T-Cup® Compact Multi-Drug Urine Test Cup Product Training

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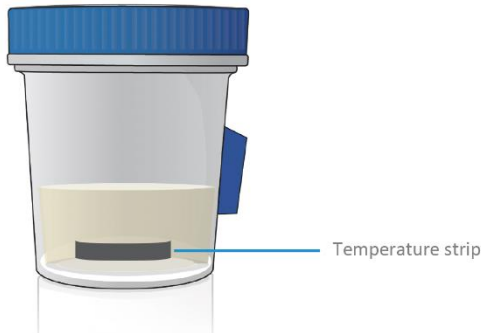
Product Technical Information

- T-Cup® Compact Multi-Drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of multiple drugs and drug metabolites in urine.

- T-Cup® Compact Multi-Drug Urine Test Cup provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

- Please refer to the package insert for complete instructions, limitations and warnings before using the T-Cup® Compact Multi-Drug Urine Test Cup.

Product Features Overview



- One step drug screen cup for up to 25 prescription and illicit drugs with 5-18 panel options
- Available with 6 adulteration tests and temperature strip to detect specimen tempering
- Easy to use, read results at 5 minutes
- Convenient to send preliminary positive specimens to confirmation lab

Available Drug Test and Cutoff

Drug (Abbreviation) Cutoff ng/mL	Drug (Abbreviation) Cutoff ng/mL
• Amphetamine (AMP) 1000*/500*/300**	• Methamphetamine (MET/mAMP) 1000*/500*/300**
• Barbiturates (BAR) 300*	• Methylenedioxymethamphetamine (MDMA) 500*
• Buprenorphine (BUP) 10*	• Morphine (MOP/OPI) 2000*/300*/100**
• Oxazepam (BZO) 300*/200**/100***	• Oxycodone (OXY) 100*
• Cocaine (COC) 300*/150*/100**	• Phencyclidine (PCP) 25*
• Cotinine (COT) 200*** or ****	• Propoxyphene (PPX) 300*
• EDDP 300*	• Nortriptyline (TCA) 1000*
• Ethyl Glucuronide (EtG) 500***	• Cannabinoids (THC/Metabolite) 50*/40**/25***
• Alcohol (ETOH) 0.04 g/dL***	• Tramadol (TRA) 1000***/200***
• Fentanyl (FTY) 20***	• Monoacetylmorphine (6-MAM) 10***
• Synthetic Cannabinoid (K2) 50***	• Kratom (KRA) 300***
• Ketamine (KET) 1000***	• Hydromorhone (HMO) 300***
• Methadone (MTD) 300*/200**	
	Adulteration Tests: Creatinine (CR), Glutaraldehyde (GL), Nitrite (NI), pH (PH), Specific Gravity (SG), and Oxidants (OX)

* CLIA Waived & 510(k) Cleared
** 510(k) Cleared Only
*** Forensic Use Only
**** Class I Exempt; Rx Use Only

Warnings and Precautions, Storage and Stability

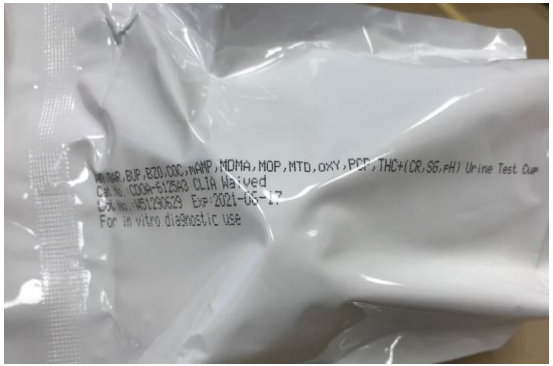
Warnings and Precautions

- The test kit is for external use only.
- Discard after first use. The test kit cannot be used more than once.
- Do not use the test kit beyond expiration date.
- Do not use the test kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.

Storage and Stability

- Store at 4°C-30°C (39°F-86°F) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

Product Information on Foil Pouch



- Drug Test, Catalogue Number, Lot Number and Expiration Date are printed on foil pouch
- Test device must remain in sealed pouch until use.
- Do not use beyond the expiration date.
- Do not use if pouch is punctured or not sealed.

Specimen Collection

When to Collect

- Collect the urine sample for the test in the minimum detection time after the suspected drug use.
- Urine collection time is very important in detecting any drug of abuse.
- Each drug is cleared by the body and is detected in the urine at different times and rates.
- Please refer to the section “WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?” for the minimum/maximum detection time for each drug.

Contents of Kit

- 25 T-Cup® Compact test devices, each in one pouch with two desiccants. The desiccants are for storage purposes only and are not used in the test procedure.
- One (1) Package Insert
- One (1) Adulteration Color Comparison Chart (If equipped).
- 25 Security Seals
- 25 Pieces of Gloves

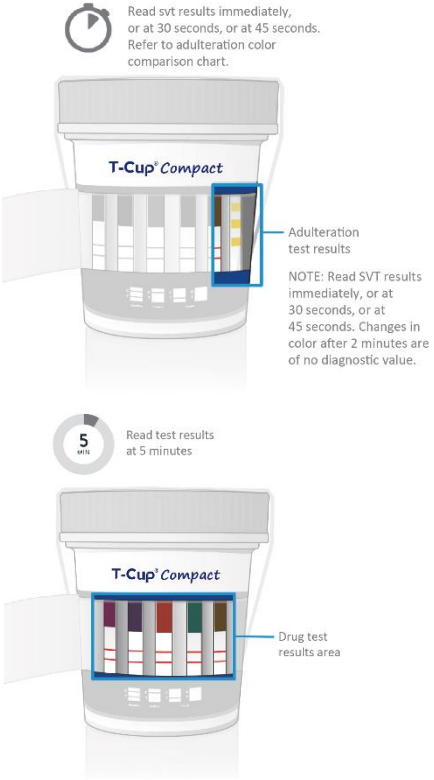
Material Needed but not Provided

- Timer or Clock

How to Collect Urine Specimen

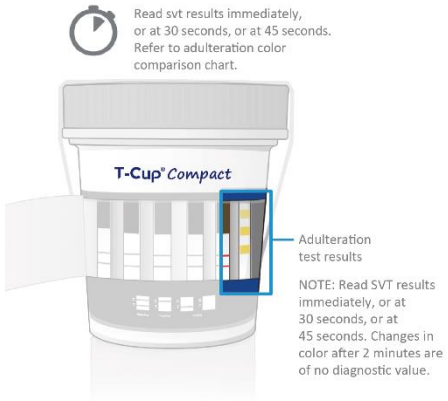
- Remove the test cup from the foil pouch by tearing at the notch. Use it as soon as possible.
- Instruct the donor to remove the test cup lid and void directly into the test cup until reach the Minimum Urine Level mark (approximately 25 mL).
- It is acceptable to collect extra volume of urine. If insufficient specimen has been collected, instruct the donor to provide urine specimen again with another new test cup.
- Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the test cup with urine specimen.
- Observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is voided into the cup. The temperature between 32°C to 38°C (90°F -100°F) indicates the fresh uncontaminated sample.
- If the temperature is out of this range, instruct the donor to provide urine specimen again with another new test cup.

How to Perform the Test



- After the urine has been collected properly, tighten the lid and place the test cup on a flat surface.
- Peel off the label from right to left.
- For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Instruct the donor to provide urine specimen again with another new test cup.
- For the drug tests, read the drug test results at 5 minutes. The results are stable for 30 minutes.

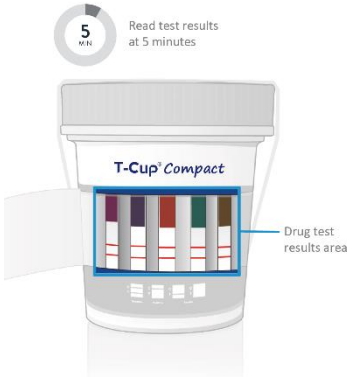
How to Interpretate the Adulteration Test Results

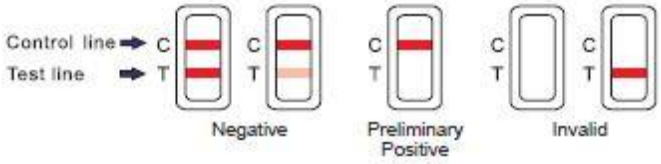


TEST AND READING TIME	ABNORMAL (LOW)	NORMAL	ABNORMAL (HIGH)
Creatinine (CR) 45 seconds	Negative 10	20 50 100 200mg/dl	
Glutaraldehyde (GL) 45 seconds		Negative	Positive
Nitrite (NI) 45 seconds		0 0.1-0.2 0.5-5.0	>15mg/dl
Oxidants/Bleach (OX) 30 seconds		Negative	Positive
pH (PH) Immediate	2 3	4 5 7 9	≥10
Specific Gravity (S.G.) 45 seconds	1.000	1.005 1.015 1.025	≥1.030

- Read adulteration results immediately, or at 30 seconds, or at 45 seconds.
- Compare each reagent area to its corresponding color blocks on the adulteration color comparison chart for the results.
- Changes in color after 2 minutes are of no diagnostic value.
- Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results, obtain a new specimen.

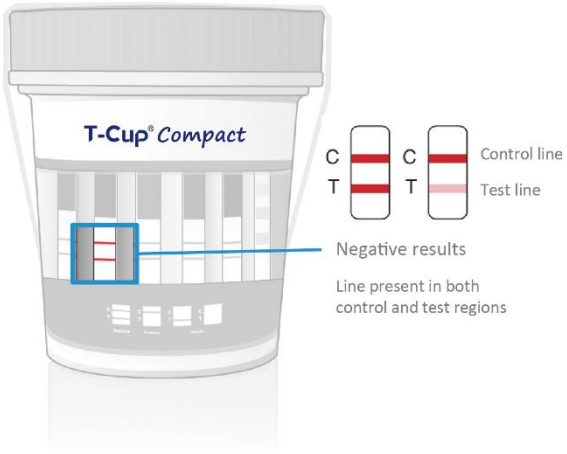
How to Interpretate the Drug Test Results





- Read the drug test results at 5 minutes. The results are stable for 30 minutes.
- Results after more than 30 minutes may be not accurate and should not be read.
- The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

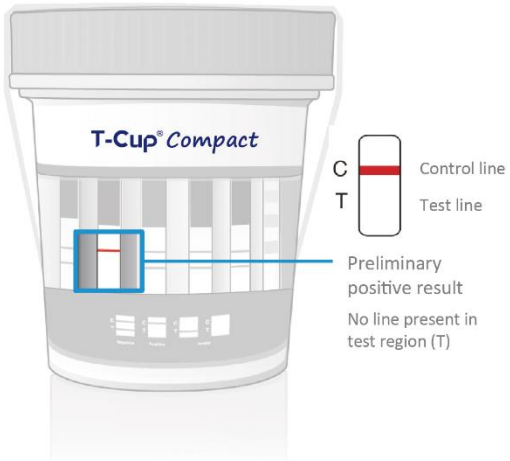
Negative Test Result Example



Negative (-)

- A colored band is visible in each Control Region (C) and the appropriate Test Region (T).
- It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.
- There is no meaning attributed to line color intensity or width. As long as a colored band is observed in the appropriate Test Region (T), no matter how faint, the result is interpreted as the Negative.

Preliminary Positive Test Result Example

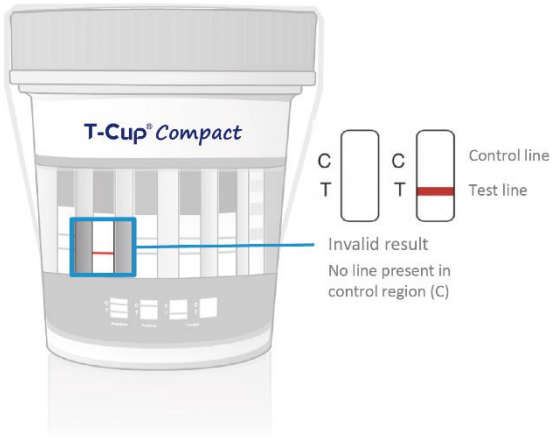


Preliminary Positive (+)

- A colored band is visible in each control region. No colored band appears in the appropriate test region.

- It indicates the preliminary positive result for the corresponding drug of that specific test zone.

Invalid Test Result Example



Invalid

- If a colored band is not visible in each of the control region or a colored band is only visible in each of the test region, the test is invalid.

- Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor.

- When calling, be sure to provide the lot number and the catalog number of the test.

Test Limitations

- The test kit has been developed for testing urine specimen only. No other fluids have been evaluated. DO NOT use it to test anything other than urine.
- Adulterated urine specimen may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
- The test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

Congratulations!

You have completed the product training.