

# Evaluation of Two Qualitative Drug Testing Devices for Detection of Drugs of Abuse in Urine

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## Amended Abstract

### Objective:

To compare patient urine samples for a qualitative analysis of drugs of abuse from the Emergency ward at Southlake Regional Health Centre. These patients were suspected of having drug overdose. We evaluated the performance of the Triage kit by Biosite Diagnostics to StarTox 5 by Starplex Scientific Inc. These testing devices are based on flow immunoassay intended for the simultaneous detection of multiple drug analytes in urine. Although both kits use the same method, the intended use is different.

### Methods:

Both the Triage and StarTox5 are competitive binding immunoassays in which a chemically labeled drug (drug conjugate) competes for antibody sites with drugs or metabolites that may be present in the urine specimen. Both kits tested for the following compounds: Amphetamine (AMP) with a cut off concentration of 1000ng/ml, Phencyclidine (PCP) with a cut off concentration of 25ng/ml, Cocaine (COC) with a cut off concentration of 300ng/ml, Cannabinoids (THC) with a cut off concentration of 50ng/l and Opiates (OPI) with a cut off concentration of 2000ng/ml in Startox5 and 300ng/ml in Triage. Both devices consist of a membrane strip to which drug conjugates are immobilized. In the triage system the strip is washed to remove the unbound conjugate and clear the background. A positive specimen produces a distinct colored bar in the Drug Detection Zone adjacent to the drug name.

In StarTox5 if the drug is present in sufficient concentrations, it will fill the entire available antibody binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. Therefore there is **no** visible line present adjacent to the drug name.

### Results:

30 patient samples from the Emergency department were tested using both kits and the results were compared. Controls were run according to manufacturer's protocol. These kits provide a rapid qualitative test result within 10 minutes. All positives were confirmed by Gas chromatography/mass spectrometry (GC/MS). Of the 30 samples tested, we had 21 positive cases with the presence of one or more of the 5 tested drugs of abuse. The result correlation was approximately 87%. The exceptions were: 1. One specimen was positive for OPI by StarTox5 and negative by Triage, but present by GC/MS. 2. One specimen was positive for OPI and THC in StarTox5 and positive for OPI only by Triage, but positive for THC **and** OPI by GC/MS. 3. One specimen was positive for OPI in both StarTox5 and Triage but absent by GC/MS. 4. One specimen was positive for AMP and THC by StarTox5 and positive for AMP only by Triage, but positive for THC **and** AMP by GC/MS.

### Conclusion:

Both testing devices compared well. Based on this study, comparing sample volume, test menu, procedure and interpretation of results, we conclude that both kits are appropriate for Point of Care testing. The Triage is the preferred choice for a hospital laboratory setting and that the StarTox5 is best suited for random Drugs of abuse testing in the work place.

## Introduction

The amount of money that is spent on testing drugs of abuse by the government, employers and other institutions will exceed 4 billion dollars this year. The increase in the recreational use of drugs in the general population and in the workplace has prompted the need for rapid, simple drug screening tests. These rapid tests allow random employment testing as well as monitoring workplace abuse, affecting productivity. Urine drugs of abuse screening kits are also used as a qualitative indicator of the presence of illicit drugs, or their metabolites in the clinical management of patients. Some screen kits are designed more for use as a detection of abuse of illicit drugs in the general population, while some are designed for use in the health care environment.

The purpose of this study was to compare two different qualitative drugs of abuse kits. Both kits are intended for use as Point of Care devices. The Starplex StarTox5 kit was designed to prevent any tampering with the integrity of the specimen and therefore; is marketed to detect abuse.

The BIOSITE Triage kit was designed for diagnostic purposes. Although they were initiated with different applications in mind, the StarTox5 and Triage compared favorably for the drugs tested.

## Methods and Procedures

30 patient samples were tested with the Starplex StarTox5 and the BIOSITE Triage drugs of abuse kits at the Southlake Regional Health Centre. All testing was performed within 1 hour of collection. The study was conducted on Amphetamines, Opiates, Phencyclidine, Cocaine and Cannabinoids. (Concentration in Table 1.1)

**Table 1.1 Concentration of Drugs**

Compound	Triage (concentration level)	StarTox5 (concentration level)
Amphetamine (AMP)	1000 ng/mL	1000 ng/mL
Opiates (OPI)	300 ng/mL	2000 ng/mL
Phencyclidine (PCP)	25 ng/mL	25 ng/mL
Cocaine (COC)	300 ng/mL	300 ng/mL
Cannabinoids (THC)	50 ng/mL	50 ng/mL

### Triage Drugs of Abuse panel plus TCA ( BIOSITE)

The Triage assay is a competitive binding immunoassay. A chemically labeled drug competes for antibody binding sites when mixed with the corresponding drug of abuse present in the urine specimen. The reaction mixture is then transferred to a membrane in the detection area. Free drug conjugate, displaced from the antibody binding sites, binds to a monoclonal antibody

on the membrane. producing a band of color indicating a positive result.

A negative result is indicated by the lack of a line because the conjugated drug was not available to bind with the monoclonal antibody on the membrane.

The specimen is a random urine sample collected in a routine urine container. The specimen should be tested immediately or can be stored for up to two days at 2-8°C.

### Procedure:

The test procedure consists of three steps.

1. Pipette 140µl of urine into the reaction cup on the panel and incubated for 10 minutes (The reaction cup consists of three pre-measured, lyophilized beads. One containing monoclonal antibodies, one containing drug conjugates and a third containing buffer.)
2. The reaction mixture is transferred from the cup to the point in the Detection Area. The mixture is allowed to soak through completely.
3. 3 drops of Wash Solution is added to the center of the Detection area and allowed to soak through completely.

Results are valid if a color bar appears in the Control Positive Zone.

There should not be any colored bars present in the Control Negative Zone.

The presence of a color bar in the Control Positive zone and any of the Drug Detection Zones adjacent to the drug names indicate a positive result. (Result interpretation Table 2.1)

### StarTox5 (Starplex Scientific Inc)

The specially labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine. The device consists of a membrane strip on which the drug conjugates are immobilized. A colloidal gold-labeled antibody complex is dried at one end of the membrane. A control line, comprised of different antibody/antigen reaction, is present on the membrane strip. The formation of a visible line in the Control area and one in the Test area occurs when the test is negative for the targeted drug.

The specimen is a random urine specimen collected directly into a self-contained, tamper-proof test device. The device consists of a specially designed closure system and a sample container. Using the collection container, collect sufficient urine specimen from the recipient to fill the container within the Min-Max fill lines.

Place the detection cap on the specimen. The specimen should be tested immediately or can be stored for up to two days at 2-8°C.

### Procedure:

The test strip is a one-step immunoassay.

1. When ready to perform the testing. Turn the dial one-quarter turn clockwise to activate the test.

Allow the test to stand until the reddish-purple Control line appears and the background has cleared (approximately 5-7 minutes).

A positive result is indicated by the **absence** of the test line for the targeted drug and by the **presence** of the control line. (Table 2.1)

**Table 2.1 Interpretation of Results**

Test Kit	Control Line	Test Line	Interpretation
Triage	line present at ctrl neg zone	line present at drug detection zone	invalid results
	line present at ctrl pos zone	line present at drug detection zone	positive test for the indicated drug
	line absent at ctrl pos zone	line present at drug detection zone	invalid results
StarTox5	no control line present	no test line present	invalid results
	control line present	test line present	negative results
	control line present	test line absent	positive test for the indicated drug
	no control line present	test line present	invalid results

**Table 3.1 Result Comparison**

	Test Subject	Positive drugs in Triage Kit	Positive drugs in StarTox5	Positive drugs by GC/MS
	<b>Positive control</b>	PCP, BZO, COC, AMP, THC, OPI, BAR, TCA	AMP, OPI, PCP, COC, THC	
<b>1</b>	<b>16 YR F</b>	neg	neg	
<b>2</b>	<b>41 YR F</b>	neg	neg	
<b>3</b>	<b>45 YR F</b>	neg	insufficient volume	
<b>4</b>	<b>23 YR M</b>	THC	THC	THC, Lidocaine, Diphenhydramine
<b>5</b>	<b>15 YR F</b>	neg	neg	
<b>6</b>	<b>41 YR F</b>	neg	neg	
<b>7</b>	<b>33 YR M</b>	THC	THC	THC
<b>8</b>	<b>25 YR F</b>	THC	THC	THC
<b>9</b>	<b>25 YR F</b>	THC	THC	THC
<b>10</b>	<b>35 YR M</b>	OPI	insufficient volume	not tested
<b>11</b>	<b>25 YR M</b>	OPI	OPI	Codeine, Risperidone
<b>12</b>	<b>39 YR F</b>	neg	OPI	Oxycodone
<b>13</b>	<b>46 YR M</b>	OPI	OPI	Morphine
<b>14</b>	<b>16 YR M</b>	THC	THC	THC
<b>15</b>	<b>27 YR F</b>	COC, THC	COC, THC	COC, THC, Dextromethorphan, Ephedrine
<b>16</b>	<b>49 YR F</b>	neg	neg	
<b>17</b>	<b>30 YR F</b>	THC	THC	THC
<b>18</b>	<b>24 YR M</b>	OPI	OPI, THC	THC, Codeine, Oxycodone
<b>19</b>	<b>41 YR F</b>	neg	neg	
<b>20</b>	<b>66 YR M</b>	OPI	OPI	Lidocaine, Ramitidine
<b>21</b>	<b>39 YR F</b>	THC	THC	THC, Diphenhydramine
<b>22</b>	<b>26 YR M</b>	OPI	OPI	Codeine
<b>23</b>	<b>21 YR M</b>	COC	COC	COC
<b>24</b>	<b>20 YR M</b>	THC	THC	THC
<b>25</b>	<b>42 YR M</b>	OPI, COC, THC	OPI, COC, THC	COC, THC, Codeine
<b>26</b>	<b>36 YR M</b>	THC	THC	THC
<b>27</b>	<b>36 YR M</b>	OPI, COC	OPI, COC	Cocaine metabolite (BEG), Lidocaine
<b>28</b>	<b>25 YR M</b>	neg	neg	neg
<b>29</b>	<b>17 YR M</b>	AMP	AMP, THC	THC, Ecstasy
<b>30</b>	<b>38 YR M</b>	THC	THC	THC

## Results

30 random patient samples were tested from the Emergency department of Southlake Regional Health center using both kits and the results were compared. Controls were run according to manufacturer's protocol. These kits provide a rapid qualitative test result within 10 minutes. All positive results were confirmed by Gas chromatography/mass spectrometry (GC/MS) by Hospital for Sick Kids. Of the 30 samples tested, there were 21 positive urine specimens with the presence of one or more of the 5 drugs of abuse tested. The correlation between the two kits was 87%. Results are compiled in the above table (Table3.1).

## Discussion

The four discrepancies between the two kits were:

1. Specimen #12 was positive for OPI by StarTox5, negative by Triage, and the presence of Oxycodone was detected by GC/MS. This appears to be a false negative result for Triage based on detection levels stated by the manufactures. Manufacturer's performance studies state their threshold concentration for a positive result for Oxycodone (OPI) is at 50,000ng/ml for StarTox5 and 20,000ng/ml for Triage.
2. Specimen #18 was positive for OPI and THC by StarTox5 and positive for OPI only by Triage, the presence of OPI and THC was confirmed by GC/MS. The discrepancy in the presence of THC could be due to a false negative result or due to a possible misinterpretation of a faint line by the Triage Kit. Both kits detect the same concentration of THC.
3. Specimen #20 was positive for OPI by both kits but absent by GC/MS. This could be due to the presence of a drug within the Opiate group, which was not included in the GC/MS testing. The only drugs tested for OPI group by GC/MS was: Morphine, Codeine, Oxycodone, Hydrocodone, Hydromorphone and Meperidine. The two kit methods test for a broader base of opiates that the GC/MS method.
4. Specimen #29 was positive for AMP and THC by StarTox5 and positive for AMP only by Triage, but presence of AMP and THC was confirmed by GC/MS. The discrepancy in the presence of THC could be due to a false negative result by the Triage kit. Both kits detect the same concentration of THC.



## Conclusion

When evaluated at Southlake Regional Health Centre against the Triage kit, the StarTox5 compared more favorably as confirmed by the GC/MS. We conclude that the StarTox5 is a reliable screening tool for drugs of abuse. It is a self contained, tampered resistant one step collection and test kit that is simple to use. It requires a fairly large volume of specimen (35-55 ml). Also a positive is depicted by the absence of the formation of a line. For these reasons we conclude that it is best suited for a random drugs of abuse screening test in the workplace and clinical setting.

The Triage kit appeared to have had two false negative results as confirmed by GC/MS; however we conclude that the Triage is the preferred choice in our hospital laboratory setting. It requires a small sample volume (140µl sample) and the interpretation of a positive is the formation of a line, which is consistent with other kit methods used in the hospital laboratory. The Triage kit also tests for therapeutic drugs (e.g. Barbiturates) and Tricyclic antidepressants (TCA) in addition to testing for drugs of abuse, which aids in diagnosis and treatment.

## References

- StarTox5 package insert. (Starplex Scientific Inc 02116, 09/02)
- Triage Drugs of Abuse panel plus TCA package insert (BIOSITE 8X80101, 1996)