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Title: Point of Care - Alere UScreen® 12 Drug Test Cup with Specimen Validity Tests		
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Alere UScreen® 12 Drug Test Cup with Specimen Validity Tests

Purpose:

The Alere Uscreen 12 Drug Test Cup is a rapid screening test for the qualitative detection of multiple drugs in human urine at specified cut-off levels:

Identifier & Drug	Drug/Metabolite	Cut Off	Detection Time in Urine
THC Marijuana	11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid	50 ng/mL	Up to 5+ days
COC Cocaine	Benzoylecgonine	300 ng/mL	2-4 days
MOP Morphine	Morphine	300 ng/mL	2-3 days
MET Methamphetamine	d-Methamphetamine	1000 ng/mL	2-4 days
AMP Amphetamine	d-Amphetamine	1000 ng/mL	2-4 days
BZO Benzodiazepines	Oxazepam	300 ng/mL	1-4 days
BAR Barbituates	Secobarbital	300 ng/mL	1-3 weeks
MTD Methadone	Methadone	300 ng/mL	1-3 days
BUP Buprenorphine	Buprenorphine Glucuronide	10 ng/mL	1-3 days
MDMA Ecstasy	3,4-Methylenedioxymethamphrtamine	500 ng/mL	2-4 days
OXY Oxycodone	Oxycodone	100 ng/mL	1-2 days
PCP Phencyclidine	Phencyclidine	25 ng/mL	7-14 days

This is a preliminary screen test that detects drugs of abuse in urine at specified detection levels. For quantitative results or to confirm preliminary positive results, a more specified method, such as Gas Chromatography/Mass Spectrometry (GC/MS), must be used.

Clinical consideration and professional judgement must be applied to any drug test result, particularly when a preliminary positive result is indicated.

Principle:

The UScreen 12 Drug Test Cup utilizes a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The device consists of individual test strips, assembled into separate chambers of a plastic insert, which can detect 12 drugs in human urine at various cutoff concentrations.

- The presence of a color band at a specific test region indicates a ***negative result*** for that particular test.
- The absence of a color band at a specific test region indicates a ***presumptive positive result*** for that particular test.

When the test is activated, the urine absorbed into each test strip by capillary action, mixes with the respective drug antibody conjugate and flows across a pre-coated membrane. When the drug levels within the urine sample are below the detection level of the test, drug antibody conjugate binds to the drug-protein conjugate immobilized in the T region (T) of the device. This produces a colored Test line, which regardless of its intensity, indicates a negative result.

When the sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective antibody conjugate, preventing the respective drug antibody conjugate from binding to the respective drug-protein conjugate immobilized in the T Region of the device. This prevents the development of a distinct colored band in the test region, indicated a preliminary positive result.

To serve as a procedural control (Internal control), a colored line will appear at the C Region (C), if the test has been performed properly because of the antibody-dye conjugate binding to the anti-rabbit IgG immobilized in the C Region of the device.

The adulteration tests are not intended for use in the diagnosis of diseases or illness.

Specimen Validity Test (Adulteration Test)

Adulteration of urine samples may cause erroneous results in drugs of abuse by either interfering with the drug screening test and or destroying the drugs in the urine. Dilution of urine with water is probably the simplest urine adulteration method. It is important to insure the integrity of urine samples in drugs of abuse testing.

The UScreen 12 Drug Test Cup with adulteration tests is based on the color response of chemical indicators in the presence of adulterants Creatinine (Cr), Specific Gravity (S.G.) and pH.

Specimen:

Patient Preparation:

- None

Specimen Requirement:

- Fill UScreen Cup to the minimum fill line (Approximately 30 mL of urine)

 All body fluids are handled as if capable of transmitting infectious diseases. Use Standard Precautions when in contact with such materials. Refer to Laboratory Infection Policy.

Calibration:

None

Reagents and Supplies:

- One test cup per pouch. Each pouch contains a test cup with integrated test card.
  - Store as packaged at (36-86°F) 4-30°C in the sealed pouch up to the expiration date.
  - Keep away from direct sunlight, moisture and heat.
  - DO NOT FREEZE
- Desiccant –The desiccant is for storage purposes only, remove from pouch and discard.
- Package insert / instruction sheet
- Adulteration color comparison chart for interpretation of adulteration test results.
  - *Do not perform any testing with the UScreen if you are color blind*.

Not included:

- Timer with a second hand to time the patient testing result.

Quality Control Material

- Negative Control – Alere Professional Cup Urine Drug Controls
- Positive Control – Alere Professional Cup Urine Drug Controls
- Package Insert

Quality Control:

Internal Quality Control:

Alere UScreen 12 Drug Test Cup incorporates an internal quality control. The presence of a color band in the Control (C) region at the top of each drug test strip confirms that sufficient urine specimen volume and adequate membrane wicking exist.

QC Result Interpretation/Reporting:

- The presence of a color band in the control area indicates that the results in the drug test areas are valid.
- The absence of a color band in the control area indicates that the results in the drug test areas are invalid.
- When performing external QC, document the internal QC for each test strip on the QC log sheet.
- When performing a patient test, the internal QC for each test strip is recorded on the Patient Test Log.

External Quality Control:

The Alere Professional Cup Urine Drug Controls are designed to monitor and validate the performance of drug of abuse detection methods at levels established by SAMHSA, CAO/AACC and many state programs. They are compatible with all qualitative drug procedures which are sufficiently sensitive to detect the control constituents.

These controls are manufactured using a human based matrix that has been stabilized to ensure that each product will be viable until the date of expiration.

Each bottle contains stabilized human based urine.

- Positive control urines have been spiked with authentic reference drug standards and or appropriate metabolites.
- Negative control urines are certified negative by immunoassay screening methods and GC/MS.

Storage and Stability:

- Unopened, the controls are stable until the manufacturers expiration dates when stored refrigerated at 35-46°F (2-8°C).

Note:

- No stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated.

- In spite of storing material at the manufacturers recommended temperature, in certain conditions, there may be a gradual decline in THC levels over time.

After results are found to be acceptable and recorded, discard the remaining QC material.

External Quality Control Procedure:

Quality Control is performed on receipt of each shipment of UScreen 12 Drug Test Cups. If multiple boxes are in a shipment and they all have the same lot number, Quality Control is only performed once. If there are multiple boxes with different lot numbers in a shipment, Quality Control must be done on each lot number.

- Remove box from refrigerated storage
- Take both bottles out of the box and allow controls to come to room temperature; this takes approximately 20 minutes.
- Label one UScreen Cup "Positive Control"
- Label one UScreen Cup "Negative Control"
- Record the UScreen Cup shipment lot number and expiration date and number of boxes in the shipment on the Quality Control Log Sheet.
- Record the lot number and expiration date for positive and negative liquid controls in their respective areas on the shipment QC log sheet.
- Gently swirl or mix by inversion before use. DO NOT SHAKE.
- Match the test cup labeled Positive with the control labeled Positive and pour entire contents of QC material into UScreen Cup.
- Repeat process for Negative control.
- Start the timer for 5 minutes.
- Read the QC results at 5 minutes. (Do not read results after 5 minutes as they may not be accurate)
- Record results on the QC result log. (Specimen validity tests are not recorded for QC)

External Quality Control Expected Results/Interpretation/ Reporting:

- The color band control line at the top of the test strips (C) area must be present for both controls for the results to be valid. At the top of each test strip are two abbreviations, each for the drug it represents.
- If there is not color band in the control region, the QC test is invalid. Repeat the test using a new Cup.
- The presence of a color band for each drug test area on each test strip indicates a negative test result.
- The absence of a color band for each drug test area on each test strip indicates a positive test result.
- When you get results that you don't expect, repeat the test with a new cup. If the problem corrects, you can use the UScreen Cups for patient testing.
- If the problem persists, contact the Point of Care office at extensions x4643 and x4645.

- Please record all activity performed for problem solving.
- Sign and Date the bottom of the QC Log.

Patient Test Procedure with Specimen Validity Testing:

- Test must be performed at room temperature, 65-85°F (18-30°C).
- Remove a UScreen Cup from sealed pouch when ready to test.
- Label the cup with the patient name, MRN or DOB, today's date and the time the specimen is collected.
- Hand the labeled cup to the patient for sample collection.
- Fill in the patient information on the patient result log.
- After the patient voids, confirm that the cup is filled to the minimum line. Tighten the lid and place the cup on a flat surface.
- Remove the cup label and verify that adulterant pad colors are within acceptable range according to adulteration guide.
- Remove label and read the results. Wait 5 minutes to determine a positive result.

Specimen Validity Test - Temperature

- Read the temperature immediately to verify that the urine temperature is within the acceptable range 90-100°F (32-38°C).
- A dot with a green color is the temperature you will record.
- If the temperature is outside of the test range, the temperature strip will remain black. The color of the dots will change as the temperature of the sample changes becoming black as the temperature of the sample drops below 90°F.
- Record the temperature on the Patient Result Log.
- Start a 5 minute timer.

Specimen Validity Test – Creatinine (Cr), Specific Gravity (SG) and pH

- Remove the UScreen Cup label and verify that adulterant pad colors are within acceptable range according to adulteration guide.
    - Cr: Creatinine reacts to form a purplish-brown color complex if present at a normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 20 mg/dL produces a very light, or no pad color change; which indicates adulteration in the form of specimen dilution.
    - SG: The specific gravity pad will change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.005 or above 1.025 is considered abnormal.
    - pH: Normal urine pH ranges from 4.5-8.0. Values below 4.0 or above 9.0 are indicative of adulteration.

Patient Urine Drug Test Results

- When the timer alarms after 5 minutes, read the results. Do not read results after 5 minutes. Results after more than 5 minutes may not be accurate and should not be read.
- Record all results on the Patient Result log along with the date and your initials.

Interpretation of Test Results:

- Each test strip has a Control Region (C) at the top
- There must be a visible color band in the (C) region in each test strip for the test to be valid.
- A blank space in the (C) region of the strip indicates that the test is invalid.
- The reported test results are Positive or Not Detected.
- The presence of a test line, even if very faint, is considered a Not Detected result.
- When a drug is present in an amount that is greater than the cut off, the result is positive and no line will be present in the test region on the test strip.

Preliminary Positive Not Detected Invalid

Test Limitations:

- This test has been designed for testing urine samples only. No other fluids have been evaluated. Do not use this device to test substances other than urine.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
- Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
- This test is single use only.
- Do not use the UScreen cup after the printed expiration date on the pouch.
- Keep the UScreen cup in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.

Specificity:

To test the specificity of the UScreen 12 Drug Test Cup, the device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Amphetamine (AMP)	
d-Amphetamin	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000
Phentermine	3,000
d-methamphetamine	>100,000
l-methamphetamine	>100,000
3,4-Methylenedioxyethylamphetamine(MDE)	100,000
(+/-)3,4-methylenedioxumethamphetamine	100,000

Barbiturates (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butathal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	10,000

Benzodiazepines (BZO)	
Oxazepam	300
Alprazolam	200
a-Hydroxyalprazolam	1,500
Bromazepam	1,500
Chlordiazepoxide	1,500
Clonazepam HCl	800
Clobazam	100
Clonazepam	800
Clorazepate dipotassium	200
Delorazepam	1,500
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
D,L-Lorazepam	1,500
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Temazepam	100
Trazolam	2,500

Marijuana (THC)	
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	30
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500
Δ8- Tetrahydrocannabinol	7,500
Δ9- Tetrahydrocannabinol	10,000
Cannabinol	100,000
Cannabidiol	100,000

Cocaine (COC)	
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000

Methadone (MTD)	
Methadone	300
Doxylamine	50,000

Buprenorphine(BUP)	
Buprenorphine	10
Buprenorphine -3-D-Glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-Glucuronide	200

Methamphetamine (MET)	
D(+)-Methamphetamine	1,000
D-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
(-)-Methamphetamine	25,000

(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
ß-Phenylethylamine	50,000
Trimethobenzamide	10,000
Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDE)	300

Morphine (MOP)	
Morphine	300
Codeine	300
Ethyl Morphine	300
Hydrocodone	5,000
Hydromorphone	5,000
Morphinie-3-β-d-glucuronide	1,000
Thebaine	30,000

Phencyclidine (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12500

Oxycodone(OXY)	
Oxycodone	100
Dihydrocodeine	20,000
Codeine	100,000
Hydromorphone	100,000
Morphine	>100,000
Acetylmorphine	>100,000
Buprenorphine	>100,000
Ethylmorphine	>100,000

Interfering Substances:

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, with a drug concentration 25% below the cutoff, and the urine with a drug concentration 25% above the cutoff and were tested with the UScreen drugs of abuse test. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetominophen (4-Acetamidophenol) (except OXY test)	Fenoprofen	Oxolinic acid
Acetophenetidin	Furosemide	Oxymetazoline
N-Acetylprocainamide (except OXY test)	Gentisic acid	Papaverine
Acetylsalicylic acid	Hydralazine (except BZO test)	Penicillin-G
Aminopyrine	Hydrochlorothiazide (except BZO test)	Pentobarbital (except BZR, OXY test)
Amoxicillin	Hydrocodone (exceptBZO,MOP,OXY test)	Perphenazine
Ampicillin	Hydrocortisone	Phenelzine
Apomorphine	O-Hydroxyhippuric acid	Phencyclidine(except PCP, OXY tests)
Aspartame	3-Hydroxytyramine	Prednisone
Atroine excet BAR test	Ibuprofen (except OXY test)	Procaine (except BZO, MOP, OXY tests)
Benzilic acid	D,L-Isoproterenol (except AMP, BAR test)	DL-Propranolol
Benzoic acid	Isoxsuprine	D-Propoxyphene (except OXY, test)
Benzoylecgonine (except COC,OXY test)	Ketamine (except OXY test)	D-Pseudoephedrine(except AMP, BAR tests)
Bilirubin	Ketoprofen	Quinine
Cannabidiol (except THC, OXY tests)	Labetalol	Ranitidine
Chloralhydrate	Loperamide	Salicylic acid
Chloramphenicol	Maprotiline (except TCA, OXY tests)	Secobarbital (except BAR, OXY tests)
Chlorothiazide	Meperidine (except THC, OXY tests)	Serotonin (5- Hydroxytyramine)
Chlorpromazine	Meprobamate	Sulfamethazine
Chlorquine	Methadone (except MTD, OXY tests)	Sulindac
Cholesterol	Methoxyphenamine (exceptAMP,BAR test)	Tetrahydrocortisone, 3-acetate (except AMP, BAR, OXY tests)
Clonidine	Morphinie-3-β-d-glucuronide (except BZO, MOP tests)	Tetrahydrocortisone 3-(β-Dglucuronide) (except AMP, BAR, OXY tests)
Codeine (except MOP, BZO, OXY tests)	Nalidixic acid	Tetrahydrozoline
Cortisone	Naloxone	Thiamine
(-) Cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	Triamterene
Deoxycorticosterone	Niacinamide	DL-Tyrosine
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	Norcodein (except MOP, BZO, OXY tests)	Trimethoprim
Diflunisal	Norethindrone	D L-Tryptophan (except AMP, BAR tests)
Digoxin	D-Norpropoxyphene	Tyramine (except AMP, BAR tests)
Diphenhydramine	Noscapine	Uric acid
Ecgonine methyl ester	D,L-Octopamine	Verapamil
Erythromycin (except BZO test)	Oxalic acid	Zomepirac
β-Estradiol (except BZO test)	Oxazepam (except BZO, OXY tests)	

References:

Alere UScreen Drug Test Cup Package Insert. US Diagnostics, Inc, an Alere Company. Huntsville, AL 35806. Version 06/02/2017