

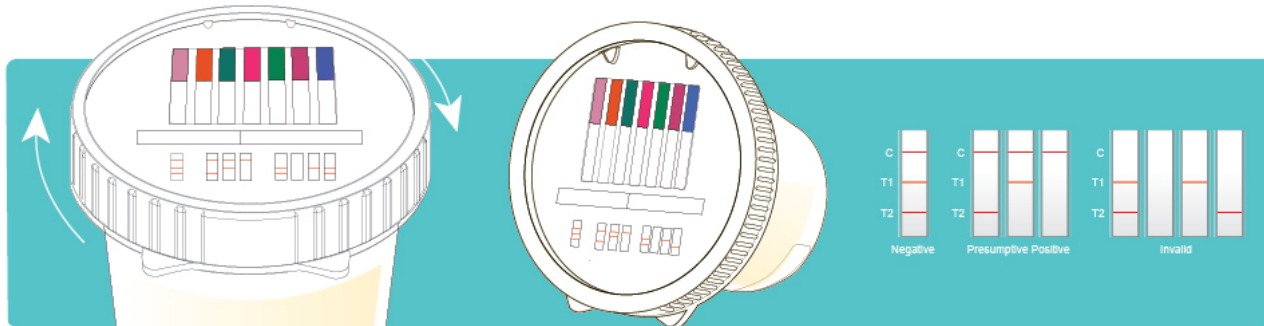
# Alere iCup® Dx 14

Also covers Alere iCup® Dx 14 SVT (with specimen validity test)

## URINE DRUG SCREEN PROCEDURE



For *in vitro* diagnostic use only.



The information in this presentation is a general overview on performing and interpreting the Alere iCup<sup>®</sup> Dx 14 urine drug screening device.

## Product Training Contents

- Technical information
- Product overview
- Specimen collection and testing procedures
- Result interpretation
- Additional support services



# Technical information

For complete instructions, limitations and warnings, please refer to the Package Insert (Instructions for Use) before using this screening device.

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The Alere iCup® Dx 14 Drug Screen Cup is available in double drug analyte dip format. It is intended for prescription point-of-care use.

Urine drug screen assay's provide only a 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-tandem mass spectrometry (LC-MS/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 indicated.



# Product overview



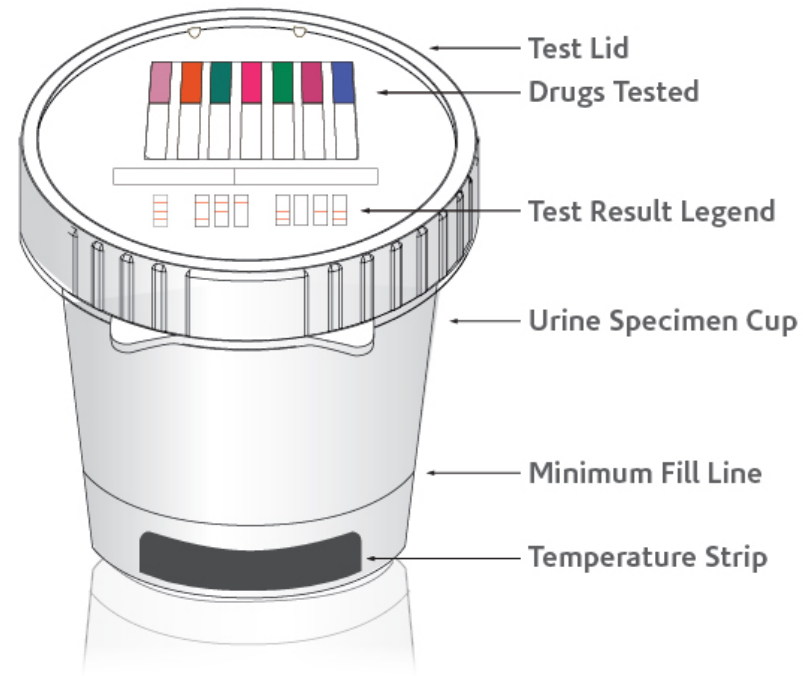


# iCup<sup>®</sup> Dx 14 overview

This training may be used with all versions of the iCup<sup>®</sup> Dx 14 test device, both with and without specimen validity tests.

## Features & Benefits

- CLIA-waived
- Integrated urine test cup targets 14 illicit and prescription drugs
- Simple procedure: collect specimen, tilt cup, and read results in five minutes
- Specimen validity test combinations available: Bleach (BL), Creatinine (CR), Nitrate (NI), pH (pH), and Specific Gravity (SG)
- Self-contained cup is ideal for sending presumptive positive specimens for confirmation
- Patented cup design
- Buprenorphine screening combined with low-level opiate cutoff makes it ideal for clinical settings



Test device components



# Abbreviations and cutoff level concentration

Drug	Identifier	Cutoff
Amphetamine	AMP	500 ng/mL
Barbiturate	BAR	300 ng/mL
Benzodiazepines	BZO	300 ng/mL
Buprenorphine Glucuronide	BUPG	10 ng/mL
Cocaine	COC	150 ng/mL
Ecstasy (3,4-Methylenedioxymethamphetamine)	MDMA	500 ng/mL
Marijuana	THC	50 ng/mL
Methadone	MTD	300 ng/mL
Methamphetamine	MET	500 ng/mL
Morphine	OPI	300 ng/mL
Oxycodone	OXY	100 ng/mL
Phencyclidine	PCP	25 ng/mL
Propoxyphene	PPX	300 ng/mL
Tricyclic Antidepressants	TCA	1,000 ng/mL

**Specimen validity tests available:**

*Bleach (BL), Creatinine (CR), Nitrate (NI), pH (pH), Specific Gravity (SG)*



# Precautions, storage and stability

## Precautions:

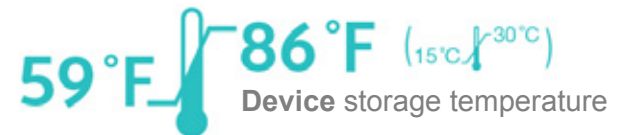
- For *in vitro* diagnostic use.
- The test is for one time use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- The used test device should be discarded according to federal, state and local regulations.
- Do not use this test if you are color-blind.

## Device Storage and Stability:

- Store packaged in the sealed pouch at 59-86°F (15-30°C).
- The tests are stable through the expiration date printed on the pouch.
- Test cap must remain in the sealed pouch until use.

### Foil Pouch

Lists available tests, storage temperature, lot, reference number and expiration date.





# Performing a urine drug screen



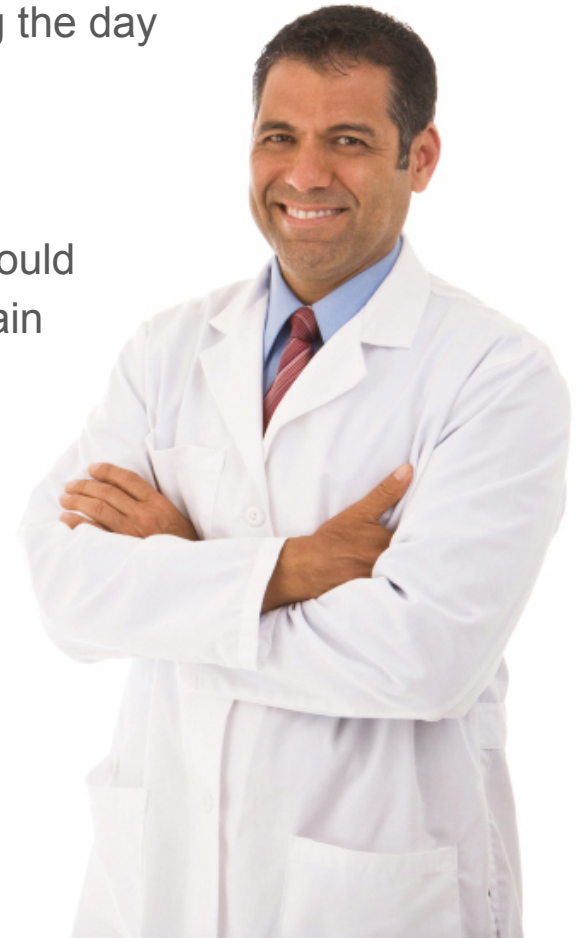




# Performing a urine drug screen

## Specimen storage and preparation

- The urine specimen must be collected in a clean and dry container, and can be collected at any time during the day
- For best results, test specimens immediately following collection
- Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing





# Performing a urine drug screen

## Gather all necessary testing supplies

### Materials provided

- 1 step-by-step test instruction
- 25 individually wrapped test lids
- 25 specimen cups
- Specimen validity color chart (*Alere iCup Dx 14 with SVT only*)

### Recommended but not provided

- Timing device (*timer, clock, watch, etc.*)
- On-Site Custody and Control Form (*supplied separately*)
- External Controls



# Performing a urine drug screen

## Alere iCup<sup>®</sup> Dx 14 foil pouch

The foil pouch contains the following information: list of drugs screened, part number, lot number, and expiration date.

- Bring pouch to room temperature before opening.
- Test device must remain in sealed pouch until use.
- Do not use beyond the expiration date.

Do not use beyond the expiration date.





# Performing a urine drug screen

## Specimen collection procedure\*

### Have donor select test device.

- Donor should hand sealed test to collector to record lot and expiration date.
- Collector records lot and expiration date information, then returns device to donor.

Note: Collector should not handle the test device again until specimen is collected, and the collector is ready to begin reading the results.

\*Recommended when using an Alere Toxicology Laboratory Custody and Control Form, or Alere Preliminary Result Form (supplied separately).



Donor selects test. Collector records lot and expiration.

# Performing a urine drug screen

## Specimen collection procedure (cont.)

### Collector returns inspected device back to donor.

- Instruct donor on proper specimen collection.
- Have donor open foil pouch and remove test lid.
- Have donor remove the test cup lid and provide urine sample.
- Instruct donor to fill cup above the minimum line  
Alere laboratories recommend filling 1/3 full as this ensures sufficient specimen volume is available for initial screen and possible confirmation testing.

Have donor open pouch to remove test lid.



Note: Desiccant pouches are part of the packaging and not a part of the screening device.



Instruct donor on proper specimen collection process.



Collect fresh urine and make sure it's above the minimum fill line.



# Performing a urine drug screen

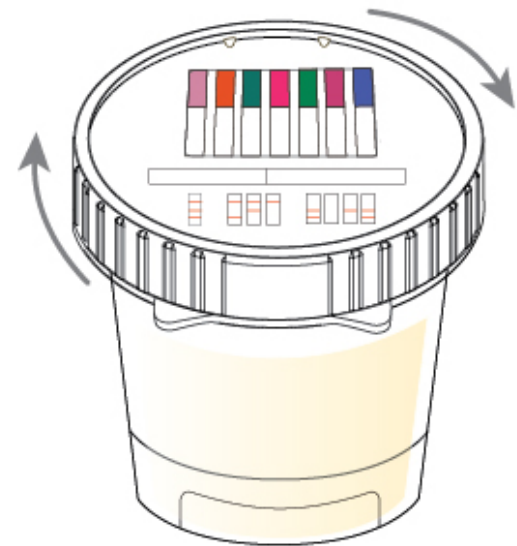
## Specimen collection procedure (cont.)

### Donor returns collected specimen back to collector

- Technician replaces and secures the lid onto the cup.

IMPORTANT: Cup lid must be secured tightly by twisting it a quarter turn after lid is snug.

Check cup cap for a tight seal.



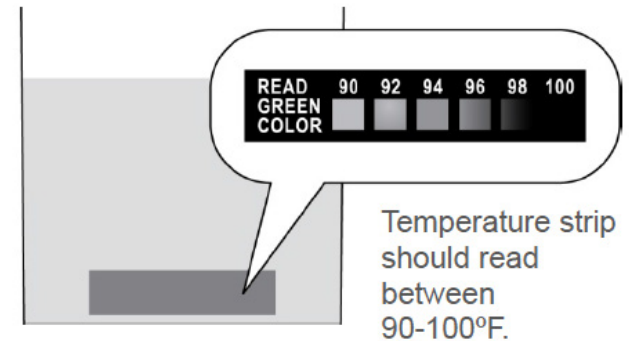


# Performing a urine drug screen

## Specimen collection procedure (cont.)

### Urine temperature verification

- A temperature strip is present on the back of the iCup Dx 14 that serves as an initial specimen validity check.
- The temperature is read at 2-4 minutes of the donor providing the specimen. Read the green color on the temperature strip.
- A freshly voided specimen will be in the range of 90-100°F.



Alere recommends the verification of urine temperature to limit sample adulteration, tampering, and dilution.





# Result interpretation



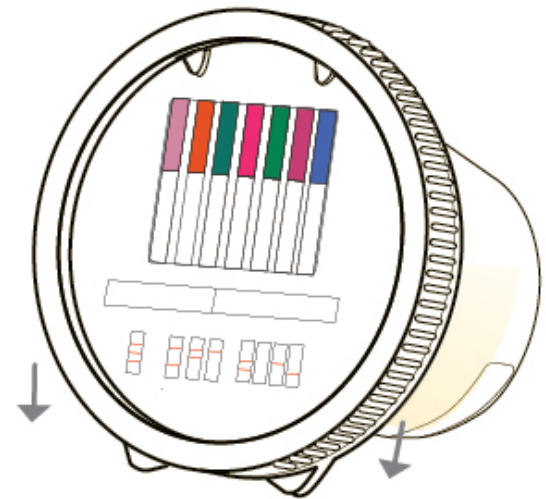


# Interpreting test results

## Activating the test

- Tilt the cup on its legs to activate the test.
- If temperature is in a valid range, read SVT at time indicated on reading times chart (next slide), read drug test results at 5 minutes.
- Do not read after 8 minutes.

Note: For detailed operation instructions, please refer to the package insert or procedure card.



Tilt the cup on its legs to activate the test.



# Interpreting specimen validity test

FOR ALERE ICUP® DX 14 WITH SVT ONLY

## Reading specimen validity test results

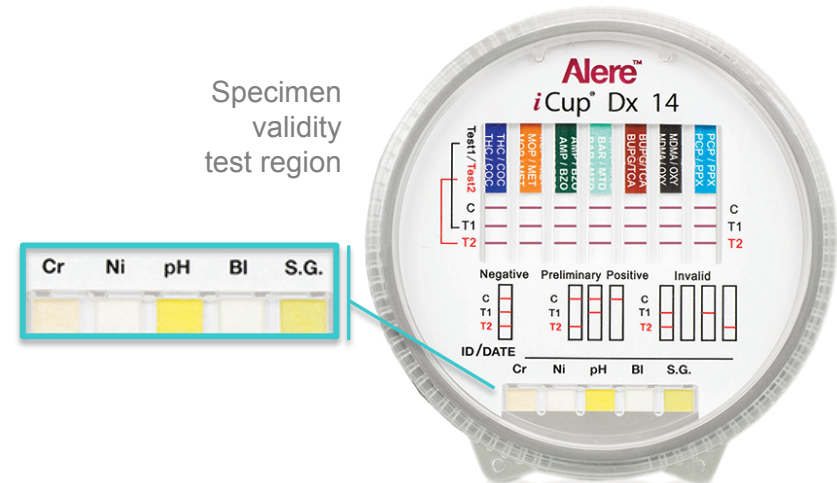
- Compare the colors of the adulteration pads to the color chart (provided).
- Read the results of adulteration test by visually comparing the color of reagent pads to the corresponding blocks on the color chart at the time indicated.

### SVT Reading Times

Read results at the time indicated.

Test	Reading Time
pH (pH)	Immediate
Bleach (BL)	45 seconds
Creatinine (CR)	45 seconds
Nitrite (NI)	45 seconds
Specific Gravity (SG)	60 seconds

## iCup Dx 14 with SVT



Specimen validity test region

### SVT Color Chart

Compare colors on adulteration strip to color chart.

TEST AND READING TIME	ABNORMAL (LOW)	NORMAL	ABNORMAL (HIGH)
<b>Creatinine (Cr)</b> 45 seconds	+10 10	20 50 100 200 mg/dl	
<b>Nitrite (Ni)</b> 45 seconds		0 0.1-0.2 0.5-5.0	> 15 mg/dl
<b>pH</b> Immediate	2 3	4 5 7 9	≥ 10
<b>Bleach (BI)</b> 45 seconds		Negative	Positive
<b>Specific Gravity (S.G.)</b> 60 seconds		1.000 1.005 1.015 1.025	≥ 1.030



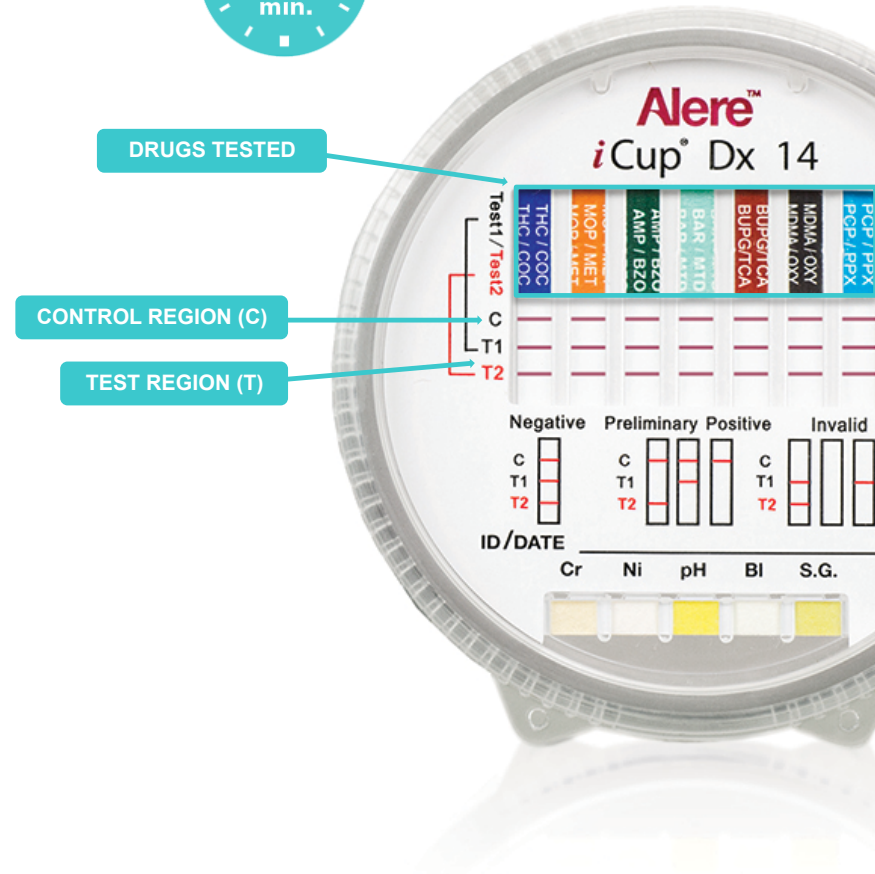
# Interpreting drug test results

## Reading drug test results

- Read the drug test results at 5 minutes.
- Do not interpret results after 8 minutes as false results may occur.
- Each test strip within the device includes an internal procedural control (C) that ensures proper device function.
- Control lines should form all control (C) lines, indicating proper functioning of the test device.



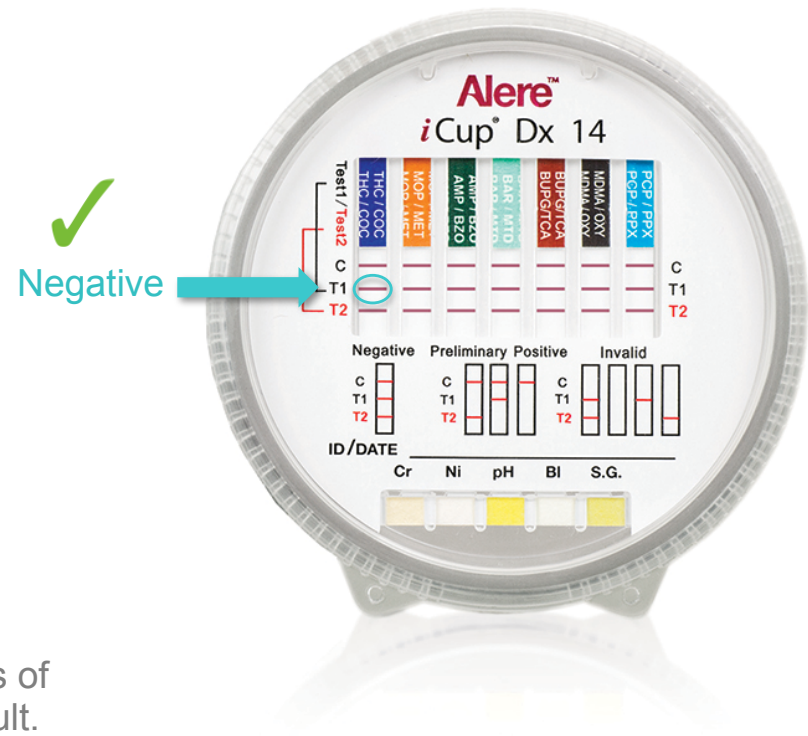
Read test results at 5 minutes.



# Negative example

## Negative test result

- A colored line appears in the Control region (C) and a colored line appears in the Test region (T) next to each drug name or number specific drug test.
- Negative results means the drug concentrations in the urine sample are below the designated cutoff levels for a particular drug tested.



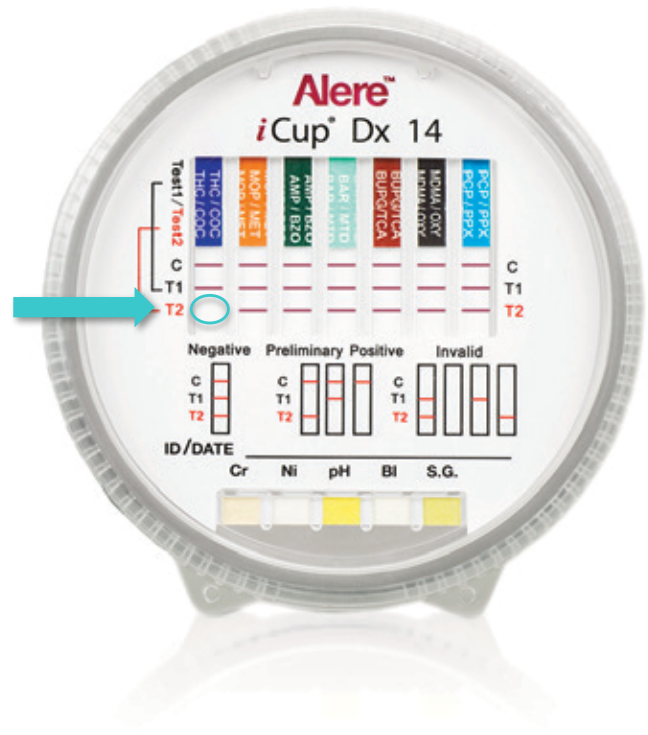
Note: Any indication of a colored line, regardless of color intensity, is considered a negative test result.

# Presumptive positive example

## Presumptive positive test result

- A colored line appears in the Control region (C) and NO line appears in the Test region (T) next to the name or number of a specific drug tested.
- The presumptive positive result means the drug concentrations in the urine sample is greater than the designated cutoff levels for a specific drug.

✓  
Presumptive positive for cocaine (COC)



The test device provides only a qualitative, preliminary analytical results. Gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS) are preferred confirmatory methods.

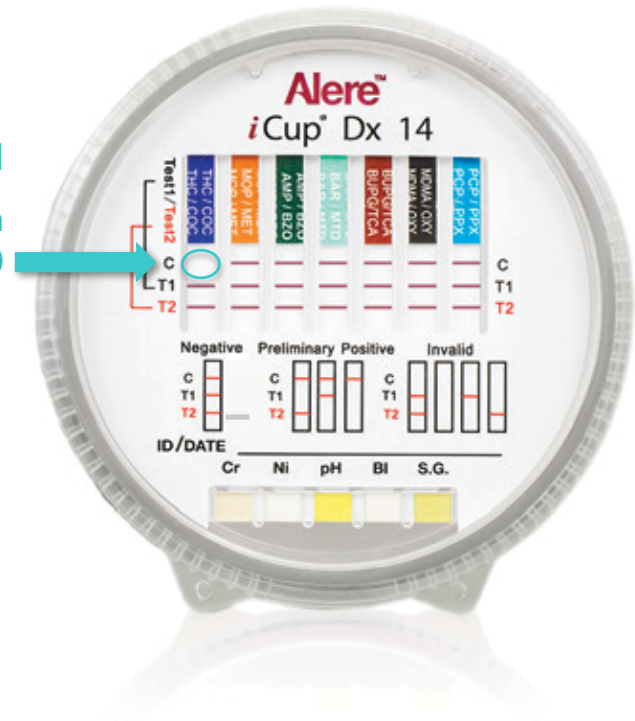


# Invalid example

## Invalid test result

- No line appears in the Control region (C).
- Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
- Read the directions again and repeat the test with a new test cup.
- If the result is still invalid, contact technical support.

  
Invalid  
No line present in control region (C)





# Interpretation of results (Cont.)

## NEGATIVE

The control line must be colored to indicate the test is valid. Any visible line, even a faint line, indicates a negative result.

### NEGATIVE RESULT



## PRESUMPTIVE POSITIVE

The control line must be colored to indicate the test is valid. The test area must be snow white to be considered positive.

Additional testing is necessary to confirm the presumptive positive results. Positive results should be “confirmed” by an alternate method such as GC-MS or LC-MS/MS.

### POSITIVE RESULT



## INVALID

When there is no line in the control line area, the result is invalid. If an invalid result is obtained repeat the test using a new test device.

### INVALID RESULT





# Urine drug control kits

It is recommended that external controls be run with each new lot of test devices and to test the products in storage monthly.

For assistance in obtaining controls, contact Alere Toxicology 800.340.4029.

Do not use commercially available urine controls since these products may not be compatible with the Alere iCup® Dx 14. Refer to Quality Control section in the package insert for troubleshooting instructions.





# Congratulations!

YOU HAVE COMPLETED THE TRAINING COURSE.



[alere toxicology.com](http://alere toxicology.com)

For additional information or assistance with this device contact Technical Support at 800.340.4029

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