ACE Rapid Test Dipstick (Urine)
Package Insert

REF DAC-101	English

A rapid test for the qualitative detection of Acetaminophen in human urine.
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The ACE Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of Acetaminophen in human urine at a cut-off concentration of 5,000ng/mL.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SUMMARY】

Acetaminophen is one of the most commonly used drugs, yet it is also an important cause of serious liver injury. Acetaminophen is the generic name of a drug found in many common brand name over-the-counter (OTC) products, such as Tylenol, and Prescription (Rx) products, such as Vicodin and Percocet. Acetaminophen is an important drug, and its effectiveness in relieving pain and fever is widely known. Unlike other commonly used drugs to reduce pain and fever (e.g., nonsteroidal antinflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding, and acetaminophen is considered safe when used according to the directions on its OTC or Rx labeling. However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e., 4 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g., an OTC product and an Rx drug containing acetaminophen). The mechanism of liver injury is not related to acetaminophen itself, but to the production of a toxic metabolite. The toxic metabolite binds with liver proteins, which cause cellular injury. The ability of the liver to remove this metabolite before it binds to liver protein influences the extent of liver injury.

The ACE Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Acetaminophen in urine. The ACE Rapid Test Dipstick (Urine) yields a positive result when Acetaminophen in urine exceeds 5,000ng/mL.

【PRINCIPLE】

The ACE Rapid Test Dipstick (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Acetaminophen, if present in the urine specimen below 5,000ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Acetaminophen conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Acetaminophen level exceeds 5,000ng/mL because it will saturate all the binding sites of anti-Acetaminophen antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse monoclonal anti-Acetaminophen antibody-coupled particles and Acetaminophen-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear specimen for testing.

Specimen Collection

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Package insert

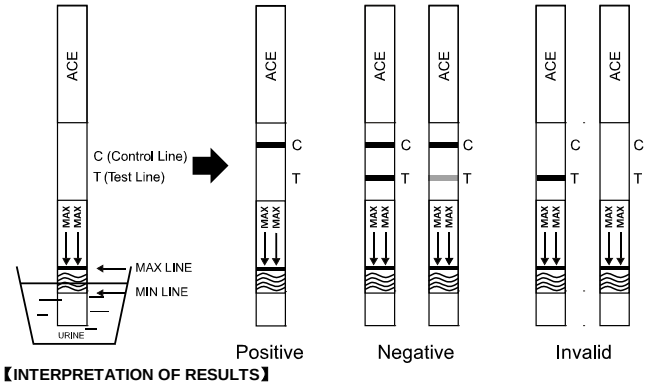
Materials Required But Not Provided

- Specimen collection container
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.
2. With arrows pointing toward the urine specimen, **immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds**. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.
3. Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Acetaminophen concentration is below the detectable level (5,000ng/mL).

***NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test line region (T). This positive result indicates that the Acetaminophen concentration exceeds the detectable level (5,000ng/mL).

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen 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.

【LIMITATIONS】

1. The ACE Rapid Test Dipstick (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.[2,3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the Acetaminophen concentration is below the detectable level of 5,000ng/mL. Positive result means the concentration of Acetaminophen is above the level of 5,000ng/mL. The ACE Rapid Test Dipstick has a sensitivity of 5,000ng/mL

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using The ACE Rapid Test Dipstick and GC/MS at the cut-off of 5,000ng/mL. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
ACE Rapid Test Dipstick	Results	Positive	Negative	
	Positive	29	1	30
	Negative	2	68	70
Total Results		31	69	100
% Agreement		93.5%	98.6%	97.0%

Analytical Sensitivity

A drug-free urine pool was spiked with Acetaminophen at the following concentrations: 0 ng/mL, 2,500 ng/mL, 3,750 ng/mL, 5,000ng/mL, 6,250 ng/mL 7,500 ng/mL and 15,000 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Acetaminophen Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
2,500	-50%	30	30	0
3,750	-25%	30	26	4
5,000	Cut-off	30	14	16
6,250	+25%	30	3	27
7,500	+50%	30	0	30
15,000	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by The ACE Rapid Test Dipstick (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
	5,000
Acetaminophen	

Precision

A study was conducted at 3 hospitals by laypersons using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Acetaminophen, 25% Acetaminophen above and below the cutoff and 50% Acetaminophen above and below the 5,000ng/mL cutoff were provided to each site. The following results were tabulated:

Acetaminophen Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2,500	10	10	0	10	0	10	0
3,750	10	9	1	9	1	8	2
6,250	10	1	9	1	9	1	9
7,500	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.034 were spiked with Acetaminophen to the concentrations of 2,500ng/mL, and 7,500 ng/mL. The ACE Rapid Test Dipstick (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Acetaminophen to 2,500 ng/mL and 7,500 ng/mL. The spiked, pH-adjusted urine was tested with The ACE Rapid Test Dipstick (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Acetaminophen positive urine. The following compounds show no cross-reactivity when tested with The ACE Rapid Test Dipstick (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetone	(+/-)-Chlorpheniramine	Hemoglobin	Pheniramine
Albumin	Creatine	Ibuprofen	Phenothiazine
Ampicillin	Dexbrompheniramine	(+/-)-Isoproterenol	L-Phenylephrine
Ascorbic	Dextromethorphan	Ketamine	β-Phenylethylamine
Aspartame	Diphenhydramine	Levorphanol	Procaine
Aspirin	Dopamine	Lidocaine	Quinidine
Atropine	(+/-)-Epinephrine	(+)-Naproxen	Ranitidine
Benzocaine	Erythromycin	Niacinamide	Riboflavin
Bilirubin	Acid Ethanol	Nicotine	Sodium Chloride
Caffeine	Furosemide	(+/-)-Norephedrine	Sulindac
Chloroquine	Glucose	Oxalic Acid	Tyramine
(+)-Chlorpheniramine	Penicillin-G	Guaiacol Glyceryl Ether	
(1R,2S)-(-)-N-Methyl-Ephedrine		4-Dimethylaminoantipyrine	

【BIBLIOGRAPHY】

1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
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