

Syntron Bioresearch, Inc. Saliva QuikScreen 5 Test

REF 70510-B

Instructions



INTENDED USE

The Saliva QuikScreen 5 Test is an immunochromatographic assay for rapid, qualitative detection of five drugs and their principal metabolites in human saliva at specified cut-off concentrations. This test is an in vitro diagnostic medical device for healthcare professional use only. A five-drug combination is composed of the following drugs:

DRUG CLASS		SENSITIVITY
OPIATES/MORPHINE	OPI/MOR	30 ng/ml
MARIJUANA	THC	20 ng/ml
COCAINE/BENZOYLECGONINE	COC	30 ng/ml
BENZODIAZEPINE	BZD	50 ng/ml
METHAMPHETAMINE	MET	50 ng/ml

Note: The test provides only preliminary data which should be confirmed by other methods such as Gas Chromatography coupled to Tandem Mass Spectrometry (GC/MS/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

The Saliva QuikScreen 5 Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening human saliva. The method employs a unique mixture of monoclonal and polyclonal antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). There is a growing interest in the use of alternate human sampling other than urine, for the diagnosis of drugs of abuse.

PRINCIPLE OF THE TEST

The Saliva QuikScreen 5 Test is a competitive binding immunoassay in which drug and drug metabolites in a saliva sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of five drugs from a single sample. The approximate run time is 10 minutes.

In the assay procedure, the saliva mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose-pink color band is produced in each Control Zone (marked "C") by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

REAGENTS AND MATERIALS PROVIDED

1. Test Devices. Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.

REF PI-70510-B

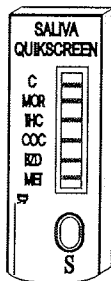
2. Saliva Collection System - Plastic Tube & Saliva Swab.

REF SYR-001



3. Saliva Extraction Buffer. REF PI-4010N

4. Test Instructions: REF PI-70510-B



MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

STORAGE AND STABILITY

Store test kit below 28°C; do not freeze. Refer to the expiration date for stability.

WARNINGS AND PRECAUTIONS

1. For forensic use only.
2. Do not use the test device beyond the expiration date.
3. Saliva specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to ensure it is intact. If the package is not intact, do not use the device--the integrity of the device might be compromised.

IMPORTANT NOTES:

1. Bring test pouch to room temperature (15°-28°C).
2. Do not break the seal of the pouch until ready to begin testing.
3. The Saliva Collection System is a one time use only system. To avoid cross-contamination, use a new Saliva Collection System for each saliva sample.
4. Make sure that there is sufficient saliva in the test (5 drops). Do not spit directly on the device. The Saliva Swab must be used to collect sample in order for the device to function correctly.
5. The result must be interpreted at 10 minutes. Waiting more than 10 minutes may cause the reading to be inaccurate. Discard used test device after interpreting the results to avoid confusion.

PATIENT SAMPLING AND TEST PROCEDURE

1. Adulterated saliva could give a false result. **Make sure that there is nothing in the patient's mouth for at least 5 minutes.**

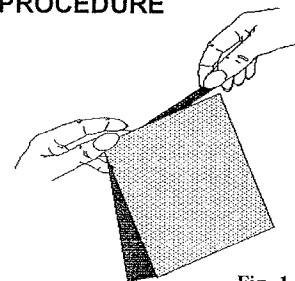


Fig. 1

2. Remove the Saliva Collection System out of the pouch, making sure not to contaminate the device.

Fig. 1.

Note: If it is your protocol to ID the device, write the patient's ID directly on the device

3. Place foam end of the syringe plunger into the patient's mouth and gently move it for up to 2 minutes to let sufficient saliva collect in the foam. (*NOTE: Have the patient pucker their mouth to get enough oral fluid.*)

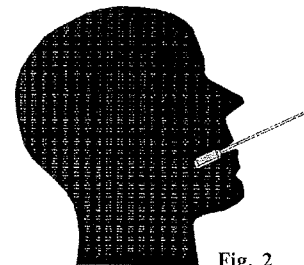


Fig. 2

4. Remove the Saliva Swab out of the patient's mouth and place it inside the syringe tube.

5. Place one drop of saliva extraction buffer into sample "S" well of the device. Wait for each drop to be completely absorbed.

6. Press the syringe plunger to extricate five (5) drops of the saliva directly onto the sample well of the device.

Fig. 3

7. Read the results at 10 minutes.

NOTE: If after adding the initial 5 drops migration is not visible, you may not have a sufficient amount of saliva in the test. Therefore, please add 1 additional drop (per minute), until migration is visible. Once migration is visible, you may start timing for reading results at 10 minutes.

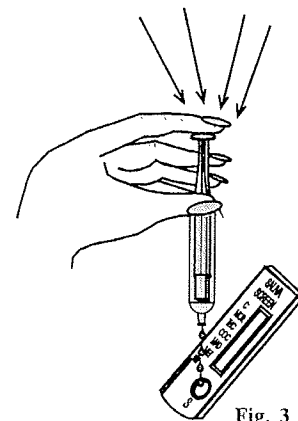
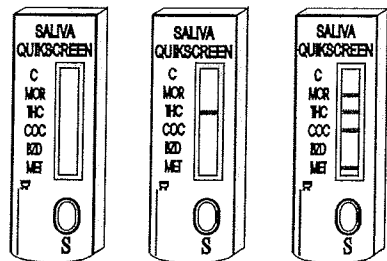
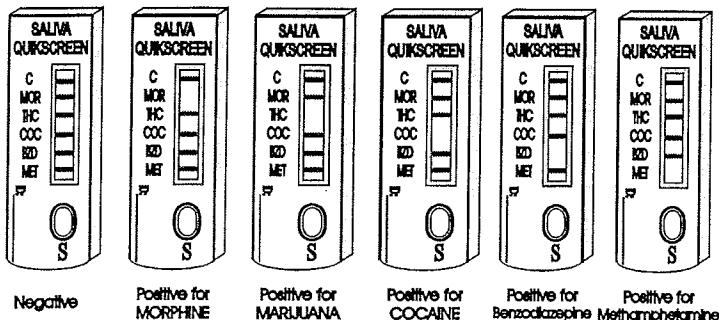


Fig. 3

For Export Only - Not For Sale or Distribution in The U.S.

INTERPRETATION OF RESULTS



Invalid- No control line.

Positive: A rose-pink band is visible in each control zone. No color band appearing in the appropriate test zone indicates a positive result for the corresponding drug of that specific test zone.

Negative: A rose-pink band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

Note: There is no meaning attributed to line color intensity or width.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

PERFORMANCE CHARACTERISTICS

- Sensitivity.** The Saliva QuikScreen 5 test detects drugs of abuse and their major metabolites in saliva at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by SAMHSA and the U.S. Department of Health and Human Service for the Immunoassay method.
- Specificity.** A Study was conducted with the Saliva QuikScreen 5 test to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cut-off levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the saliva of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test.

The following Opiates-related substances yield positive result for Opiates at 30 ng/ml cut-off:

Morphine	30 ng/ml
Morphine-3-b-D-Glucuronide	30ng/ml
Codeine	30ng/ml
Heroin	30ng/ml
Hydromorphone	5000ng/ml
Norcodeine	5000ng/ml
Oxycodone	5000ng/ml
Ephedrine	2mg/ml
Pseudoephedrine	5mg/ml

The following Marijuana-related substances yield positive results for Marijuana at 20 ng/ml cut-off:

11-Nor- Δ^8 -THC-9-COOH	20 ng/ml
11-Nor- Δ^9 -THC-9-COOH	20 ng/ml
Δ^8 -THC	20 μ g/ml
Δ^9 -THC	100 μ g/ml

The following Cocaine-related substances yield positive result for Cocaine at 30 ng/ml cut-off:

Benzoylcegonine	30 ng/ml
Cocaine	30 ng/ml
Pseudoephedrine	5 mg/ml
Ephedrine	5 mg/ml
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	0.5 mg/ml

The following Benzodiazepine-related substances yield positive results for Benzodiazepine at 50 cut-off:

Oxazepam	50 ng/ml
Flurazepam	50 ng/ml
Nitrazepam	50 ng/ml
Clonazepam	50 ng/ml
Temazepam	10 ng/ml
Diazepam	5 ng/ml
Triazolam	100 ng/ml
Timezapam	200 ng/ml
Lorazepam	200 ng/ml
Prazepam	100 μ g/ml

The following Methamphetamine-related substances yield positive results for Methamphetamine at 50 ng/ml cut-off:

+ Methamphetamine	50 ng/ml
3,4-Methylenedioxyamphetamine	50 ng/ml
d-Amphetamine	10000 ng/ml
d,l-Amphetamine	10000 ng/ml
Pseudoephedrine	250 ng/ml
Ephedrine	100 μ g/ml
(\pm) 3,4-Methylenedioxyamphetamine	10000 ng/ml

Table II: Compounds tested and found not to cross-react with the test at a 100 ng/ml concentration:

The following compounds do not cross-react with Opiates:

Acetaminophen	Diphenhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene-
Amikacin	Egonine HCl	Hydrochlorothiazide
Amitriptyline	Egonine Methyl Ester	Propranol
Ampicillin	Glucose	Phencyclidine
Arterenol	Histamine	Phenobarbital
Aspartame	Indomethacin	Phentermine
Atropine Sulfate	Ketoprofen	Phenylpropanolamine
Benzoic Acid	Levorphanol	L-Phenylephrine
Benzoylcegonine HCl	Δ -9 THC	Quinine
Caffeine	11-nor- Δ -9-carboxy-THC-9-COOH	Sodium Salicylate
Chlorpheniramine	Methylphenidate	Tryptophan
Chlorpromazine HCl	Methadone	Tetracycline
Cimetidine	Methaqualone	Tetrahydrozoline
Deoxyephedrine	Oxazepam	Theophylline
Dextromethorphan	Pendimetrazine	Thioridazine
Diazepam	Penicillin G	Trifluoperazine
Diethylpropion		

The following compounds do not cross-react with Marijuana:

Acetaminophen	Egonine HCl	Pentobarbital
Acetylsalicylic Acid	Egonine Methyl Ester	L-Phenylephrine
Amikacin	Glucose	Quinine
Ampicillin	Histamine	Ranitidine
Arterenol	Hydrocodone	Sodium Salicylate
Aspartame	Hydromorphone	Tryptophan
Atropine Sulfate	Indomethacin	Tetracycline
Benzoic Acid	Ketoprofen	Tetrahydrozoline
Benzoylcegonine HCl	Levorphanol Δ -9-THC	Theophylline
Caffeine	11-nor- Δ -9-carboxy-THC-9-COOH	Thioridazine
Chlorpheniramine	Meperidine	Trifluoperazine-d
Chlorpromazine HCl	Methylphenidate	Propoxyphene
Cimetidine	Methadone	Hydrochlorothiazide
Codeine	Methaqualone	Propranol
Deoxyephedrine	Morphine, Glucuronide	Phencyclidine
Dextromethorphan	Morphine Sulfate	Phenobarbital
Diazepam	Oxazepam	Phentermine
Diethylpropion	Oxycodone	
Diphenhydantoin	Pendimetrazine	
Doxylamine	Penicillin G	

The following compounds do not cross-react with Cocaine:

Acetaminophen	Ketoprofen	Oxycodone
Acetylsalicylic Acid	Levorphanol	Pendimethazine
Amikacin	Δ -9-THC	Penicillin G
Amitriptyline	Diethylpropion	Pentobarbital
Ampicillin	Diphenhydantoin	<i>d</i> -Propoxyphene Hydrochlorothiazide
Arteranol	Doxylamine	Propranol
Aspartame	Egonine HCl	Phencyclidine
Atropine Sulfate	Egonine Methyl Ester	Phenobarbital
Benzoic Acid	Glucose	Phentermine
Benzoylcegonine HCl	Histamine	Phenylpropanolamine
Caffeine	Hydrocodone	<i>L</i> -Phenylephrine
Chlorpheniramine	<i>11-nor-Δ-9-carboxy-THC-9-COOH</i>	Quinine
Chlorpromazine HCl	COOH	RanitidineSodium Salicylate
Cimetidine	Meperidine	Tryptophan
Codeine	Methylphenidate	Tetrahydrozoline
Deoxyephedrine	Methadone	Theophylline
Dextromethorphan	Methaqualone	Thioridazine
Diazepam	Morphine, Glucuronide	Trifluoperazine
Hydromorphone	Morphine Sulfate	
Indomethacin	Oxazepam	

The following compounds do not cross-react with Benzodiazepine:

Acetaminophen	Egonine HCl	Penicillin G
Acetylsalicylic Acid	Egonine Methyl Ester	Pentobarbital
Amikacin	Glucose	<i>d</i> -Propoxyphene Hydrochlorothiazide
Amitriptyline	Histamine	Propional
Ampicillin	Hydrocodone	Phencyclidine
Ampicillin	Hydromorphone	Phenobarbital
Arteranol	Indomethacin	Phentermine
Aspartame	Ketoprofen	Phenylpropanolamine
Atropine Sulfate	Levorphanol	<i>L</i> -Phenylephrine
Benzoic Acid	Δ -9-THC	Quinine
Benzoylcegonine HCl	<i>11-nor-Δ-9-carboxy-THC-9-COOH</i>	Ranitidine
Caffeine	Meperidine	Sodium Salicylate
Chlorpheniramine	Methylphenidate	Tryptophan
Chlorpromazine HCl	Methaqualone	Tetracycline
Cimetidine	Morp. Glucuronide	Tetrahydrozoline
Codeine	Morphine Sulfate	Theophylline
Deoxyephedrine	Oxazepam	Thioridazine
Diazepam	Oxycodone	Trifluoperazine
Diethylpropion	Pendimethazine	
Diphenhydantoin		

The following compounds do not cross-react with Methamphetamine:

Acetaminophen	Egonine HCl	Pentobarbital
Acetylsalicylic Acid	Egonine Methyl Ester	<i>L</i> -Phenylephrine
Amikacin	Glucose	Quinine
Ampicillin	Histamine	Ranitidine
Arteranol	Hydrocodone	Sodium Salicylate
Aspartame	Hydromorphone	Tryptophan
Atropine Sulfate	Indomethacin	Tetracycline
Benzoic Acid	Ketoprofen	Tetrahydrozoline
Benzoylcegonine HCl	Levorphanol Δ -9-THC	Theophylline
Caffeine	<i>11-nor-Δ-9-carboxy-THC-9-COOH</i>	Thioridazine
Chlorpheniramine	Meperidine	Trifluoperazine <i>d</i> -Propoxyphene
Chlorpromazine HCl	Methylphenidate	Hydrochlorothiazide
Cimetidine	Methadone	Propranol
Codeine	Methaqualone	Phencyclidine
Deoxyephedrine	Morphine, Glucuronide	Phenobarbital
Dextromethorphan	Morphine Sulfate	Phentermine
Diazepam	Oxazepam	
Diethylpropion	Oxycodone	
Diphenhydantoin	Pendimethazine	
Doxylamine	Penicillin G	


3. Accuracy: In order to show that the Saliva QuikScreen 5 drug test is able to detect the presence of OPI, THC, COC, BZD and MET in saliva at or above the determined cut-off levels, the following tests were performed. Forty samples of drugs free saliva and urine for each were obtained from patients. The negative saliva samples were verified by urine from same patient using commercial urine drugs tests. The same saliva sample from each patient is aliquoted into three groups: Group A(Negative Control), Group B(spiked with 50% below the determined cut-off values of each drug by GC/MS) and Group C (Spiked with 50% above the determined cut-off values of each drug by GC/MS). The results are shown below:


Substance	Spike at GC/MS value of	Saliva QuikScreen Test Results	
		NEGATIVE	POSITIVE
OPI	15 ng/ml	40	0
	45 ng/ml	0	40
THC	10 ng/ml	40	0
	30 ng/ml	0	40
COC	15 ng/ml	40	0
	45 ng/ml	0	40
BZD	25 ng/ml	40	0
	75 ng/ml	0	40
MET	25 ng/ml	40	0
	75 ng/ml	0	40


When compared to GC/MS the relative sensitivity was 100%. The relative specificity was 100%.

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 = In-Vitro Diagnostic Device

 = Authorized Rep in the EU Community

 = Manufacturer

