

hCG Control Set *(Positive and Negative)*

Instructions for Professional Use **For *In Vitro* Diagnostic Use**

CLIAwaived.comTM

For more information please contact CLIAwaived Inc. at
11578 Sorrento Valley Road ■ San Diego, CA 92121
Tel: (858) 481-5031 ■ Toll Free: (888) 882-7739
E-mail: info@cliawaived.com
Visit us on the web at: www.cliawaived.com
Distributed by: CLIAwaived, Inc.

INTENDED USE

The hCG Control Set is intended for use with the QuickVue®+ One-Step hCG Combo, QuickVue® One-Step hCG Urine or Combo, RapidVue® hCG and the QuickVue® Semi-Q® hCG Combo 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+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo Test, the results may aid in the interpretation of positive and negative test results and verify test performance.

PRINCIPLES OF THE TEST

The hCG Control Set is designed to be used as qualitative control samples in accordance with the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo 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.

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+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo Test kits.

HANDLE THESE REAGENTS AS IF THEY WERE POTENTIALLY INFECTIOUS.

KIT STORAGE AND STABILITY

Store the hCG Control Set at room temperature 15–30°C (59–86°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, when used in accordance with the test procedures described in the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo Test kits, provides this capability.

Quality control testing should be performed in accordance with the directions accompanying the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine, RapidVue hCG or QuickVue Semi-Q hCG Combo Test.

TEST PROCEDURE

The hCG Control Set is to be used in accordance with the directions accompanying the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo hCG Test kits. When following these directions, the hCG Control Set 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+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG and QuickVue Semi-Q hCG Combo tests. Please read carefully.

2. **Add four (4) drops** (approximately 160µL) of either the Positive or Negative Control to the **QuickVue+ One-Step hCG Combo** Reaction Unit's "Add Sample" well.

Add three (3) drops (approximately 120µL) of either the Positive or Negative Control to the **QuickVue One-Step hCG Urine or Combo** or **QuickVue Semi-Q hCG Combo** test cassette sample well.

Apply three (3) drops (approximately 120µL) of either the Positive or Negative Control to the assay end of the **RapidVue hCG** test strip.

3. Read test results at the designated read time specified in the package insert.

INTERPRETATION OF RESULTS

Refer to the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo Test package insert.

QuickVue+ One-Step 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 blue 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 One-Step hCG Urine or Combo

POSITIVE – The appearance of any 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 repeated.*

RapidVue hCG

POSITIVE – The appearance of any pink-to-purple 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.*

QuickVue Semi-Q hCG Combo

POSITIVE – The appearance of any pink-to-purple Test Line next to the letter “T” in the Result Window, along with a blue Procedural Control Line next to the letter “C” and a pink-to-purple Reference Line next to the letter “R”.

NEGATIVE – The appearance of the blue Procedural Control Line next to the letter “C” and a pink-to-purple Reference Line next to the letter “R” only and no pink-to-purple color development of the Test Line next to the letter “T”.

INVALID – If no blue Procedural Control Line or no Reference Line appears the test result is invalid and the control sample must be retested.*

*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 Technical Support.

LIMITATIONS

The Positive and Negative Controls in the 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 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 hCG Control Set will produce examples of the color response to be expected for negative and positive specimens when tested in the QuickVue+ One-Step hCG Combo, QuickVue One-Step hCG Urine or Combo, RapidVue hCG or QuickVue Semi-Q hCG Combo Test. These controls are calibrated to the W.H.O. 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 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 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 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.

Catalog Number: 00272 - hCG Control Set



○

1017501 (05/05)