



Biochemical Diagnostics, Inc.

A Kova International Company
ADULTER-SKREEN™

LIQUID

CONTROL

URINE

Catalog # 20300001

Kitbox contains the following:

Control A, 1 x 20 mL vial

Control B, 1 x 20 mL vial

Control C, 1 x 20 mL vial

Adulter-Skreen™ controls are prepared from a combination of synthetic and human based matrices with specified constituent levels to qualitatively monitor the performance of laboratory urine adulterant testing procedures.

Please read the entire package insert before using the controls.

INTENDED USE

The Biochemical Diagnostics, Inc. Adulter-Skreen™ controls are intended to validate the performance of laboratory urinary adulterant test 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 Adulter-Skreen™ product line of controls is manufactured using a combination of synthetic and human based urine matrices that have been stabilized to insure that the product will be viable until the date of expiration. The controls are spiked with appropriate metabolites obtained from certified manufacturers. Subsequent testing of the control material is performed qualitatively to ascertain that abnormal controls test abnormal and normal controls test normal for the claimed life of the product.

DESCRIPTION

Adulter-Skreen™ controls are manufactured in accordance to the following specifications:

Constituent	CONTROL A	CONTROL B	CONTROL C
Creatinine	Positive (High Normal)	30 -90mg/dL (Normal)	Negative
Nitrite	Negative	Negative	Positive
Glutaraldehyde	Negative	Positive	Negative
pH	6.0-7.5 (Normal)	2.0-3.0 (Low Abnormal)	11.0-12.0 (High Abnormal)
Specific Gravity	1.030-1.040 (High Abnormal)	1.005-1.025 (Normal)	1.000-1.002 (Low Abnormal)
Oxidant	Negative	Positive (PCC)	Positive (H ₂ O ₂)

PRECAUTIONS

For in vitro diagnostic use only

Please read the entire package insert before using the Adulter-Skreen™ control urines. Please use the same safety precautions you would use for processing any "unknown" urine sample containing potentially infectious biological material. Contains a non-azide preservative. Protect product from exposure to direct sunlight. Discard control if cloudiness develops.

Do not use beyond the expiration date.

STORAGE & STABILITY

Unopened:

The controls are stable until the expiration date when stored refrigerated at (2-8°C) and protected from light.

After Opening:

The controls are stable for 60 days or until the expiration date, whichever comes first, when stored refrigerated (2-8°C).

PROCEDURE

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

EXPECTED RESULTS

The abnormal Adulter-Skreen™ constituents must test abnormal and the normal Adulter-Skreen™ constituents must test normal.

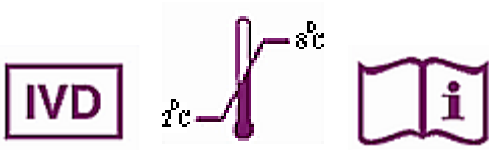
LIMITATIONS OF PROCEDURE

This control is meant to be used to validate the performance of qualitative urine adulterant screening methods.

Consult test manufacturer's 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.

Due to the variable nature of colorimetric test pads on adulterant devices and test strips by various manufacturers, certain constituents may be difficult to interpret. If your test device is detecting a higher result for the 1.000-1.002 specific gravity, DiH_2O may be used to replace Control C on that assay. On certain oxidant test strips, the light green/blue for negative oxidant may be difficult to interpret. Controls B and C contain two different types of oxidants which may give different results depending on test strip manufacturers.



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.

Biochemical Diagnostics, Inc.

180 Heartland Blvd, Edgewood, NY 11717 • Phone (631) 595-9200

Fax (631) 595-9204 • www.biochemicaldiagnostics.com