



**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.

**PROCEDURE**

1. Allow controls to come to room temperature followed by **gentle swirling or inversion** before use.
2. Transfer an appropriate aliquot of Adulter-Skreen™ control urine as required by the test device or screening method.

**DESCRIPTION**

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

Constituent	CONTROL A	CONTROL B	CONTROL C
<b>Creatinine</b>	Negative	>100 mg/dL (High Normal)	30-90 mg/dL (Normal)
<b>Nitrite</b>	Negative	Negative	Positive
<b>Glutaraldehyde</b>	Positive	Negative	Negative
<b>pH</b>	6.0-7.5 (Normal)	2.0-3.0 (Low Abnormal)	10-11 (High Abnormal)
<b>Specific Gravity</b>	1.000-1.002 (Low Abnormal)	>1.035 (High Abnormal)	1.005-1.025 (Normal)
<b>Oxidant</b>	Negative	Positive (PCC)	Positive (H <sub>2</sub> O <sub>2</sub> )

## 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. *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).

## EXPECTED RESULTS

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

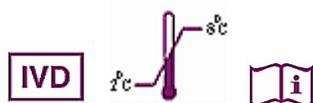
## LIMITATIONS OF PROCEDURE

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<sub>2</sub>O 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.



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