283.531 Precision DX-12 Urine Drug Screen CLIA Waived WTVAHCS

Copy of version 1.0 (approved and current)

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Comments for version 1.0
Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/26/2024	1.0	yahyaelshimali JohnYahya Elshimali	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	3/22/2024	3/26/2024	Indefinite

West Texas V A Health Care System
Ancillary Testing

Precision Dx Urine Drug Screen CLIA Waived

PRINCIPLE

The PrecisionDX-DUD6124N tests are competitive binding, lateral flow, immunochromatographic assays for qualitative and simultaneous detection of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO/BZD), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methamphetamine (MET), Methadone (MTD), Morphine (Opiates) (OPI) and Oxycodone (OXY).

Intended Use: The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam (Benzodiazepine), Secobarbital (Barbiturate) and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgement should be exercised with any drug of abuse test result, particularly when the preliminary is positive. The test only provides preliminary results just as the lab based assays do. A more specific alternative chemical method must be used in order to confirm positive results if confirmation is deemed to be needed. GC/MS or LC/MS is the preferred confirmatory method. Contact the lab for confirmation testing. NOTE: the Precision DX-12 cup cannot be used for confirmatory testing. If a second cup was not collected at the same time as the Precision DX-12 cup than a new sample will need to be obtained.

SPECIMEN COLLECTION

Use Standard Precautions while handling the sample.
While the sample may be collected directly into the testing cup the below assumes that a primary sterile cup was collected first.

1. Laboratory does not provide observed collection. The clinic or treatment area will need to determine their own policy for observed collection.
2. Give the patient a sterile cup labeled with their full name and a second complete identifier. (The last four of the social security number is NOT a complete identifier.)
3. Have patient collect at least 30 cc of urine in the provided cup.
4. If other testing is required and the sample is being held overnight the culture preservative tube and urinalysis preservative tube and a nonpreservative tube may be filled.
5. Do not pour from the testing cup into another container to ship to the main lab. The urine from the testing cup has come into contact with reagents that may alter test results and should not be used for further testing.

REAGENT, SUPPLIES, AND EQUIPMENT

1. 1 -sterile urine cup
2. 1-culture preservative tube, if needed.
3. 1-urine preservative tube, if needed
4. 1- plain urine tube if needed
5. 1 – American Screening Corporation Precision Dx Multi-Panel Drug Test Cup REF# PREDX-DUD-6124N

Do not use kits or collection equipment beyond their expiration date. Store drug test cups and all collection supplies at room temperature (18º-25º C) .

6. Controls AM-100-25 negative control and AM-115-25 positive control.

QUALITY CONTROL

1. Each new shipment or new lot number of drug screen kit must be tested with a known positive and a known negative quality control sample that yields the appropriate intended result for each test analyte prior to patient testing. Quality control testing must be repeated every 30 days or when a new kit or shipment arrives, whichever comes first. Quality control results must be acceptable, recorded and records stored according to laboratory requirements.
2. Each individual drug analyte also has its own internal control within each test cup. The internal control must be valid per the manufacturers' instructions in order to report patient results for that analyte.
3. Testing personnel must be properly trained by the using methods set up by Ancillary Testing Coordinator (ATC) initially and competency maintained in order to perform and report patient results. Initial written training will be online followed by direct observation of test performance by the ATC or their designee.

PROCEDURE

Use Standard Precautions while handling urine.

1. After completion of specimen collection in 2.0 above, open a new Precision DX Multi-Panel Drug Test Cup. Ensure that the cup is within acceptable expiration date.
2. Pour urine into the cup to the maximum fill and screw on the lid until it clicks shut. NOTE: To ensure that the temperature strip registers within the acceptable temperature range (90 – 100 F), add sample to the cup within 2 to 4 minutes after patient has voided.
3. Label the cup with patient name, ID number(full SS# or date of birth) and date and time of collection.
4. Place the cup on a flat surface. Using a calibrated timer set a timer for 5 minutes.
5. After 5 minutes, read the results according to illustration on the test cup package, package insert or in 6.0 below.

RESULTS AND INTERPRETATION

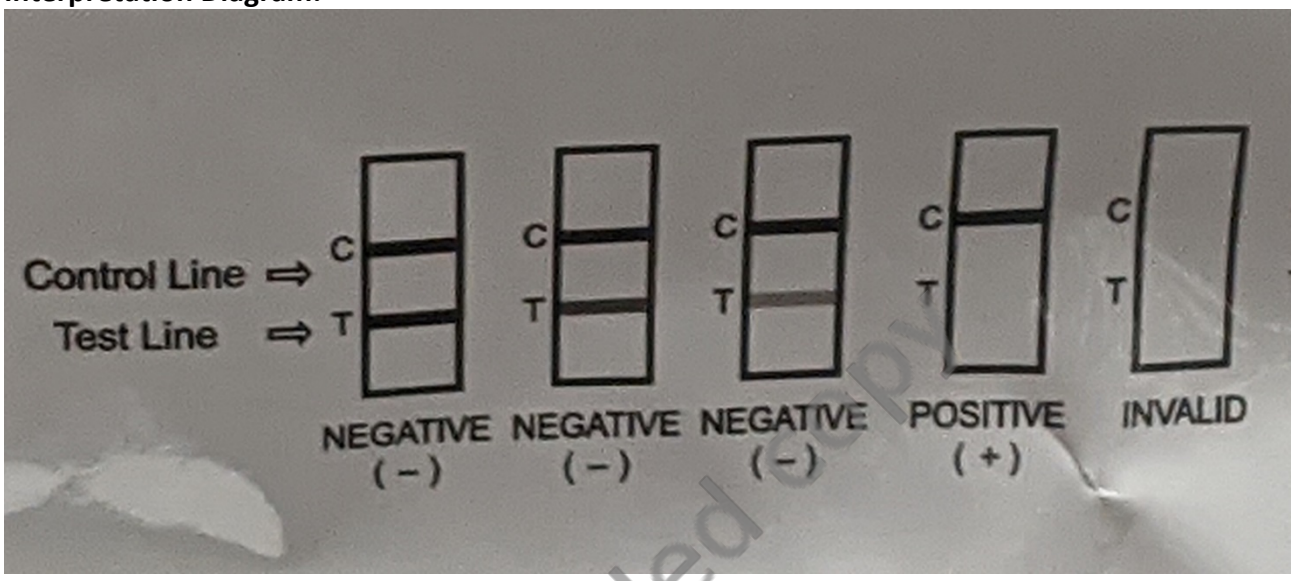
For the Drug Screen portion:

a. Negative Result: Two colored bands appear on the strip. One appears in the control region (C) and another band appears in the test region (T)**.**

Preliminary Positive Result: Only one colored band appears in the control region of the strip (C). No apparent colored band appears in the test region (T).

Invalid: If NO line appears in the control region (C), of the strip, then results are invalid and cannot be interpreted for the test region (T) of the strip, regardless of whether or not a line appears in the (T) region.

b. Interpretation Diagram:



For the adulterant portion:
Adulterant screening is to detect the most common methods of attempts to falsify drug screens. The most common adulterant is by dilution. This may occur when the client drinks an excessive amount of water before the test or if they dilute the sample with water. This can often be detected by a low specific gravity and a low urine creatinine value. Strips to detect both of these are built into the cup.
Another test that may indicate that something has been added to the cup is the pH. Normal urine pH is usually 5-9. The cup registers any thing below 4 and above 9 as abnormal. Please note that very low and very high pH have the potential to cause skin and eye damage. Any sample reading in these ranges should be handled carefully.

Record results in VISTA using fast bypass for point of care drug screen.
If the adulterant tests indicate an issue note that in the comments.

6. **LIMITATIONS OF THE PROCEDURE**
   - **a.** Test is for urine only. Do not use whole blood, plasma, serum or other body fluids.
   - **b.** Results may be adversely affected by additives or sample adulteration. If results are suspect, repeat testing with a fresh sample and kit cup.
   - **c.** A false positive test may occur with certain drugs in similar or same drug classes as those in the test cup. Certain foods and supplements may also yield false positive results. Consult the package insert for performance characteristics of each drug tested in this kit. Positive results may be confirmed using an alternate method of testing at the providers request. Contact the main lab at WTVAHCS for information on what confirmatory test should be ordered. NOTE: Some confirmatory testing may only be ordered by laboratory staff.

d. A false negative result may occur when samples are diluted or altered or if the drug in question is present at levels below the cut-off detection limit for the test kit. Consult the package insert of specific detectability cut-off levels and time to detection for each specific drug in the kit.

e. Urine creatinine and urine specific gravity can also be affected in patients with renal disease. Abnormal results may be seen in patients with impaired creatinine clearance or other kidney disease. Confirmatory testing may be indicated if necessary.

7. **REFERENCES AND ADDITIONAL RESOURCES**

a. Precision Dx Quick Cup M2000 package insert
b. Tests Granted Waived Status Under CLIA, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf
c. CLIA Waived Urine Drug Screens, search engine. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Detail.cfm?ID=39943&NoClia=1
d. Carl Vinson VA Medical Center Ancillary Testing Procedure.