

PREGNANCY-SKREEN hCG Serum Controls

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

Please read the entire package insert before using these controls.

INTENDED USE

The PREGNANCY-SKREEN hCG Controls are intended to validate the performance of qualitative hCG serum procedures and immunochromatographic devices. 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 serum that has been stabilized to ensure 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 human based serum matrix. The low positive control is spiked with hCG in a target range from 10-40 mIU/mL of human based serum matrix. The negative control is prepared from a human based serum that tested negative for hCG. The standard material used for spiking was obtained from human pregnancy 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 the positive controls tested positive, and the negative controls tested negative for the claimed life of the product.

DESCRIPTION

Each vial contains stabilized human-based serum in a convenient liquid form. Positive controls have been spiked with known quantities of purified Human Chorionic Gonadotropin (hCG). Negative control is certified negative for Human Chorionic Gonadotropin.

ORDERING INFORMATION

CATALOG#	DESCRIPTION
702032	KOVA [®] poc PREGNANCY-SKREEN hCG Liquid Control Serum -/+ Low Positive Kit containing: 20700000 Negative 4mL dropper bottle 20702032 Low Positive 4mL dropper bottle
702033	KOVA [®] poc PREGNANCY-SKREEN hCG Liquid Control Serum -/+ Positive Kit containing: 20700000 Negative 4mL dropper bottle 20702033 Positive 4mL dropper bottle

PRECAUTIONS

For *in vitro* diagnostic use only.

Please read the entire package insert before using the PREGNANCY-SKREEN hCG Serum Control. Please use the same safety precautions you would use for processing any "unknown" 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.

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. Pipette an appropriate aliquot of PREGNANCY-SKREEN hCG Control human-based serum 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 serum hCG methods that screen serum for hCG levels consistent with pregnancy. Consult test manufacturers' instructions when using this product; changes in reagents, sample requirement, or methodology may affect 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.



Biochemical Diagnostics, Inc.
180 Heartland Blvd.
Edgewood, NY 11717 USA
Phone: (631) 595-9200
Email: support@biochemicaldiagnostics.com
Website: www.kovaintl.com



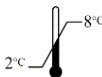
For additional information on our other PREGNANCY-SKREEN products please contact us or refer to our website.



Advena Ltd.
Tower Business Centre
2nd Flr., Tower Street
Swatara, PA 17013 MALTA



Advena Ltd.
Pure Offices, Plato Close
Warwick CV34 6WE
United Kingdom



SYMBOL LEGEND	
	Consult Instructions for Use
	Temperature Limits
	<i>In Vitro</i> Diagnostic Medical Device
	Batch Code
	Product Catalog Number
	Unique Device Identification
	Country of Manufacture
	Manufacturers Identification
	Use by Date
	For Prescription Use Only