

**PREMARKET NOTIFICATION  
510(k) SUMMARY  
(As Required By 21 CFR 807.92)**

807.92 (a):

1. **Submitter's Name:** STC Technologies, Inc.  
**Address:** 1745 Eaton Avenue, Bethlehem, PA 18018  
**Telephone Number:** (610) 882-1820  
**Contact Person:** R. Sam Niedbala, Ph.D., BCFE  
**Date Prepared:** 03/23/00
2. **Device Name:**  
**Proprietary Name:** Amphetamine-Specific Intercept™ MICRO-PLATE EIA  
**Usual Name:** Amphetamine-Specific Intercept™ System  
**Classification Name:** Enzyme Immunoassay, Amphetamines
3. **Device to Which Substantial Equivalence Is Claimed:**  
 Roche Diagnostic Systems, Abuscreen ONLINE® kit for amphetamines (urine); K933052

4. **Description of Device:**

**Principle of the Assay**

The STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA is a competitive micro-plate immunoassay for the detection of amphetamine in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for amphetamine, there is a competition between the drug and the enzyme-labeled hapten to bind the antibody fixed onto the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured for each well at 450 nm is inversely proportional to the amount of amphetamine present in the specimen or calibrator/control. Because currently there are no SAMHSA assigned cutoffs for amphetamine testing using oral fluid, STC recommends a cutoff of 100 ng/mL when testing oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. This cutoff is within the limit of detection by the STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA.

REAGENTS AND CONTROLS
<b>Anti-Amphetamine Coated Plate</b> – Mouse anti-amphetamine monoclonal antibody immobilized on a polystyrene plate supplied in dry form.
<b>Enzyme Conjugate</b> -- Horseradish peroxidase labeled with an amphetamine hapten diluted in a protein matrix of bovine serum with protein stabilizers.
<b>Substrate Reagent</b> -- One bottle containing 3,3', 5,5' tetramethylbenzidine.
<b>Stopping Reagent</b> -- Each bottle contains 2 N sulfuric acid.
<b>Oral Fluid Negative Calibrator</b> – Oral Fluid Diluent negative for amphetamine.
<b>Oral Fluid Negative Control</b> – Oral Fluid Diluent containing 50 ng/mL (v/v) d-amphetamine.
<b>Oral Fluid Cutoff Calibrator</b> – Oral Fluid Diluent containing 100 ng/mL (v/v) d-amphetamine.
<b>Oral Fluid Positive Control</b> – Oral Fluid Diluent containing 200 ng/mL (v/v) d-amphetamine.

**Principle of the Intercept™ DOA Oral Specimen Collection Device**

Saliva is a complex mixture of parotid, submandibular, sublingual and minor salivary gland secretions mixed with mucin, bacteria, leukocytes, sloughed epithelial cells and gingival crevicular fluid. The fact that amphetamine is present in oral fluid following human use is well documented.

The Intercept™ DOA Oral Specimen Collection Device was developed for the purpose of collecting oral fluid for diagnostic testing. The collection device consists of a treated absorbent cotton fiber pad affixed to a nylon stick (Collection Pad) and a preservative solution in a plastic container (Specimen Vial). The Collection Pad is impregnated with a mixture of common salts and gelatin which creates a hypertonic

environment and an increased osmotic pressure wherever it contacts oral mucosal cells. The pad is placed in contact with the gingival mucosa (between the lower gum and cheek) which enhances the flow of mucosal transudate across the mucosal surfaces onto the absorptive cotton fibers of the pad. Following the collection period, the Collection Pad is placed into a vial containing a preservative solution which serves to inhibit the growth of oral micro-organisms recovered on the Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing. Following processing, a fluid containing a mixture of saliva components and the preservative solution is recovered which is suitable for testing for the presence of amphetamine in the Amphetamine-Specific Intercept™ MICRO-PLATE EIA manufactured by STC Technologies, Bethlehem, PA. Refer to the Intercept™ DOA Oral Specimen Collection Device product insert for specific instructions on the proper collection, handling, and adequacy of oral fluid samples.

5. *Intended Use Statement:*

The STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of amphetamine in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. **For In Vitro Diagnostic Use.**

6. *Summary of Technological Characteristics:*

The STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA is based on the principle of solid phase competitive enzyme immunoassay. This application is for the use of the STC Amphetamine-Specific Intercept™ EIA as a screening tool for the detection of amphetamine using specimens collected with the Intercept™ DOA Oral Specimen Collection Device manufactured by Epitope, Inc., Beaverton, Oregon.

807.92 (b):

1. *Non Clinical Data:*

**Analytical Sensitivity/Limit Of Detection** - The Limit of Detection (LOD) was defined from the signal-to-noise ratio at the zero-drug concentration as the mean zero absorbance ( $A_0$ ) minus the noise times three ( $LOD = A_0 - 3SD$ ). The LOD was determined by obtaining the average absorbance value for 80 readings of blank Oral Fluid Diluent and calculating the standard deviation (SD) and 3SD of the absorbance. The absorbance value minus 3SD was then extrapolated from the curve and represents the sensitivity of the assay. The LOD was calculated to be 25.5 ng/mL.

**Precision** - The precision of the STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA was assessed by testing Oral Fluid Diluent containing 0, 50, 100, 150, and 200 ng/mL amphetamine. The intra-assay precision was determined by analyzing each level 16 times per run for 4 runs. Inter-assay precision was determined by analyzing 2 samples at each level twice per day for 20 days. The results of this testing are described in the following table:

Amphetamine Concentration (ng/mL)	Mean O.D.	Intra-Assay % CV (n=64)	Inter-Assay % CV (0-40d; 20-daily)
0	1.905	3.9	6.7
50	1.005	3.5	6.7
100	0.709	4.0	7.5
150	0.563	4.5	7.7
200	0.438	6.4	7.9

**Analytical Specificity/Cross-Reactivity** - The analytical specificity of an immunoassay is defined as the cross-reactivity of substances in the assay which are structurally related to the target compound. The percent cross-reactivity of a compound in the STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA is defined as the apparent amphetamine concentration divided by the spiked concentration times 100.

The cross-reactivity of structurally related compounds was calculated at several spiked concentrations in Oral Fluid Diluent. The following table indicates the apparent concentration of amphetamine for

each substance at a concentration which cross-reacted in the assay. Note: D-Amphetamine was used as the kit standard and, therefore, will exhibit 100% cross-reactivity.

The following compounds cross-react in the assay at the levels shown:

Compound	Concentration (ng/mL)	Absorbance Reading (OD)	Cross-Reactivity (%)
β-Phenethylamine	100	1.15	1.15
Diphenhydramine	1000	5.05	0.51
d-Methamphetamine	1000	9.07	0.91
Doxylamine	10000	0.06	< 0.01
Fenfluramine	10000	4.43	0.04
Isoxsuprine	1000	13.26	1.33
l-Ephedrine	10000	O/R*	n.d.*
l-Methamphetamine	100	5.33	5.33
l-Phenylalanine	1000	1.25	0.13
MDA	100	48.93	48.93
MDEA	1000	1.15	0.12
MDMA	10000	0.83	0.01
Mephentermine	100	14.59	14.59
Phentermine	100	4.36	4.36
Phenylephrine	1000	4.29	0.43
Phenylpropanolamine	10000	7.41	0.07
Procaine	10000	O/R*	n.d.*
Pseudoephedrine	100	3.25	3.25

\*out of range: not detectable

The user should be aware that the determination of amphetamine equivalents for each compound is only to calculate the % cross-reactivity of these compounds in the assay. For many of these compounds, the absorbance readings obtained were below the limit of detection of 25.5 ng/mL for the assay. As a result, the % cross-reactivities for these compounds at the levels tested are considered estimates only.

The following compounds were spiked into Oral Fluid Diluent at a target concentration of 10,000 ng/mL and tested for cross-reactivity. None were found to produce a signal less than or equal to that of the Oral Fluid Cutoff Calibrator.

Acetylsalicylic Acid	Cocaethylene	Ibuprofen	Nordiazepam
Alprazolam	Cocaine	Imipramine	Penicillin
Amobarbital	Codeine	Lidocaine	Pentobarbital
Ampicillin	Cotinine	Medazepam	Phencyclidine
Benzoylcegonine	Dextromethorphan	Meperidine	Phenobarbital
Butabarbital	Diacetylmorphine	Methadone	Procainamide
Butalbital	Fenoprofen	Metroprolol	Quinidine
Caffeine	Gemfibrozil	Morphine	Temazepam
Chlordiazepoxide	Gentisic Acid	Nalorphine	Theophylline
Chlorpromazine	Glipizide	Naproxen	Δ <sup>9</sup> -THC
Clonazepam	Hydrocodone	Niacinamide	Zomepirac
Chlorazepate	Hydromorphone	Norchlordiazepoxide	

It is possible that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

## 2. Clinical Data

Three studies were conducted to determine the clinical accuracy of the STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA. For oral fluid testing, the cutoffs for EIA and GC/MS were 100 ng/mL and 75 ng/mL, respectively. For urine testing, the cutoffs were 1,000 ng/mL and 500 ng/mL respectively, for the initial screen and GC/MS confirmation based on SAMHSA guidelines.(1)

In the first study, 1568 oral fluid samples were randomly screened. Five (5) specimens were presumed positive by EIA and were tested by GC/MS. Of the 5 presumptive positives, three were positive by GC/MS and contained 95 ng/mL, 115 ng/mL and 381 ng/mL amphetamine. The remaining 2 samples were negative by GC/MS.

In the second study, oral fluid and urine specimen pairs were collected from 229 individuals in a drug rehabilitation clinic. Four (4) specimen pairs were presumed positive by EIA. These samples were confirmed positive by GC/MS and contained 691 ng/mL, 785 ng/mL, 7800 ng/mL and 2500 ng/mL amphetamine.

In the third study, two (2) oral fluid specimens and one urine specimen were collected from 22 individuals who self-reported use of amphetamines in the past 4 days. All oral fluid specimens were tested using the STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA and confirmed by GC/MS. All urine samples were screened using a commercial immunoassay kit for amphetamines and confirmed using GC/MS. Of the 44 oral fluid samples tested, 14 samples containing 92–798 ng/mL amphetamine were confirmed positive by GC/MS. 26 samples were confirmed negative by GC/MS. 4 samples that were negative by EIA were positive by GC/MS and contained 79 ng/mL, 76 ng/mL, 80 ng/mL and 125 ng/mL amphetamine.

For purposes of calculating % agreement, the data from the three studies were combined as shown below:

		Oral Fluid GC/MS (75 ng/mL)	
		+	-
STC Oral Fluid EIA (100 ng/mL cutoff)	+	21	2
	-	4	26

% Agreement = 89%

### 3. Conclusions

A comparison of the performance data for the new device vs. the predicate device is given below:

#### 1. Limit of Detection

Assay	LOD (ng/mL)
Amphetamine-Specific Intercept™ MICRO-PLATE EIA	25.5 ng/mL
Roche Abuscreen ONLINE®	< 30 ng/mL

#### 2. Precision

Assay	Intra-Assay % CV Range	Inter-Assay % CV Range
Amphetamine-Specific Intercept™ MICRO-PLATE EIA	3.5-6.4	6.7-7.9
Roche Abuscreen ONLINE®	3-6	4-7

#### 3. Sample pH Effect

Assay	pH Effect
Amphetamine-Specific Intercept™ MICRO-PLATE EIA	False positives at pH ≤ 5.0
Roche Abuscreen ONLINE®	Not Tested

#### 4. Effect of Common Materials

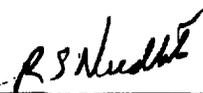
Amphetamine-Specific Intercept™ MICRO-PLATE EIA	Those Tested Did Not Affect the Assay
Roche Abuscreen ONLINE®	Not Tested

#### 5. Cross-Reactivity

Compound	% Cross Reactivity	
	Oral Fluid	Urine
β-Phenethylamine	1.15	2
3-Hydroxytyramine	not tested	<0.2
d,l-Ephedrine	not tested	<0.2
d,l-Methamphetamine	not tested	0.2
d-Ephedrine	not tested	<0.2
d-Methamphetamine	0.91	0.5
d-Phenylpropanolamine	not tested	0.2
d-Pseudoephedrine	not tested	<0.2
Diphenhydramine	0.51	not tested
dl-Amphetamine	not tested	51
Doxylamine	< 0.01	not tested
Fenfluramine	0.04	not tested
Isoxsuprine	1.33	not tested
l-Amphetamine	not tested	2
l-Ephedrine	n.d.*	<0.2
l-Methamphetamine	5.33	0.2
l-Norpseudoephedrine	not tested	<0.2
l-Phenylalanine	0.13	not tested
l-Phenylpropanolamine	not tested	1
l-Pseudoephedrine	not tested	<0.2
MDA	48.93	32
MDEA	0.12	not tested
MDMA	0.01	0.2
Mephentermine	14.59	<0.2
p-Hydroxyamphetamine	not tested	14
p-Hydroxymethamphetamine	not tested	0.3
Phendimetrazine	not tested	<0.1
Phentermine	4.36	<0.1
Phenylephrine	0.43	not tested
Phenylpropanolamine	0.07	0.7
Procaine	n.d.*	not tested
Propylhexidine	not tested	0.5
Pseudoephedrine	3.25	not tested
Tyramine	not tested	0.3

#### 6. References

- (1) "Urine Testing for Drugs of Abuse", National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.

  
 R. Sam Niedbala, Ph.D., BCFE  
 Chief Science Officer



APR 3 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

R. Sam Niedbala, Ph.D., BCFE  
Executive Vice President  
STC Technologies, Inc.  
1745 Eaton Avenue  
Bethlehem, Pennsylvania 18018-1799

Re: K992918  
Trade Name: STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA  
Regulatory Class: II  
Product Code: DKZ  
Dated: February 11, 2000  
Received: February 16, 2000

Dear Dr. Niedbala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

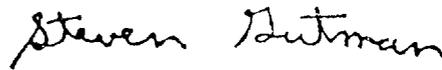
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

510(k) Number (if known): K992918

Device Name: STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA

Indications For Use: The STC Amphetamine-Specific Intercept™ MICRO-PLATE EIA is intended for use in the qualitative determination of amphetamine in oral fluid collected with the Intercept™ Drugs of Abuse (DOA) Oral Specimen Collection Device. For In Vitro Diagnostic Use.

*Jean Cooper*  
\_\_\_\_\_  
Division Sign-Off  
Division of Clinical Laboratory Devices  
510(k) Number K992918

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

\_\_\_\_\_  
**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_