



**Biochemical
Diagnostics, Inc.**

A Kova International Company

PREGNANCY-SKREEN™
hCG LIQUID CONTROL URINE

The PREGNANCY-SKREEN™ Human Chorionic Gonadotropin (hCG) Positive and Negative controls are prepared from human based urine. These hCG controls can be used to monitor the performance of qualitative immunochromatographic hCG detection devices.

Please read the entire package insert before using the control urines.

INTENDED USE

The PREGNANCY-SKREEN™ hCG Controls are intended for use with the PREGNANCY-SKREEN™ hCG test device. They should be treated as any “unknown” specimen while following the specific protocol of the assay being used.

This product is intended to be used by health care professionals as an integral part of good laboratory practices.

SUMMARY AND EXPLANATION

The PREGNANCY-SKREEN™ hCG product line of controls is manufactured using a human based urine matrix that has been stabilized to insure that the product will be viable until the date of expiration. The positive control is spiked with hCG in a target range from 200-400 mIU/mL of urine matrix. The negative control is prepared from a urine pool that tested negative for hCG. The standard material used for spiking was obtained from human pregnancy urine lyophilized and found negative by ELISA to HIV-1, antibody for HCV and for HBSAG. The initial assay of the lyophilized material used for spiking was performed by radioimmunoassay. Subsequent testing of the control material is performed qualitatively to ascertain that positive controls tested positive and the negative controls tested negative for the claimed life of the product.

DESCRIPTION

Each vial contains stabilized human based urine in a convenient liquid form. Positive control urines have been spiked with known quantities of purified hCG. Negative control urine is certified negative for the constituents listed in this insert.

ORDERING INFORMATION

CATALOG #	DESCRIPTION
18030367	PREGNANCY-SKREEN™ hCG Liquid Control Urine Kitbox, containing: 1 Positive, 4mL dropper bottle 1 Negative, 4mL dropper bottle
20100005	PREGNANCY-SKREEN™ hCG Liquid Control Urine, Positive, 5 mL vial
20100007	PREGNANCY-SKREEN™ hCG Liquid Control Urine, Negative, 5 mL vial

PRECAUTIONS

For *in vitro* diagnostic use only

Please read the entire package insert before using the PREGNANCY-SKREEN™ hCG Control urines. Please use the same safety precautions you would use for processing any “unknown” urine sample containing potentially infectious biological material. Protect product from exposure to direct sunlight. Discard control if cloudiness develops.

PRECAUTIONS cont'd

Do not use beyond the expiration date.

Repeated dipstick immersion can compromise the performance of this product due to adsorption losses. It is recommended that a maximum of 10 immersions be performed on an opened vial of the PREGNANCY-SKREEN™ hCG control.

Contains Sodium Azide: To prevent formation of explosive metal azides, dispose of discarded material by flushing or diluting with copious amounts of water or according to local governing regulations.

STORAGE & STABILITY

Refrigerated Storage:

When stored refrigerated (2-8°C), the unopened controls are stable until the expiration date. Once opened, the controls are stable at refrigerated storage temperatures for 31 days from the date of opening or until the expiration date, whichever comes first.

Room Temperature Storage:

If stored at room temperature (18-25°C), the controls are stable for 31 days or until the expiration date, whichever comes first, regardless of the date opened.

This product should never be stored frozen.

PROCEDURE

1. Allow controls to come to room temperature followed by gentle swirling or inversion before use.
DO NOT SHAKE.
2. Add an appropriate aliquot of Pregnancy-Skreen™ control urine as required by the hCG immunochromatographic device or screening method.

LIMITATIONS OF PROCEDURE

This control is meant to be used to validate the performance of qualitative urine hCG methods that screen urine for hCG levels consistent with pregnancy. Consult test manufacturers' instructions when using this product; changes in reagents, sample requirement, or methodology may effect test results.

This product is not meant to be used as a standard or calibrator.

EXPECTED RESULTS

The positive PREGNANCY-SKREEN™ hCG Control must test positive and the negative PREGNANCY-SKREEN™ hCG Control must test negative.



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SYMBOL LEGEND	
	Consult Instructions for Use
	Temperature Limits
	In Vitro Diagnostic Medical Device
	Batch Code
	Product Catalog Number
	Manufacturers Identification
	Use by Date