PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

Intended Use

A CLIA*waived* Multidrug Cup is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. The multidrug cup may be used to test any number of drugs, from a single drug up to 11 different drugs. The drug combinations may be composed of any of the following drugs, at the noted cut-off concentrations:

Drug Class	Abbreviations	Sensitivity
Amphetamine	AMP	1000 ng/ml
Barbiturates	BAR	300 ng/ml
Benzodiazepines	BZD	300 ng/ml
Cocaine/Benzoylecgonine	COC/BEG	300 ng/ml
Marijuana	THC	50 ng/ml
Methadone	MAD	300 ng/ml
Methamphetamine	MET	1000 ng/ml

Opiates/Morphine	OPI/MOR	2000 ng/ml
Phencyclidine	PCP	25 ng/ml
Tricyclic Antidepressant	TCA	1000 ng/ml

Reagents and Material Provided

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions	Complete instructions guide can be viewed here: http://www.cliawaived.net/items/addonfiles/1347_CLIA_waived_drug_testing_cup_urine.pdf.
Optional:	
3. Negative Control I	Contains buffered protein solution with sodium azide.
4. Amphetamine Positive Control	Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide.
5. Barbiturates Positive Control	Contains BAR at 1000 ng/ml in a in a buffered protein solution with sodium azide.
6. Benzodiazepines Positive Control	Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide.

7. Cocaine Positive Control	Contains COC/BEG at 1000 ng/ml in a buffered protein solution with sodium azide.
8. Marijuana Positive Control	Contains THC at 150 ng/ml in a buffered protein solution with sodium azide.
9. Methadone Positive Control	Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide.
10. Methamphetamine Positive Control	Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide.
11. Opiates Positive Control	Contains OPI/MORE at 5000 ng/ml in a buffered protein solution with sodium azide.
12. Oxycodone Positive Control	Contains OXY at 300 ng/ml in a buffered protein solution with sodium azide.
13. Phencyclidine Positive Control	Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide.
14. Tricyclic Antidepressant Positive	Contains TCA at 3000 ng/ml in a buffered protein solution with sodium azide.

Control	

Warnings and Precautions

1. Do not use the test device beyond the expiration date.

2. Urine specimens may be infectious; properly handle and dispose of urine in the toilet by draining it out of the test device. Fasten cap on the device and throw the empty urine cup in the garbage.

3. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.

Storage and Stability

Store test kit below 28°C, **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

Specimen Collection and Preparation

The **CLIA*waived* Multidrug** device employs a **thermal strip that should be checked immediately** after collection to validate urine specimen. Substance Abuse and Mental Health Services Administration (SAMHSA) regulations specify that any temperature below 90.5°F must be considered adulterated. No additive or preservatives are required.

The Substance Abuse and Addiction Working Group identified the CLIA*waived* Multidrug device as being the one used by SAMHSA. To aid comparability, the Working Group recommended that the investigator record the make and manufacturer of the device being used for testing.

Test Procedure

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the test cup from the foil pouch.
3. Collect urine specimen directly into the test cup. Ensure that the sample amount meets the minimum level as indicated on the side of the test cup.
4. Read the results at 5 minutes. Do not interpret results after 30 minutes.

***Note**: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.*

Interpretation of Results

Positive: A *rose-pink* band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

Negative: A *rose-pink* band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

***Note**: There is no meaning attributed to line color intensity or width.*

Limitations of the Test

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used.

If adulteration is suspected, obtain another urine specimen.

Protocol source: https://www.phenxtoolkit.org/protocols/view/510602