

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

A. 510(k) Number:

k050037

B. Purpose for Submission:

Reagent formulation change – addition of one reagent (acetaminophen) to an existing toxicology control.

C. Measurand:

Acetaminophen

D. Type of Test:

immuno-fluorescence

E. Applicant:

Biosite Incorporated
11030 Roselle Street
San Diego, CA 92121

F. Proprietary and Established Names:

Triage® TOX Drug Screen Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3280: Clinical toxicology control material

2. Classification:

Class I(reserved)

3. Product code:

DIF

4. Panel:

(91) - Toxicology

H. Intended Use:

1. Intended use(s):

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

2. Indication(s) for use:

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

3. Special conditions for use statement(s):

N/A

4. Special instrument requirements:

This control is only intended for use with the Biosite Triage® family of meters.

I. Device Description:

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Drug Screen tests and Triage MeterPlus to assist the laboratory in monitoring test performance. This toxicology control consists of drug and drug metabolites dissolved in preserved human urine. The control is provided in 2 levels, analyte negative and analyte positive, to facilitate verification of the outcome of Triage® MeterPlus tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Triage TOX Drug Screen Controls

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

K012999

3. Comparison with predicate:

Similarities		
Item	Device(K050037)	Predicate(K012999)
Analytes:	Present	Present
Amphetamines (AMP)	Present	Present
Methamphetamines (mAMP)	Present	Present
Barbiturates (BAR)	Present	Present
Benzodiazepines (BZO)	Present	Present
Cannabinoids (THC)	Present	Present
Cocaine (COC)	Present	Present
Opiates (OPI)	Present	Present
PCP (PCP)	Present	Present
Tricyclic Antidepressants (TCA)	Present	Present

Differences		
Item	Device(K050037)	Predicate(K012999)
Analyte Concentrations	Approximately 2-4 times device cutoff	Approximately 1.75 times device cutoff
New Analyte	Acetaminophen	Not Present
Storage at user facility	Storage at -20 °C at the back of the freezer	Storage at -20 °C

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

Not Applicable

L. Test Principle:

The product under submission is used to verify the performance of Biosite Triage meters. The control is treated as a typical sample. Processing is done per instrument instructions.

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):*

No Traceability is provided.

The predicate and pre-market devices serve as controls for specific Biosite clinical equipment. The stability of the components is one of the primary criteria for acceptance.

Stability is measured by:

Real-time studies of material stored at –20 °C. There is no extrapolation performed to determine expiration dating. The expiration date is based on real-time closed vial stability data. Concentrations of the analytes in the stored controls are determined by measurements with the Biosite Triage meters. Currently, the expiration dating will reflect an 8 week shelf life. The shelf life will be updated as necessary over time as the closed vial stability study progresses.

The reported stability is within the error limits stated with the product. The measured stability is consistent with the shelf life claimed on the product insert.

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:*

The performance of these controls was verified by comparing them to the existing controls on the required Biosite instrument. The assigned range for these controls was based upon replicate assays of samples of the product on multiple instruments and lots of measurement cassettes in accordance with directions accompanying the Biosite meters.

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):

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.