

CLIA WAIVED PROCEDURE CARD

multi-CLIN™ Drug Screen Test Device

- Please read instructions carefully before performing the test.
- For detailed instructions, please refer to the Package Insert
- A certificate of waiver is needed for your laboratory in order to run this test
- Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. If the manufacturer's instructions are NOT followed, then the test is considered high complexity and is no longer CLIA Waived.

Recommendations for Quality Control Procedures:

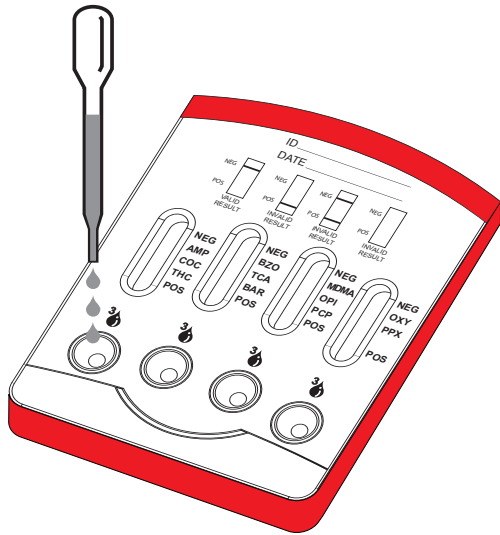
- (1) External positive and negative controls should be tested with each new lot or shipment of product, with each change in operator within the test kit and weekly as a check on continued storage conditions.
- (2) External positive and negative controls are not provided in the kit. Please contact your distributor for a list of approved controls that have been validated with the multi-CLIN™ Drug Screen Test Device. Use of any other control material is not advised and could produce irregular results.
- (3) If unexpected results are seen when running the controls, review the Directions for Use, Interpretation of Results and Limitations sections of the Package Insert and repeat the test with another device. If the problem persists, discontinue use of the test kit immediately and contact the manufacturer at 858-535-2030.

CLIA WAIVED PROCEDURE CARD

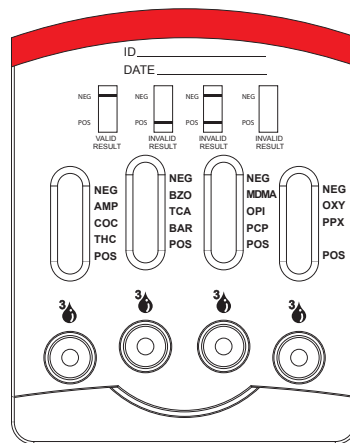
multi-CLIN™ Drug Screen Test Device

Allow test device and urine sample to reach room temperature before testing.
 Remove the test device from the sealed pouch and use it within 1 hour of opening.
 Place the test device on a clean and level surface.

1. Add 100 µL of urine (3 drops using pipette) to EACH sample well.

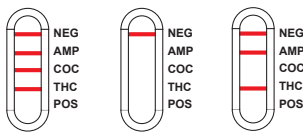


**2. Wait 5 minutes to read results.
 Do not read past 15 minutes**



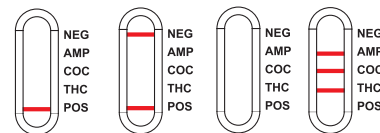
3. Confirm validity of results by checking NEG and POS Control Regions.

There should be NO line in the Positive Control Region (POS) and a visible line in the Negative Control Region (NEG)

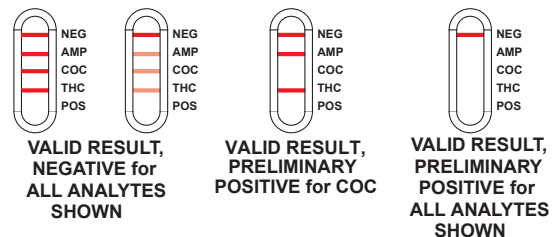


EXAMPLES OF VALID RESULTS

**4. Interpret Results at 5 minutes.
 Do not read past 15 minutes**



INVALID RESULTS



**VALID RESULT,
 NEGATIVE for
 ALL ANALYTES
 SHOWN**

**VALID RESULT,
 PRELIMINARY
 POSITIVE for COC**

**VALID RESULT,
 PRELIMINARY
 POSITIVE for
 ALL ANALYTES
 SHOWN**

Precautions:

- (1) The multi-CLIN™ Drug Screen Test Device provides only a qualitative, preliminary analytical result. gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.
- (2) Do not use cloudy samples or urine samples with visible precipitates for testing.
- (3) Color blindness may affect interpretation of results.
- (4) All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
- (5) The used test device should be discarded according to federal, state and local regulations.