hCG Control Set – Urine
Positive and Negative

QUIDEL

Instructions for Professional Use

INTENDED USE
The hCG Control Set – Urine is intended for use with QuickVue+® hCG Combo, QuickVue® hCG Urine or Combo, and RapidVue® hCG Test. These controls provide an aid in the interpretation of positive and negative test results and verify proper test performance.

SUMMARY AND EXPLANATION
The Positive Control contains purified human chorionic gonadotropin (hCG) in a buffered solution. The Negative Control contains no detectable human chorionic gonadotropin.

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 sample in the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test, the results may aid in the interpretation of positive and negative test results and verify test performance.

PRINCIPLE OF THE TEST
The hCG Control Set – Urine is designed to be used as qualitative control samples in accordance with the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test Package Insert procedures.

REAGENTS AND MATERIALS SUPPLIED
- One (1) vial (4.5 mL) hCG Negative Control: Contains buffered solution, with 0.1% sodium azide as a preservative.
- One (1) vial (4.5 mL) hCG Positive Control: Contains hCG in a buffered solution, with 0.1% sodium azide as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED
- Watch or clock that measures minutes.

WARNINGS AND PRECAUTIONS
- For *in vitro* diagnostic use.
- DO NOT use beyond the labeled expiration date marked on the outer kit label.
- DO NOT interchange the caps of any reagent bottles.
- Dispose of containers and unused contents in accordance with Federal, State, and Local requirements.

- Controls contain sodium azide which may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide buildup.
- The Controls are designed for use only with QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test kits.

HANDLE THESE REAGENTS AS IF THEY WERE POTENTIALLY INFECTIOUS.

KIT STORAGE AND STABILITY

Store the kit at room temperature 15°C to 30°C (59°F to 86°F). Do not freeze.

QUALITY CONTROL

External controls may be used to verify that all reagents and procedures are performing properly. The hCG Control Set – Urine, when used in accordance with the test procedures described in the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test kits, provide this capability.

Quality Control testing should be performed in accordance with the directions accompanying the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Tests.

TEST PROCEDURE

The hCG Control Set – Urine is to be used in accordance with the directions accompanying the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test kits. When following these directions, the hCG Control Set – Urine is to be used in the same manner as a patient sample.

1. Gently mix the hCG Controls by shaking the vials prior to use.
   Important – The quantity of drops required to perform the control assay differs between the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, and RapidVue hCG tests. Please read carefully.
2. **Add 4 drops** (approximately 160 µL) of either the Positive or Negative Control to the **QuickVue+ hCG Combo** Reaction Unit's "Add Sample" well.

   Add 3 drops (approximately 120 µL) of either the Positive or Negative Control to the **QuickVue hCG Urine or Combo** Test Cassette Sample well.

   Add 2 drops (approximately 80 µL) of either the Positive or Negative Control to the "dip" end of the **RapidVue hCG** Test Strip, below the orange line.
3. Read test results at the designated read time specified in the Package Insert.

INTERPRETATION OF RESULTS

Refer to the QuickVue+ hCG Combo, QuickVue hCG Urine or Combo, or RapidVue hCG Test Package Insert.

QuickVue+ hCG Combo

POSITIVE – The appearance of any vertical pink-to-purple Test Line intersecting the pre-printed horizontal blue line in the Read Result Window, along with a procedural Control Line in the Control Window, is a positive result.

NEGATIVE – The appearance of the pre-printed horizontal blue line only in the Read Result Window, along with the blue procedural Control Line in the Control Window, is a negative result.

INVALID – A blue procedural Control Line should always appear. If no procedural Control Line appears, the test result is invalid and the control sample must be retested.*

QuickVue hCG Urine or Combo

POSITIVE – The appearance of any vertical pink-to-red line next to the letter "T" AND a blue line next to the letter "C" in the Results Window is a positive result.

NEGATIVE – The appearance of a blue line next to the letter "C" AND NO pink-to-red test line is a negative result.

INVALID – A blue line next to the letter "C" should always appear. If no blue line appears, the test result is invalid and the control sample must be retested.*

RapidVue hCG

POSITIVE – The appearance of any pink-to-red Test Line along with a blue Control Line is a positive result.

NEGATIVE – The appearance of a blue Control Line only is a negative result.

INVALID – A blue Control Line should always appear. If no blue Control Line appears, the test is invalid, and the control sample must be retested.*

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*An invalid result indicates either the assay was not performed correctly or the reagents were not working properly. If an invalid result occurs, re-test the control sample using a new test unit. If the problem persists, please contact Quidel Technical Support.

LIMITATIONS

The Positive and Negative Controls in the hCG Control Set – Urine 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 hCG Control Set – Urine must be used at room temperature 15°C to 30°C (59°F to 86°F). Performance of the assay at other temperatures may yield invalid results.

EXPECTED VALUES

The hCG Control Set – Urine will produce examples of the color response to be expected for negative and positive specimens when tested in the QuickVue+ hCG Combo, QuickVue Urine or Combo, and RapidVue hCG Test. These controls are calibrated to the WHO 4th International Standard for Chorionic Gonadotropin, Human, for Bioassay (4th I.S. 75/589).

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

PHYSICIAN'S OFFICE LABORATORY (POL) STUDY

To evaluate the performance of the hCG Control Set – Urine in the physician's office laboratory (POL), a panel consisting of 20 coded specimens were tested on three different days by physician's office personnel at three different locations. The physician's technicians had diverse educational backgrounds and work experience.

100% of the tests were interpreted properly by these POL users.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. and 5:00 p.m. Pacific Time, U.S.A. If outside the U.S., contact your local distributor or technicalsupport@quidel.com.

REF 00272 – hCG Control Set – Urine

IVD

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quidel.com

1017503EN00 (01/15)

REF Catalogue number	LOT Batch code
Use by	Manufacturer
Temperature limitation	Intended use
IVD For *In Vitro* diagnostic use	CONTROL + Control positive
CONTROL – Control negative	