



Biochemical Diagnostics, Inc.

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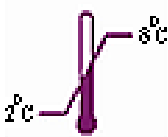
PREGNANCY-SKREEN™

hCG

LIQUID

CONTROL

URINE



Temperature Limit



Consult Instructions for Use



For In Vitro Diagnostic Use

Please call for additional information on our stock controls or our custom toxicology control manufacturing. Custom manufacturing is available with many bottling options and constituent levels.

Available in the following levels:

Positive, 5 mL Vial

Negative, 5 mL Vial



EMERGO EUROPE

Molenstraat 15
2513 BH, The Hague
The Netherlands



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Pregnancy-Skreen™ controls are prepared from human based urine available as a negative and at positive hCG levels to qualitatively monitor the performance of urine pregnancy immunochromatographic detection devices and procedures.

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

INTENDED USE

The Biochemical Diagnostics, Inc. Pregnancy-Skreen™ controls are intended to validate the performance of qualitative urinary hCG methods. 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™ 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 bottle contains stabilized human based urine in a convenient liquid form. Positive control urines have been spiked with known quantities of purified Human Chorionic Gonadotropin (hCG). Negative control urine is certified negative for the constituents listed in this insert.

CATALOG #	DESCRIPTION
20100007	PREGNANCY-SKREEN™ hCG Liquid Control Urine, Negative, 5 mL vial
20100005	PREGNANCY-SKREEN™ hCG Liquid Control Urine, Positive, 5 mL vial

PRECAUTIONS

For in vitro diagnostic use only

Please read the entire package insert before using the Pregnancy-Skreen™ 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.

Do not use beyond the expiration date.

PRECAUTIONS, cont'd

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 bottle of Pregnancy-Skreen™ 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

Unopened:

The controls are stable until the expiration date when stored refrigerated at (2-8°C). When stored at room temperature (18-25°C) the controls are stable for 31 days or until the expiration date, whichever comes first.

This product should never be stored frozen.

After Opening:

The controls are stable for 31 days or until the expiration date, whichever comes first, when stored refrigerated (2-8°C) or at room temperature (18-25°C).

PROCEDURE

1. Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.
2. Pipette 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™ control must test positive and the negative Pregnancy-Skreen™ control must test negative.