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SCANGUARD™ DRUG ASSAY BARBITURATE (BAR) - TEST STRIP

NAME AND INTENDED USE

HCD's **ScanGuard™ Drug Assay Test Strip**- Barbiturate is a rapid, qualitative, competitive binding immunoassay for the determination of d-Barbiturates in urine/saliva at the cutoff of 200 ng/mL in a convenient one step strip test format. This test is not intended to monitor drug levels, but only to screen urine/saliva s for the presence of Barbiturates. Both the testing and results are intended to be used by medical and forensic professionals only. The test should not be used without appropriate supervision. The **ScanGuard™ Drug Assay Test Strip** - Barbiturate Assay is not intended for Over the Counter (OTC) sale to lay persons.

ScanGuard™ Drug Assay Test strip - Barbiturate is a rapid, qualitative, competitive binding immunoassay for the determination of Barbiturates in urine/saliva at the cutoff of 200 ng/mL. **The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrophotometry(GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated⁶. HCD's ScanGuard™ Drug Assay test strip - Barbiturate is not intended to monitor drug levels, but only to screen urine/saliva s for the presence of Barbiturate and its metabolites.**

EXPLANATION OF THE TEST

The ScanGuard™ Drug Assay Test strip - Barbiturate test kit is an easy, fast, and visually read competitive binding immunoassay test strip method for screening for Barbiturates in urine/saliva without the need for instrumentation to arrive at a determination. The method employs unique monoclonal antibodies to selectively identify Barbiturate in test samples at the cutoff level of 200 ng/mL. Barbiturates are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being². Large doses of Barbiturate could develop tolerances and physiological dependency and lead to its abuse. Barbiturates are controlled substances, and the mandated allowable level for a Barbiturate is set at 200 ng/mL in urine/saliva by the confirmatory GC/MS method with ≥ 200 ng/mL of

barbiturates specified by the National Institute on Drug Abuse³.

PRINCIPLE OF THE PROCEDURE

The ScanGuard™ Drug Assay Test strip - Barbiturate consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming and antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 200 ng/mL which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area. A **POSITIVE** specimen produces only one color band in the control area. There is no meaning attributed to color or its intensity of either line.

REAGENTS

HCD's ScanGuard™ Drug Assay Test strip - Barbiturate consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. The method employs unique monoclonal (mouse) antibodies to selectively identify Barbiturates in test samples at the cutoff level of 200 ng/mL. The membrane of the test device is coated with goat anti-mouse antibody and Barbiturates-BSA conjugate. The sample pad contains a colloidal gold labeled mouse monoclonal anti-Barbiturate antibody.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area. A **POSITIVE** specimen produces only one color band in the control area. There is no meaning attributed to color or its intensity of either line.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Clock or Timer.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch.
4. Use a new specimen container and dropper for each test to avoid cross contamination of urine/saliva samples.
5. Urine/saliva specimens may be infectious. Upon completion of ALL TESTING dispose of residual urine/saliva in a medically approved manner. Properly handle and dispose of all used reaction devices in an approved biohazard container.
6. Visually inspect the foil package to insure it is intact. If the package is not intact discard the device.

STORAGE AND STABILITY

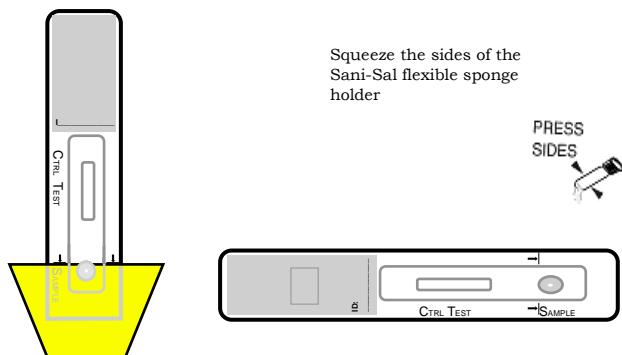
The reagents supplied can be stored under refrigeration (2°-8°C)(36°-46°F) (**DO NOT FREEZE**) or at room temperature (18°-30°C)(65°-85°F) and will be stable until the expiration date.

SAMPLE COLLECTION AND PREPARATION

Using **Saliva** as a sample: The test is specifically designed to utilize a saliva sample collected with a Sani-Sal™ saliva collector. Saliva collected by any other means may not yield accurate results. Urine/saliva - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine/saliva specimens may be refrigerated (2°-8°C) and stored up to 48 hours, or frozen (-20°C or colder) prior to assay. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine/saliva samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Remove One Step device from its protective foil wrapper by tearing at the notch.
2. Add 3-4 drops of urine or saliva to the sample well of the slide. Alternatively, dip the strip into the sample to be tested, up to the sample well, for 30 seconds. The urine/saliva level should not be higher than the maximum fill line indicated on the slide.
3. Read the results after three (3) to five (5) minutes. Test results should not be interpreted after 10 minutes.

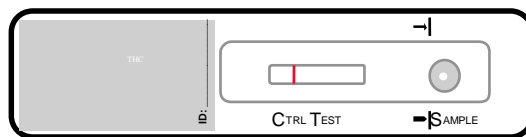


NOTES:

1. Refrigerated slides should be allowed to come to room temperature before opening the pouch.
2. There is no meaning attributed to line color, intensity, or width.

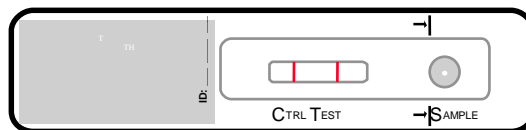
READING THE TEST RESULTS

1. **POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Barbiturate level is above the detection cutoff level of 200 ng/mL.



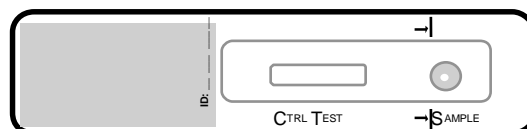
POSITIVE RESULT

2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Barbiturate level is below the detection cutoff level 200 ng/mL.



NEGATIVE RESULT

3. **INVALID:** If there is no distinct color bands in both the upper and lower portions of the read area, (lower portion of the slide), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be re-tested.



INVALID RESULT

QUALITY CONTROL

Each reaction strip has its own built-in quality control indicator. If, after performing the test, no line is visible on the slide, the device may have been placed into the tube incorrectly or the test strip may have deteriorated. The assay will have to be repeated using a new ScanGuard™ Drug Assay Test strip - Barbiturate.

Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Uro-Qual Abutrol, Utak and Alltech are available for validation of the device functionality. NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte at levels at least 20% above and below the cut off value of 200 ng/mL (160-240 ng/mL).

AFTER TESTING

Urine/saliva specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine/saliva should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

Sensitivity:

HCD's ScanGuard™ Drug Assay Test strip – Barbiturate has been designed for the detection of Barbiturates in urine/saliva at the detection cutoff level of 200 ng/mL which is suggested for the immunoassay test strip method.

Precision:

Within Lot Reproducibility of HCD's ScanGuard™ Drug Assay Test strip – Barbiturate

Three lots of human urine/saliva demonstrated to be negative for Barbiturate by GC/MS were spiked with Barbiturate to levels of 0, 100, 160, 200, 240 and 600 ng/mL. A single lot of HCD's ScanGuard™ Drug Assay test strip - Barbiturate devices was used to test the reproducibility of HCD's ScanGuard™ Drug Assay Test strip - Barbiturate. Fifteen (15) devices per concentration were tested and the results are presented in Table I below.

Table I – Within Lot Reproducibility

Level ng/ml	N	Expected	Found
0	15	Negative	Negative
100	15	Negative	Negative
160	15	Negative	Negative
200	15	Positive	Positive
240	15	Positive	Positive
600	15	Positive	Positive

The data presented in Table I clearly demonstrates excellent within lot repeatability of HCD's ScanGuard™ Drug Assay Test strip - Barbiturate within a lot of devices and across multiple samples of human urine/saliva.

Inter Lot Reproducibility

To test the inter lot reproducibility, normal human urine/saliva known to be negative for Barbiturate and its metabolites were spiked with Barbiturate to the following levels: 0, 100, 160, 200, 240 and 600 ng/mL. The negative samples were aliquoted into 12 vials and assigned a letter code. The positive samples were aliquoted into 12 vials and assigned non-overlapping letter codes. These were used to test three different lots of devices over a period of 45 days. The results of these tests are presented below in Table II.

Table II

Barbiturate Concentration	Lot 07078694				Lot 0806794				Lot 0904794			
	N	+	-	Correct %	N	+	-	Correct %	N	+	-	Correct %
0 ng/ml	25	0	25	100	25	0	25	100	25	0	25	100
100 ng/ml	25	0	25	100	25	0	25	100	25	0	25	100
160 ng/ml	25	3	22	88	25	2	23	92	25	3	22	88
200 ng/ml	25	25	0	100	25	25	0	100	25	25	0	100
240 ng/ml	25	25	0	100	25	25	0	100	25	25	0	100
600 ng/ml	25	25	0	100	25	25	0	100	25	25	0	100

The results reported in Table II demonstrate that there is no appreciable inter lot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

Kit Comparisons:

The accuracy of ScanGuard™ Drug Assay Test strip - Barbiturate test was first tested in 215 individual urine/saliva samples by Health-Chem and subsequently in a clinical trial of 302 individual urine/saliva s submitted to a NIDA certified laboratory. In both cases the laboratories used Emit® II Barbiturate run at 200 ng/mL as their screening procedure. The data was combined and is presented in Table III below.

Table III – Comparison HCD's One Step (200 ng/mL) Drugs of Abuse Test strip - Barbiturate™ to Emit® II (200 ng/mL) Results

HCD Slide	Emit II (+)	Emit II (-)	Row Total
(+)	184	0	184
(-)	0	327	327
Col. Totals	184	327	511

The concordance of the combined data was 100%. All positive samples by either screening method were confirmed by GC/MS.

The results indicate an agreement within positive samples of 184/184 or 100% with a similar value reported for agreement within negative samples. The concordance for the combined data was 511/511 or 100%.

Related compounds giving cross-reactivities at very high levels are as follows:

Table IV – Compounds that will produce a positive result

Compound	Conc. (ng/mL)
Secobarbital	200
Amobarbital	200
Barbital	200
Butobarbital	200
Phenobarbital	200
Pentobarbital	200
Bromocriptine	200
Zoloft	200

There is no interference by the following substances at a 10 ng/mL concentration in urine/saliva:

Table V – Compounds which produce no reaction

Acetaminophen	Δ-9-THC
Acetylsalicylic Acid	11-nor-Δ-9-carboxy-THC-9-CooH
Amikacin	Meperidine
Amitriptyline	Methylphenidate
Ampicillin	Methadone
Arterenol	Methaqualone
Aspartame	Morp. Glucuronide
Atropine Sulfate	Morphine Sulfate
Benzoic Acid	Oxazepam
Benzoylcegonine HC1	Oxycodone
Caffeine	Pendimethazine
Chlorpheniramine	Penicillin G
Chlorpropmazine HC1	Pentobarbital
Cimetidine	d-Propoxyphene Hydrochlorothiazide
Codeine	Propanol
Deoxyephedrine	Phencyclidine
Dextromethrophan	Phenobarbital
Diazepam	Phentermine
Diethylpropion	Phenylpropanolamine
Diphenylhydantoin	L-Phenylephrine
Doxylamine	Quinine
Ecgonine HC1	Ranitidine
Ecgonine Methyl Ester	Sodium Salicylate
Glucose	Tryptophan
Histamine	Tetracycline
Hydrocodone	Tetrahydrozoline
Hydromorphone	Theophylline
Indomethacin	Thioridazine
Ketoprofen	Trifluoperazine
Levorphanol	

M., and Johansen, K., Clin. Chem., 39(1): 104-108 (1993).

- Department of Health and Human Services, Fed. Regist., 53(69): 11970-89 (1988).
- FDA Guidance for Labeling Urine/Saliva Drugs of Abuse Screening Testing, Kshitij Mohan, 7/21/1987.

Manufactured in the USA by:

HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
 Website: www.healthchemdiagnostics.com

LIMITATIONS OF THE TEST

- This product is designed to be used for the detection of Barbiturate in human urine/saliva only.
- Although the ScanGuard™ Drug Assay Test strip - Barbiturate is very accurate (100%) in detecting Barbiturates in the urine/saliva in the clinical trial when compared to Emit II, there is a possibility of false results due to the presence of interfering substances in urine/saliva and/or factors beyond the control of the manufacturer, e.g. technical or procedure errors associated with the testing.
- The test is a qualitative screening assay and is not suggested for determining the quantitative Barbiturate level in urine/saliva.
- Adulterants, such as bleach or other strong oxidizing agents, when added to urine/saliva specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine/saliva specimen.

BIBLIOGRAPHY

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- Dasgupta, A., Saldana, S., Kinnaman, G., Smith,