



# hCG Controls

**IVD** For *in vitro* diagnostic use



## PRODUCT INSERT

<b>REF</b>	PS25-POS	hCG Positive Control 25 mIU/ml	5ml
<b>REF</b>	P-NCS	hCG Negative Control 0 mIU/ml	5ml

### INTENDED USE

Human chorionic gonadotropin (hCG) urine controls are intended to monitor the positive and negative performance of the rapid hCG test.

### SUMMARY AND EXPLANATION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced in pregnancy. Certain immunoassays utilize antibodies to bind hCG in blood and urine as a means of testing for pregnancy. The use of quality control material to monitor test determinations in the clinical laboratory is well established. The hCG controls provide a useful means of ascertaining the performance of qualitative hCG antibody assays.

### PRINCIPLES OF PROCEDURE

hCG Controls can be used to test performance of assays to detect hCG. These controls have been derived from serum containing human serum containing hCG. Levels of hCG have been tested and confirmed using semi-quantitative methods for hCG detection. The positive control contains ~25 mIU/ml hCG. The negative control contains 0 mIU/ml hCG. These controls should be utilized as one would utilize a serum sample in a prospective hCG test method.

### REAGENTS

#### Storage and Preparation

Store all reagents at 2-8°C. Do not freeze.

#### Precautions

All human derived components used have been tested for HBsAg, HCV, HIV-1 and 2 and HTLV-I and found negative by FDA required tests. However, human blood derivatives and patient specimens should be considered potentially infectious. Follow good laboratory practices in storing, dispensing and disposing of these materials.

#### Materials provided

<b>CONTROL+ hCG</b>	<b>REF</b>	PS25-POS	hCG Positive Control. 25 mIU/ml, 5ml. Ready for use.
<b>CONTROL- hCG</b>	<b>REF</b>	P-NCS	hCG Negative Control. 0 mIU/ml, 5ml. Ready for use.

### PROCEDURE

#### Procedural Notes

hCG controls are used along with a one-step or other similar type test for hCG in urine. Use the controls in the same manner as patient specimens. Sample volumes are the same as indicated in the test procedure for patients.

Carefully read the hCG test product insert before starting the assay.

#### Test Method

1. Remove control set from refrigerator just prior to use and allow controls to reach room temperature.
2. Follow the directions for use in the hCG test kit package insert. Remove the screw caps from the controls, invert the plastic vial and squeeze the required number of drops of the control as would be the case for the actual patient specimen.

#### Interpretation

Refer to hCG test kit package insert for interpretation of results.

#### LIMITATIONS OF PROCEDURE

The individual using hCG controls should be familiar with the hCG test system being utilized and should follow the instructions and observe the precautions for use of the product.

#### REFERENCES

1. Biosafety in Microbiological and Biomedical Laboratories. Centers for Disease Control National Institutes of Health. 1993; (HHS Pub No [CDC] 93-8395).

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MAR2009  
Document No. PIPS25-POS