



SURESTEP™ MULTI-DRUG SCREEN CUP

Training Guide





The information in this presentation is a general overview on performing and interpreting the SureStep™ Drug Screen Cup.

Product Training Contents

- Technical information
- Product overview
- Performing a urine drug screen
- 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.

The SureStep™ Multi-Drug Screen Cup is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine.

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.

For in vitro diagnostic use only.



Product overview



The SureStep™ Drug Screen Cup Overview

Features & Benefits

Integrated test cup screens for 6-8 drugs

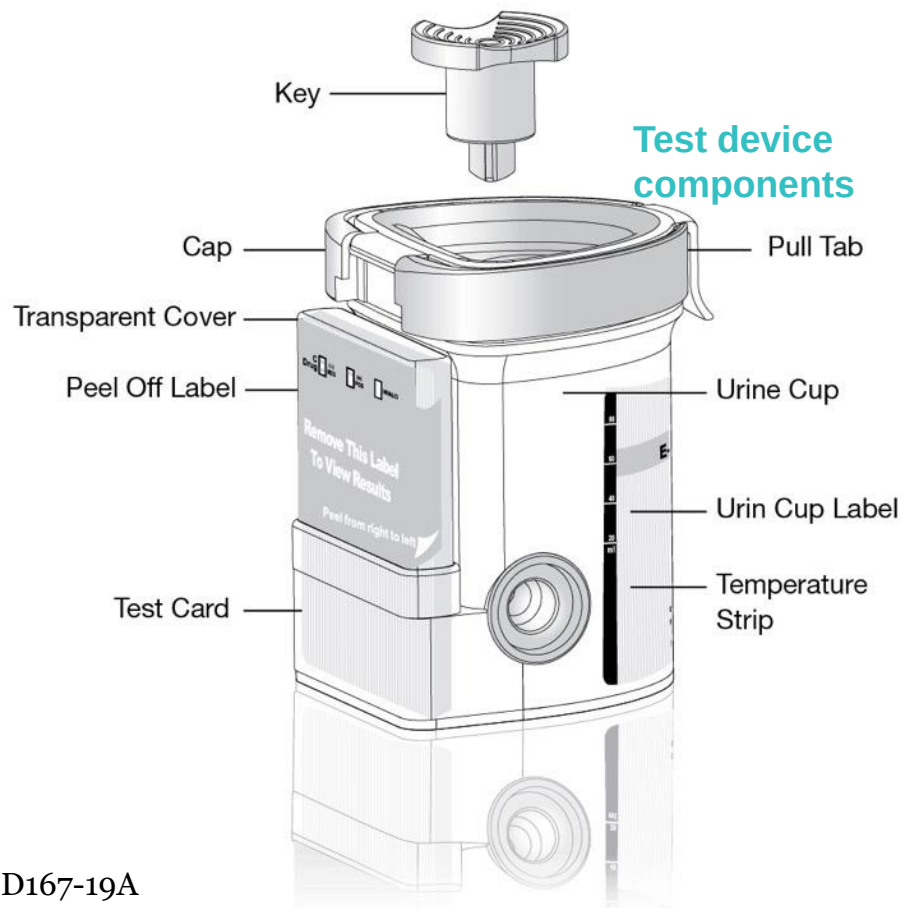
6 drugs as per AS/NZS 4308:2008 listed cut offs.

Self-contained cup minimizes exposure to urine

Fast results in 5 minutes

TGA ARTG entry is 208049

Drug	Cut Off
THC	50
BZO	300
AMP	300
METH	300
MOP	300
COC	300
EDDP (8Panel)	300
BUP (8Panel)	10



IVDBD167-19A

Adulterant Checks 6 panel cup: OX, NIT, S.G, GLUT, pH, CRE

IVDBE-187-191

Adulterant Checks 8 panel cup: OX, CRE, pH



The SureStep™ Drug Screen Cup Overview

Features & Benefits

Integrated test cup screens for 10 drugs

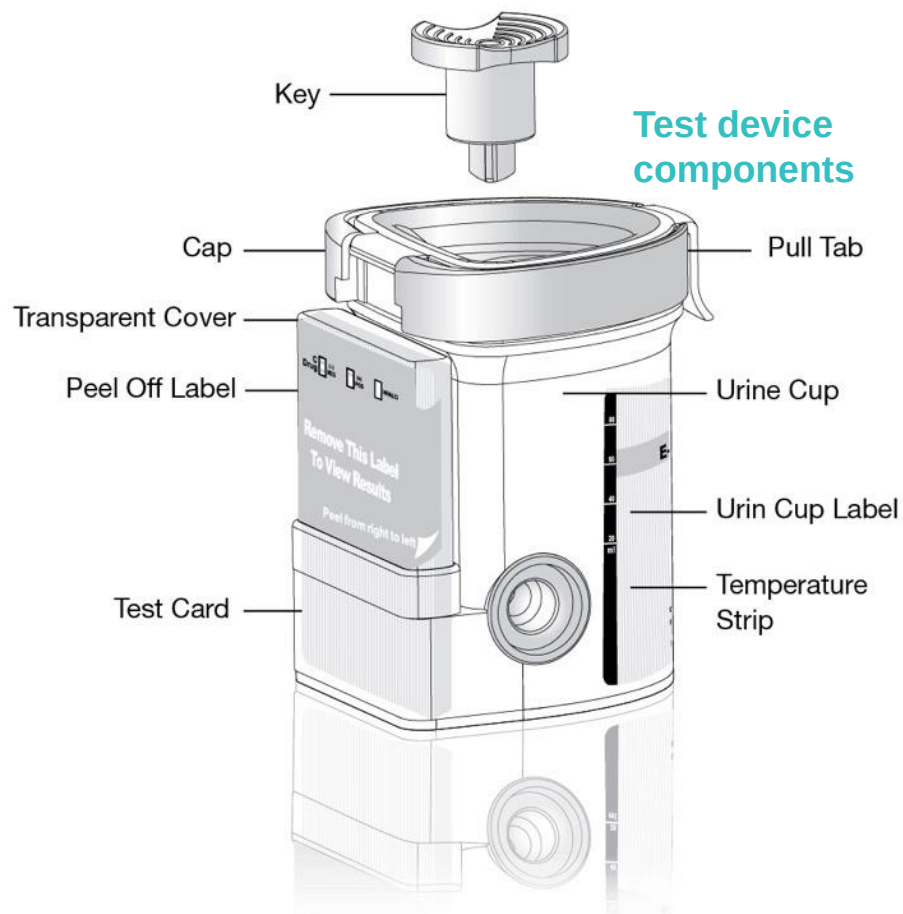
Broad clinical screen

Self-contained cup minimizes exposure to urine

Fast results in 5 minutes

TGA ARTG entry is 208049

Drug	Cut Off
THC	50
BZO	300
AMP	1000
METH	1000
MDMA	500
MOP	300
COC	300
OXY	100
BUP	10
MTD	300



Precautions, storage and stability



Foil Pouch

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



Device Storage and Stability:

Store packaged in the sealed pouch
at 2-30°C

The tests are stable up to the expiration
date printed on the pouch

Test cups must remain in the sealed
pouch until use

DO NOT FREEZE test devices

A security seal is included in the carton. If
required this seal may be used to seal and identify
the specimen for laboratory confirmation.



A smiling female healthcare professional with long dark hair, wearing a white lab coat, stands in a bright, clinical setting. A blue horizontal band is overlaid across the middle of the image, containing the title text.

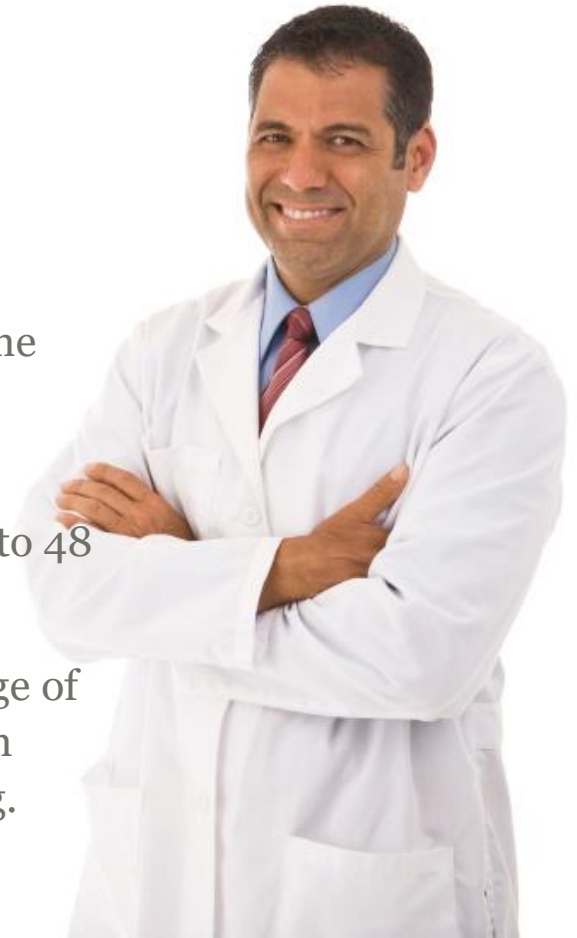
Performing a urine drug screen



Performing a urine drug screen

Preparation

- Bring cup foil pouch to room temperature before opening.
- Test device must remain in sealed pouch until use.
- Do not use beyond the expiration date.
- Urine specimen can be collected prior to running the test.
 - The specimen must be stored in a clean dry container and stored between 2 - 8 ° C for up to 48 hours.
- In order to screen effectively for adulterants, storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.



Performing a urine drug screen

Specimen collection procedure (cont.)

- Remove SureStep™ Drug Screen Cup from the foil pouch
- Remove the key by twisting it from the center of the cup cap and then provide urine sample.
- Instruct donor to fill cup to at least 1/3 full.



Instruct donor on proper specimen collection process.



Fill cup at least 1/3 full.



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

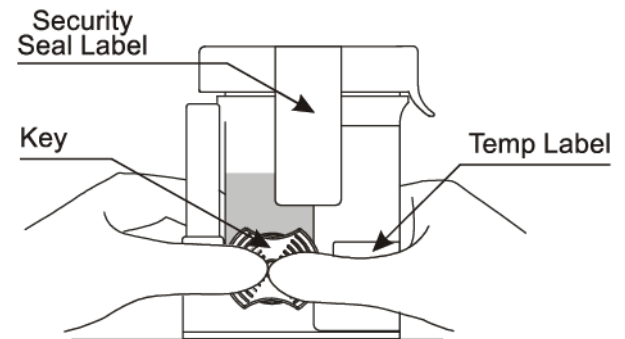
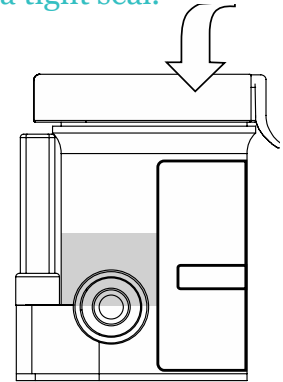
Performing a urine drug screen

Specimen collection procedure (cont.)

- Places the **cup on a flat surface** and secures the cap tightly by pressing down on the pull tab until an audible click is heard.
- If required place security seal over top and sides of the cup.
- Collector pushes the key to a fully closed position to initiate the test for result interpretation.

DO NOT TILT the SureStep™ Drug Screen Cup
The test must be run on a **FLAT** surface.

Check cup cap
for a tight seal.



Place seal over lid and down sides
of cup (if required). Push
in key to initiate the test.

Performing a urine drug screen

Specimen collection procedure (cont.)

Urine temperature verification

- A temperature strip is present on the back of the cup 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 32-38°C.



Read **GREEN** colour

Verification of urine temperature to limit sample adulteration, tampering, and dilution is recommended.

A smiling male doctor with short dark hair, wearing a white lab coat over a green shirt and a patterned tie. He has his arms crossed and is standing in a bright, modern clinical or hospital setting with blurred background elements like doors and equipment.

Result interpretation



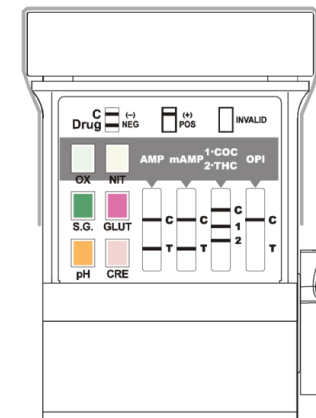
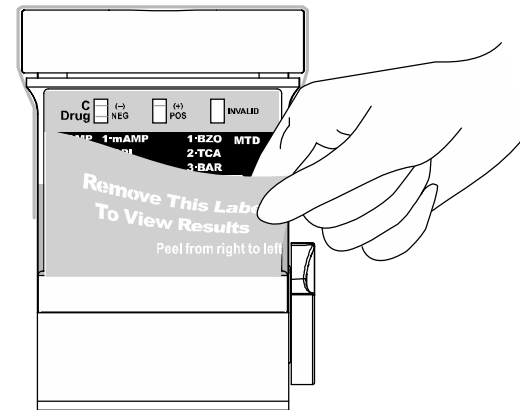
Interpreting test results

Reading test results

- Technician removes the label from the front of the device to view results.
- If temperature is in a valid range, read Adulterants at 3-5 minutes, read drug test results at 5 minutes.
- The drug test results remain stable for up to sixty (60) minutes.

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

Peel label to reveal test result window.



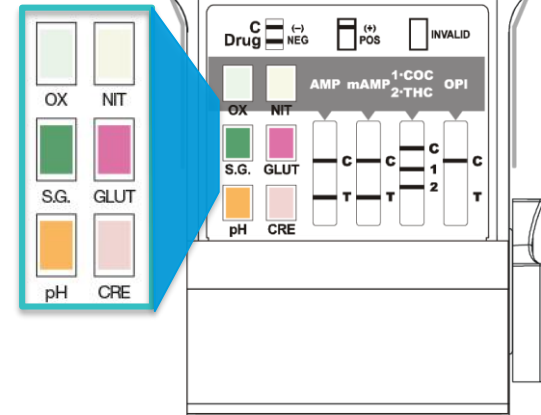
Interpreting specimen validity test

Reading Adulterant test results

Read the adulteration strips between **3-5 minutes**.

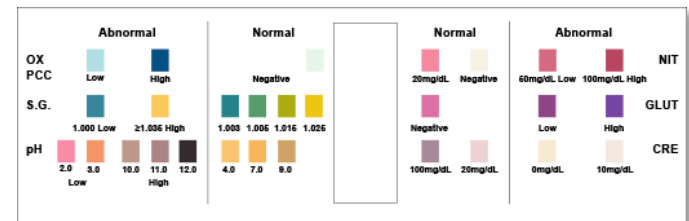
- Compare the colors of the adulteration pads to the color chart (provided).
- If the results indicate adulteration, do not read the drug test results (or refer to your Drug Free Policy for guidelines).

Specimen
validity
test region



SVT Color Chart

Compare colors on adulteration strip to color chart.



Compare Adulterant results
at 3-5 minutes.



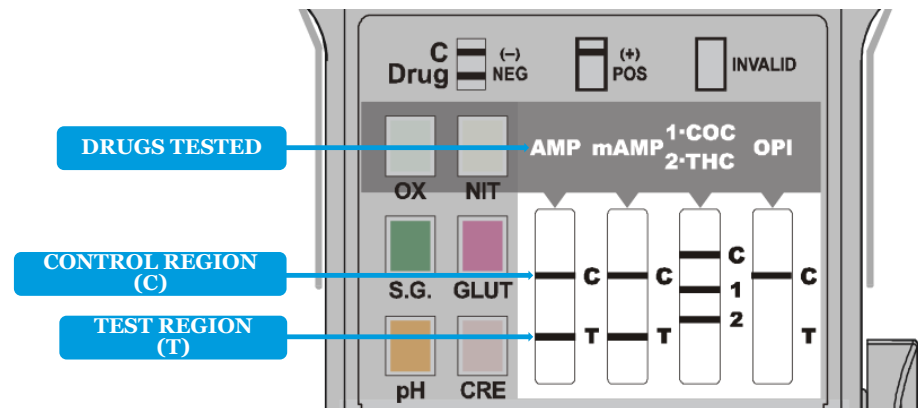
Interpreting drug test results

Reading drug test results

- Read the drug test results at 5 minutes.
- Do not interpret results after 60 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.



Please note- illustrations show a generic drug screen. Drugs screened on ANZ devices are as listed previously.



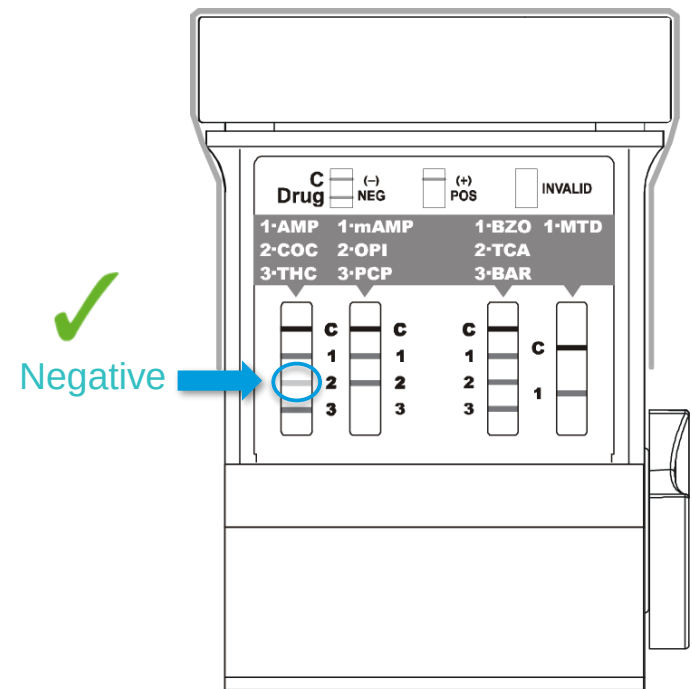
Negative example

Please note- illustrations show a generic drug screen. Drugs screened on ANZ devices are as listed previously.

Negative test result

- A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/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.

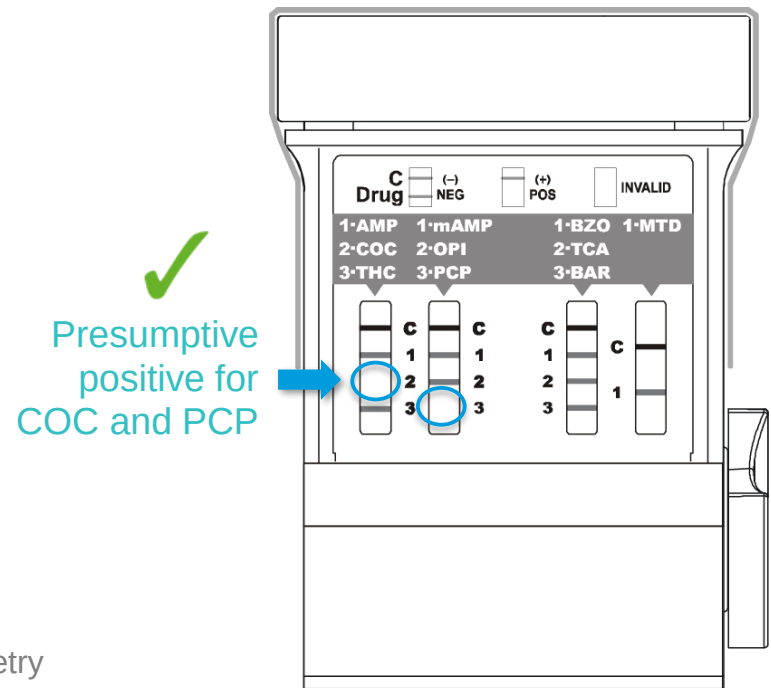


Presumptive positive example

Presumptive positive test result

- A colored line appears in the Control region (C) and NO line appears in the Test region 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.

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.



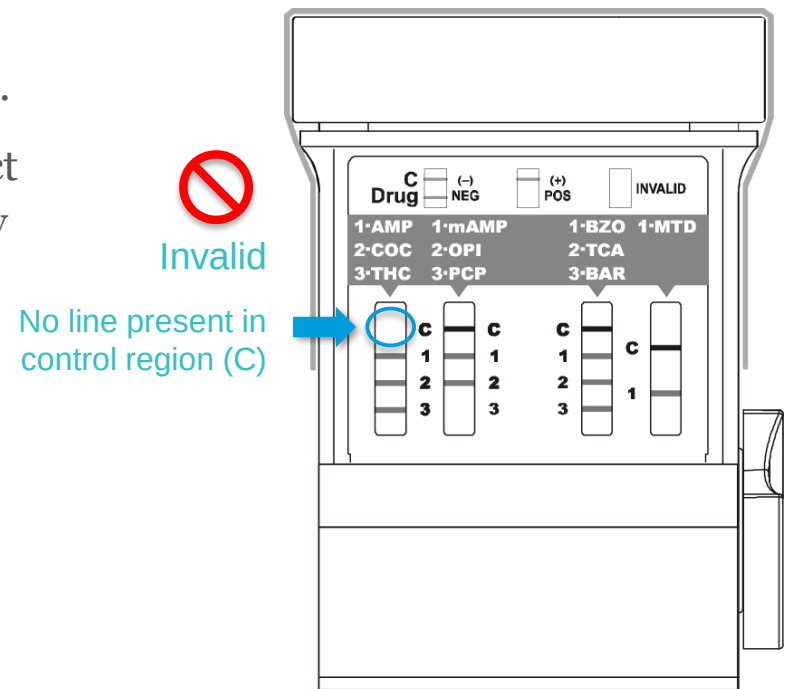
Please note- illustrations show a generic drug screen. Drugs screened on ANZ devices are as listed previously.



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.



Please note- illustrations show a generic drug screen. Drugs screened on ANZ devices are as listed previously.

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

C  *Test is valid*
DRUG  *Line is present*

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

C  *Test is valid*
DRUG  *Line is not present*

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

C  *Test is not valid*
DRUG 



 **Congratulations!**

YOU HAVE COMPLETED THE TRAINING COURSE.

Abott





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