

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k062942

B. Purpose for Submission:

Clearance to market a urine-based control material

C. Measurand:

Cotinine

D. Type of Test:

Gas chromatograph/Mass spectroscopy

E. Applicant:

Quantimetrix Corporation

F. Proprietary and Established Names:

Quantimetrix NiCosure Cotinine Urine Control

G. Regulatory Information:

1. Regulation section:

21 CFR §862.3280: Clinical toxicology control material.

2. Classification:

Class I (reserved)

3. Product code:

LAS

4. Panel:

(91) Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The Quantimetrix Corp. NiCosure Cotinine Urine Control is intended as a means of monitoring the performance of GC/MS and other drugs of Cotinine methods used for detecting the Cotinine levels in unknown urine specimens.

Use of quality control materials is an integral part of diagnostic procedures. Daily monitoring of control values establishes intra-laboratory parameters for accuracy and precision of the test method.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

None

I. Device Description:

The Quantimetrix Corp. NiCosure Cotinine Urine Control is intended as a means of monitoring the performance of GC/MS and other drugs of Cotinine methods used for detecting the Cotinine levels in unknown urine specimens. The device is provided in 3 levels of control in a human urine matrix. Sodium azide is used as a preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DetectAbuse™ Control

2. Predicate 510(k) number(s):

k925586

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Cotinine	Same
Matrix	Human urine	Same
Preservative	Sodium Azide	Same

Differences		
Item	Device	Predicate
Levels of Control	3	2
Stability	60 days once opened when stored at 2-8 °C	30 days once opened when stored at 2-8 °C

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable to this device.

b. Linearity/assay reportable range:

Not applicable to this device.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The company maintains their own traceability for the proposed device. Concentration targets are met by gravimetric measurement of chemically pure material. New lots of material are assayed via GC/MS to ensure concentration assignments.

The company substantiated their claim for a shelf life using accelerated aging studies. The company stored samples of their device at 37 °C for extended periods of time followed by storage at 2-8 °C to mimic use by their customers. At the end of the testing cycle, the company determined that concentrations of

Cotinine were within the limits specified in their product insert for all three levels. The data supplied by the company supports their claim for a 3 year shelf life for the proposed device when stored at 2-8 °C.

The company substantiated their claim for an opened, capped and refrigerated shelf life using real-time aging studies. Samples of the device were opened and then stored at 2-8 °C. The samples were periodically removed from refrigeration to mimic use by their customers. At the end of the testing cycle, the company determined that concentrations of Cotinine were within the limits specified in their product insert for all three levels. The data supplied by the company supports their claim of a 60 day shelf life for opened, refrigerated for the proposed device when stored at 2-8 °C.

d. Detection limit:

Not applicable to this device.

e. Analytical specificity:

Not applicable to this device.

f. Assay cut-off:

Not applicable to this device.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable to this device.

b. Matrix comparison:

Not applicable to this device.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable to this device.

b. Clinical specificity:

Not applicable to this device.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable to this device.

4. Clinical cut-off:

Not applicable to this device.

5. Expected values/Reference range:

The package insert contains the mean value and expected range for all three control levels determined by GC/MS.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.