

hCG Controls Set Instructions

INTENDED USE

First Sign® hCG Controls Set includes a positive control containing stabilized Human Chorionic Gonadotropin and negative control containing Tris buffer, bovine serum albumin, and 0.05% Sodium Azide. First Sign® hCG Control Set is for use exclusively with the First Sign® hCG Test Kit. These controls provide an aid in the interpretation of positive and negative test results and verify proper test performance.

The controls can be used to independently verify the functionality and performance of the test; they are not for use as general-purpose controls.

MATERIALS

Materials Provided:

1. Positive Control (2mL) contains purified Human Chorionic Gonadotropin, Tris buffer, bovine serum albumin and 0.05% Sodium Azide.

2. Negative Control (2mL) contains Tris buffer, bovine serum albumin, and 0.05% Sodium Azide.

Bovine materials are from a U.S.A. source.

Materials Required but Not Provided:

1. First Sign® hCG Test Kit.
2. Timer

PRECAUTIONS

1. For *In Vitro* Diagnostic Use.
2. CAUTION: The Positive Control is prepared from Purified human Chorionic Gonadotropin. The source material is tested for the presence of antibodies to human immunodeficiency virus (HIV) and Hepatitis B Surface antigens (HBsAg) and found to be negative. However no test method can offer complete assurance that HIV, HBsAg, or other infectious agents are absent; these controls should be

handled as potentially infectious. Such materials should be handled as bio-safety Level 2, as defined by the U.S. Centers for Disease Control and Prevention.

3. Avoid contamination of controls. DO NOT interchange bottle caps between Positive and Negative Controls.
4. WARNING: The Positive and Negative Controls contain sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up.
5. Avoid contact with eyes, mucous membranes, skin lesions or other body surfaces. If contact occurs, flush affected areas with water for at least 10 to 15 minutes and immediately consult your physician.
6. DO NOT use controls beyond their labeled expiration dates.
7. DO NOT use any control from a container that appears to have leaked.

STORAGE

1. Store product at 2°C to 8°C.
2. When stored as directed, First Sign® hCG Control Set will remain stable until the labeled expiration date.

PROCEDURES

1. Follow the Procedure in the First Sign® hCG Test Kit package insert.
2. The hCG Control Set is suggested to be used at room temperature 15°C to 30°C (59°F to 86°F). When running Controls, add 3 drops of Positive or Negative Control to the test device using dropper bottles in place of samples.
3. Wait 5 minutes and read test results.

INTERPRETATION OF RESULTS

1. The test is positive (+) if two lines (Control and Test) are visible in the viewing window. Any trace of a pink line in the Test line area is a positive test result.
2. The test is negative (-) if only the Control line is visible and there is no trace of a pink line in the Test line area.
3. The test is invalid if the control line does not appear, if this occurs, the test should be repeated.

Notes on Interpretation:

1. Positive test results may appear before 5 minutes. To verify a negative test result, be certain to wait a full 5 minutes.
2. Test results should not be read after 10 minutes.
3. Neither the intensity nor the shade of the line produced by the Positive Control should be used as a reference for the appearance of a positive result.

4. If invalid results occur repeatedly or for technical assistance, contact Hemosure at: 1-888-436-6787 (Hemosure)

PERFORMANCE CHARACTERISTICS

The Positive Control contains purified human chronic gonadotropin and gives a positive result with First Sign® hCG Test Kit. The Negative Control contains a buffer and no human chorionic gonadotropin and gives a negative result with the First Sign® hCG Test Kit.

PRODUCT INFORMATION

First Sign® hCG Test Kit is CLIA Waived.

Please visit www.hemosure.com for more information and product catalog.

Manufactured for:

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HEMOSURE, INC.

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