

# Healgen®

## Multi-Drug Urine Test Dip card

### Package Insert

#### INTENDED USE

The Healgen Multi-Drug Urine Test Dip Card is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, EDDP, Nortriptyline and Methadone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1,000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1,000 ng/mL
Morphine	2,000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300ng/mL
2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300ng/mL
Nortriptyline	1,000ng/mL

Configuration of the Healgen Multi-Drug Urine Test DipCard can consist of any combination of the above listed drug analytes up to a maximum of 14 analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital, Nortriptyline and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized drug levels for Buprenorphine, Oxazepam, Secobarbital, Nortriptyline or Oxycodone in urine. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

#### SUMMARY

**Healgen® Multi-Drug Urine Test Dip Card** is used to test for the presence of certain drugs in a person's urine. If the result is preliminary positive, the result is then confirmed with additional laboratory testing.

#### PRECAUTIONS

- The test is intended only for use outside the body to test for drugs in a person's urine.
- It should not be used after the stated expiration date.
- The package should remain unopened until ready for use.

#### STORAGE AND STABILITY

Keep **Healgen® Multi-Drug Urine Test Dip Card** in the package until ready for use. The package may be stored at room temperature or refrigerated (39-86°F). **DO NOT FREEZE.**

The product will remain stable through the expiration date printed on the sealed pouch. Do not use beyond that date.

#### SAMPLE COLLECTION AND PREPARATION

The urine sample must be collected in the urine cup provided. Urine may be collected at any time of the day.

#### MATERIALS PROVIDED

- Test Dip Card
- Urine Cup
- Package insert
- Labeled vials for shipping "preliminary positive" sample to the laboratory
- Plastic transportation bags
- Prepaid mailing boxes

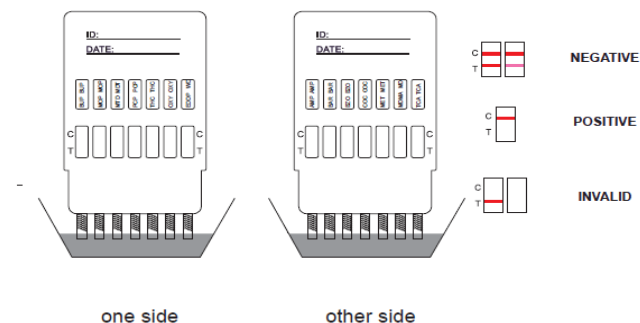
#### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or watch

#### DIRECTIONS FOR USE

- Remove the Dip Card from the foil wrapper.
- Fill the urine cup with fresh urine. Dip the Dip Card into the urine with the arrow end pointing toward the urine and start the timer or note the time on a watch. Do not cover the urine over the MAX (maximum) line. Take the Dip Card out after a minimum of 15 seconds in the urine and lay the Dip Card flatly on a non-absorptive clean surface.
- Read results at 5 minutes.

#### DO NOT INTERPRET RESULT AFTER 5 MINUTES.



#### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** \* Two lines will appear. One red line is in the control region marked (C), and another is in the test region marked (T). \*NOTE: Even a faint pink line is a negative result.

**PRELIMINARY POSITIVE:** One red line appears in the control region (C). No line appears in the test region (T).

**INVALID :** Control line fails to appear. If this happens, review the directions for use and repeat the test using a new test device. If the problem persists, contact Healgen at (866) 982-3818

The tester should be careful in reading the test results. A preliminary positive result does not always mean that someone took illegal drugs. Likewise, a negative result does not always mean that illegal drugs were not taken. This is why further laboratory confirmation for preliminary positive test results is required.

#### What Is A False Positive Test?

A false positive test result is when the drug is not present, but the test produces a preliminary positive result. This can be caused by certain foods and medicines, diet plan drugs and nutritional supplements in the urine.

#### What Is A False Negative Test?

A false negative test means that the drug is present, but it is not detected by the test. Adding water or some other liquid to the urine before testing can cause this to happen.

#### LIMITATIONS

- Intentionally adding bleach or other liquids to the urine sample may produce incorrect results.
- The test cannot distinguish between drugs that are abused and some medications.

#### MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

- Pour urine from the cup into the labeled vial. Ensure that the labeled vial is about two thirds (2/3) full. Close the cap.
- Check off the drugs that came up positive on the label.
- Write your cell phone number on the mailing box.
- Place the labeled vial in the plastic bag and seal the plastic bag.
- Place the sealed plastic bag in the pre-addressed mailing box. Close the mailing box and secure it with packing tape.
- Take the mailing box to any US Postal Service Office.

#### ASSISTANCE

If you have any question regarding the use of this product, please call our Technical Support Number

1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

#### QUESTIONS AND ANSWERS

- What is the **Healgen® Multi-Drug Urine Test Dip Card**?  
This test is designed to detect one or more prescription or illegal drugs in a person's urine.
- What do I do if the test result is preliminary positive?  
The sample must be sent to the lab for an additional test.
- What should I do if the lab test confirms that the urine sample contains one or more prescription or illegal drugs?  
It is important to remain calm and consult with your healthcare provider or with our staff for additional information and guidance.

#### QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be performed with each new lot, each new shipment and every thirty days to check storage. Please contact our Technical Support at 1-866-982-3818 for controls that work with the device.

Follow local, state and federal laws and regulations

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

The accuracy of the test was evaluated by testing 80 clinical urine specimens for each drug in parallel with GC-MS. The results are shown below.

##### Methamphetamine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

% agreement among positives is 94.4%

% agreement among negatives is 100%

##### Cocaine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Operator B	Positive	0	0	0	14	24
	Negative	10	17	13	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

% agreement among positives is 87.5%

% agreement among negatives is 100%







	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
Phencyclidine	-100% Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
MDMA	-100% Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
EDDP (Methadone Metabolites)	-100% Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
Nortriptyline	-100% Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%

Manufacturer

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#### BIBLIOGRAPHY

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3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986*
4. Tietz NW. *Textbook of Clinical Chemistry.* W.B. Saunders Company. 1986; 1735
5. *FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be used by the Consumer, 1997*

#### ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information 1-800-729-6686

Substance Abuse and Mental Health Center/HHS SAMHSA [www.samhsa.gov](http://www.samhsa.gov)

Center for Substance Abuse Treatment [www.health.org](http://www.health.org) 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence [www.ncadd.org](http://www.ncadd.org) 1-800-NCA-CALL

American Council for Drug Education (ACDE) [www.acde.org](http://www.acde.org) 1-800-488-DRUG

#### INDEX OF SYMBOLS



Keep away from sunlight



Store between 2°C and 30°C



Keep dry



Do not re-use



Healgen Scientific LLC