

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

A. 510(k) Number:

k060788

B. Purpose for Submission:

New device (addition of methadone to an existing toxicology control)

C. Measurand:

Not applicable

D. Type of Test:

Not applicable

E. Applicant:

Biosite, Inc.

F. Proprietary and Established Names:

Triage[®] TOX Drug Screen Controls

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.3280

2. Classification:
Class I (reserved)

3. Product code:
DIF

4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for use below.

2. Indication(s) for use:

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Screen tests and Triage Meters to assist the laboratory in monitoring test performance.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Biosite Triage Meters

I. Device Description:

Level 1 of the Triage TOX Drug Screen Controls is a negative control prepared from drug-free urine. Level 2 is a positive control prepared by adding d/l-methadone, acetaminophen, d-amphetamine, d-methamphetamine, pentobarbital, estazolam, desipramine, phencyclidine, morphine, benzoylecgonine, and tetrahydrocannabinol to human urine. The concentrations for each drug in the positive control are 2-4 times the cutoff concentration of the respective drug assays.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Biosite Triage TOX Drug Screen Controls

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

k050037

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Qualitative control for common drugs of abuse
Matrix	Same	Liquid (human urine)
Positive control concentrations	Same	2-4 times cutoff concentration for each analyte
Storage	Same	-20° C or below

Differences		
Item	Device	Predicate
Constituents	Same, with the addition of d/l-methadone	acetaminophen, d-amphetamine, d-methamphetamine, pentobarbital, estazolam, desipramine, phencyclidine, morphine, benzoylecgonine, and tetrahydrocannabinol

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

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability

The controls are traceable to commercially available drug-free urine and d/l-methadone. The negative control is drug-free urine with a zero concentration of all analytes. The d/l-methadone is solubilized in distilled water to produce a concentrated stock solution, which is then diluted with drug-free urine to the final concentration of the positive control.

Stability

The sponsor's real-time stability protocol uses the following formula to calculate recovery at specific storage times at -20°C:

$$\% \text{ recovery} = (\text{measured concentration at time point})_{-20\text{C}} / (\text{measured concentration at time point})_{-70\text{C}}$$

The sponsor's stability criteria are met when all of the time point recoveries at -20°C are within 80 to 120 percent of the recoveries at -70°C or when the trendline recovery lies within an 80 to 120 percent recovery acceptance window.

At the time of submission, the sponsor had collected two weeks of stability data on the controls. On-going real-time stability testing of the controls will continue until the material fails the pre-determined acceptance criteria. The shelf life of the controls will be extended based upon the on-going real-time stability data.

All stability claims are for closed-vial stability only. Open-vial stability is not applicable to this device since it is intended for one time use.

Value Assignment

The negative control consists of drug-free urine and therefore contains none of the drugs of abuse currently available on the Triage system. To add methadone to the previously cleared positive control, a concentrated

stock solution was diluted with drug-free urine to a final concentration of 750 ng/mL (calculated gravimetrically). Values were verified by analyzing 90 replicates of each control using three lots and two operators over three days. All of the negative control replicates produced negative results for all analytes and all of the positive control replicates produced positive results for all analytes.

- d. Detection limit:*
Not applicable
 - e. Analytical specificity:*
Not applicable
 - f. Assay cut-off:*
Not applicable
2. Comparison studies:
- a. Method comparison with predicate device:*
Not applicable
 - b. Matrix comparison:*
Not applicable
3. Clinical studies:
- a. Clinical Sensitivity:*
Not applicable
 - b. Clinical specificity:*
Not applicable
 - c. Other clinical supportive data (when a. and b. are not applicable):*
4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
Not applicable

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.