

WARNINGS AND PRECAUTIONS

- Do not use beyond labeled expiration date marked on the outer kit label.
- Do not interchange the caps or rubber stoppers of any reagent bottles.
- Dispose of containers and unused contents in accordance with Federal, State, and Local requirements.
- The Controls are designed for use only with QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo kits.

These components contain material of human origin which has been tested using FDA-approved methods and has been found negative for antibody to human immunodeficiency virus (HIV-I and HIV-II), antibody to Hepatitis C virus and for Hepatitis B surface antigen (HBsAg). No known test method can offer total assurance that HIV-I and HIV-II, Hepatitis B virus, Hepatitis C virus or other infectious agents are absent. **HANDLE THESE REAGENTS AS IF THEY WERE POTENTIALLY INFECTIOUS.** Information on handling human serum is provided in the CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories" (U.S.A. HHS publication No. (NIH) 88-8395).

KIT STORAGE AND STABILITY

Store the Serum hCG Control Set refrigerated at 2–8°C (36–46°F). Do Not Freeze. Kit can be used until the expiration date printed on the outer kit box or 2 weeks after reconstitution.

QUALITY CONTROL

External controls may be used to verify that all reagents and procedures are performing properly. The Serum hCG Control Set, when used in accordance with the test procedures described in the QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo package inserts, provide this capability.

Quality Control testing should be performed in accordance with the directions accompanying the QuickVue One-Step hCG Combo or QuickVue+ One-Step hCG Combo.

TEST PROCEDURE

The Serum hCG Control Set is to be used in accordance with the directions accompanying the QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo. When following these directions, the Serum hCG Control Set is to be used in the same manner as a patient specimen.

INTERPRETATION OF RESULTS

QuickVue One-Step hCG Combo
Refer to the QuickVue One-Step hCG Combo package insert.

QuickVue+ One-Step hCG Combo
Refer to the QuickVue+ One-Step hCG Combo package insert.

LIMITATIONS

The Positive and Negative Controls in the Serum hCG Control Set are qualitative reagents and are not to be used as quantitative calibrators. They should not be diluted and may be incompatible for use with other assays.

The Serum hCG Control Set must be used at room temperature 15–30°C (59–86°F). Performance of the assay at other temperatures may yield invalid results.

EXPECTED VALUES

The Serum hCG Control Set will produce examples of the color response to be expected for negative, low positive and high positive specimens when tested in the QuickVue One-Step hCG Combo and QuickVue+ One-Step hCG Combo. These controls are calibrated to the WHO 3rd International Standard for Chorionic Gonadotropin, Human, for Bioassay (3rd I.S. 75/537).

The failure to obtain a negative result with the Negative Control or a positive result with the Low Positive Control or the High Positive Control indicates that the test was not performed properly or that the test reagents were not functioning properly.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support number, (800) 874-1517 (toll-free in the U.S.A.) or (858) 552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m. Pacific Time, U.S.A. If outside the United States, contact your local distributor or technicalsupport@quidel.com.

REF 00281 – Serum hCG Control Set

IVD

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QUIDEL®

0450203 (11/08)

CONTROL + Positive control

CONTROL − Negative control


Biological risks

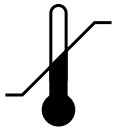
REF Catalogue number


Manufacturer


Use by

LOT Batch code

IVD For *In Vitro* diagnostic use


Temperature limitation