PHENCYCLIDINE
7013D008T0871

One step test device for the qualitative detection of Phencyclidine in human urine
For professional in vitro diagnostic use only.

INTENDED USE

The ***Drug*Control PHENCYCLIDINE** is a lateral flow chromatographic immunoassay for the detection of Phencyclidine and metabolite in human urine at the cut-off concentrations shown below:

TEST DEVICE	SUBSTANCE	CAS - No	Cut Off Limit Value [ng / mL]
Phencyclidine	Phencyclidine	[60124-79-0]	25
	4-Hydroxy-Phencyclidine	[-]	12,500

This assay provides 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) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

REAGENTS

The ***Drug*Control PHENCYCLIDINE** contains anti-Phencyclidine antibody-coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not moisten nitrocellulose membrane with urine samples.
- Use proper sample volume (min 240 µl per assay).
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test device should be discarded according to federal state and local regulations.

STORAGE AND STABILITY

The ***Drug*Control PHENCYCLIDINE** can be stored 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

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 to settle to obtain a clear specimen for testing. Urine specimens may be stored at 2 - 8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

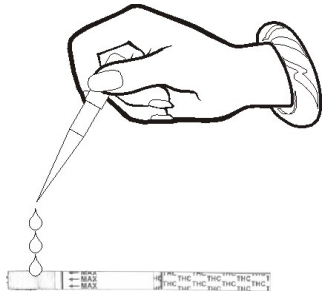
MATERIALS PROVIDED

- Test device
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

Dip the *DrugControl* **PHENCYCLIDINE** strip into urine specimen

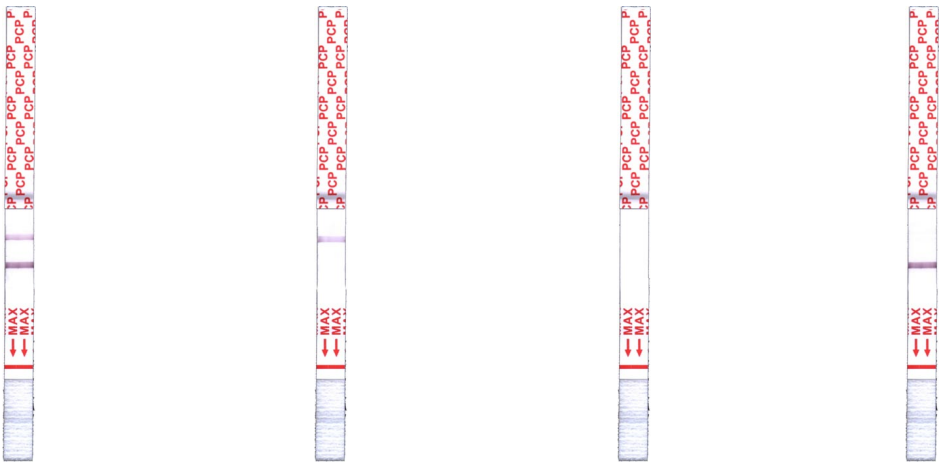


Pipette 3 – 4 drops of urine specimen onto the adsorbent tip of *DrugControl* **PHENCYCLIDINE** strip

DIRECTIONS FOR USE

1. Allow the test, urine specimen, and / or controls to reach room temperature (15 – 30 °C) prior to testing.
2. Bring the pouch to room temperature before opening it.
3. Remove the test device from the sealed pouch and use it as soon as possible.
4. Place the test device on a clean and level surface.
5. Add 3 – 4 drops of urine (approx. 240µl) to the specimen well or immerse the test vertically in the urine specimen for at least 10-15 seconds.
6. Do not pass the maximum line (Dipping line) on the test when immersing the strip.
7. Place the test on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear.
8. The result should be read at 10 minutes.

INTERPRETATION OF RESULTS



Negative **Positive** **Invalid** **Invalid**

Negative:*	Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Phencyclidine concentration is below the detectable level (25 ng/mL).
Positive:	One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Phencyclidine concentration exceeds the detectable level (25 ng/mL).
Invalid:	Control line 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 device. If the problem persists, discontinue using the lot immediately and contact distributor / manufacturer.

* **Note:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

Detailed informations regarding this lateral flow chromatographic immunoassay are given in the respective instructions for use:

PHENCYCLIDINE TEST

CE