Medetomidine Rapid Test Strip (Urine, Powder)

For forensic use only.

INTENDED USE

The Medetomidine Rapid Test Strip (Urine, Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of Dexmedetomidine in powder specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
MTM	Dexmedetomidine	500

PRINCIPLE

Dexmedetomidine is an a2-adrenoceptor agonist with sedative, anxiolytic, sympatholytic, and analgesic sparing effects, and minimal depression of respiratory function. It is potent and highly selective for a2-receptors with an a2:a1 ratio of 1620:1. Dexmedetomidine is rapidly distributed and is mainly hepatically metabolized into inactive metabolites by glucuronidation and hydroxylation.Dexmedetomidine is almost completely biotransformation and is rarely excreted in its original form from urine and feces. Biotransformation includes direct glucosylation and cytochrome P450 mediated metabolism. The main metabolic pathway of Dexmedetomidine is direct N-glucuronidation into inactive metabolites; The hydroxylation of fats (mainly mediated by CYP2A6) produces 3-hydroxydexmedetomidine, 3-hydroxydexmedetomidine glucuronide, and 3-carboxydexmedetomidine; N-methylation of Dexmedetomidine produces 3-hydroxy-N-methyldexmedetomidine, 3-carboxy-N-methyldexmedetomidine, and N-methyl-O-glucoside Dexmedetomidine. The quality balance study confirmed that after 9 days of intravenous infusion of radiolabeled Dexmedetomidine, an average of 95% of the radioactive active substance was recovered from urine and 4% was in feces. The prototype of Dexmedetomidine can be detected in urine.

The MTM Rapid Test Strip (Urine, Powder) detects Dexmedetomidine through visual interpretation of color development on the strip. Drug conjugates are immobilized on the test region of the membrane. During testing, the sample reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the sample, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the sample is negative for the drug. If drug molecules are present in the sample above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of sample has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test strips (individually pouched)
- Package insert

Materials Required but Not provided

- Timer
- Container

PRECAUTIONS

- The test device is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.
- A positive or negative test result is NOT an indication that the substance being examined is safe to use. Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility, and pH of the sample.
- There are no direct therapeutic or diagnostic claims being made for this product. These tests are not involved in diagnosing, treating, mitigating, or preventing a disease, disorder or symptom in humans being, nor do they restore, modify or correct a body structure, function of the human body.
- The Test Strip only gives an indication and should be used solely as a presumptive guide to work in conjunction with further analysis such as Gas Chromatography-Mass Spectrometry or High Performance Liquid Chromatography (HPLC). For complete analysis. we recommend all samples should be sent to a professionally certified laboratory.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the samples and kits are handled. It is recommended to wear protective clothing such as disposable gloves and eye protection when handling harmful substances.
- Humidity and temperature can adversely affect results. The used testing materials should be discarded in accordance with local, state and/or federal regulations.
- The Test Strip has been tested for extreme shipping conditions and its performance has not been impacted.
- Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
- Read the entire procedure carefully prior to testing.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

PROCEDURE

Bring tests, samples, buffer and/or controls to room temperature 59-86℉ (15-30°C) before use.

1. **Prepare sample**

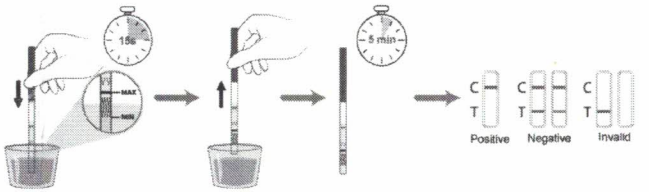
FOR URINE

Prepare a collect container, and collect urine into the container.

FOR POWDER

Mix your powder sample thoroughly before testing. Dilute the powder to be tested in water. One scoop (5-10mg) of powder sample should be diluted in 5mL of water. Refer to the advice of your local health or harm reduction authority on how much water and powder sample you should use.

2. Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.
3. Hold the strip at the handle with the product name imprints. Do not touch the membrane part of the strip to avoid contamination.
4. Dip the test strip vertically in the well-prepared specimen for 15 seconds. Immerse the strip where the wavy lines are, but not above the top of the wavy line. As the test begins to work, you will see color move across the membrane.
5. Take the strip out of the specimen afterwards and place it on a non-absorbent flat surface. Start the timer and read the result at 5 minutes. Do not read the results after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the sample.
2. Insufficient sample size, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C)) is considered an internal procedural control, confirming sufficient sample volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The MTM Rapid Test Strip (Urine, Powder) should be only used for the qualitative detection of Dexmedetomidine.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA).
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. A positive result indicates the presence of Dexmedetomidine only. A negative result does not at any time rule out the presence of Dexmedetomidine, as they may be present below the minimum detection level of the test.

PERFORMANCE CHARACTERISTICS

ACCURACY

Accuracy of the Medetomidine Rapid Test Strip (Urine, Powder) was established by running samples against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	MTM 500
Positive	97.92%
Negative	96.55%
Total	97.17%

SENSITIVITY

The sensitivity of the Medetomidine Rapid Test Strip (Urine, Powder) was determined by tested GC/MS confirmed controls to the concentration at negative, -75%, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

DrugConc.	n	MTM 500	
(Cut-off)		-	+
0	50	50	0
-50%	50	50	0
-25%	50	39	11
Cut-off	50	14	36
25%	50	7	43
50%	50	0	50
3X	50	0	50

SPECIFICITY

The following tables list the concentrations of compounds (ng/mL) above which the Medetomidine Rapid Test Strip (Urine, Powder) identified positive results at 5 minutes.

MTM 500-related compounds

Dexmedetomidine	500	Medetomidine	400

The following compounds yielded negative results up to a concentration of 100 µg/mL:

Tiletamina	Fentanyl
Quinine	Heroin
Pentylone	Procaine
S(±)-Amphetamine	Butylone
Methylone	Theophyline
Ethylone	TCMPP
Cathine	Acetylcodeine
R(-)-Amphetamine	MDBD
MCPP	Δ9-Tetrahydrocannabinol

The following compounds yielded negative results up to a concentration of 2.5 mg/mL:

MDMA	Trochiscil Levamisole Hydrochloride
Morphine	MDPV
Benzodiazepine	Diphenhydramine
Methamphetamine	Pseudoephedrine Hydrochloride
Propoxyphene	Methadone Hydrochloride
Promethazine	Lidocaine
Cocaine	Phenacetin

LITERATURE REFERENCES

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4. Clinical Pharmacokinetics and Pharmacodynamics of Dexmedetomidine. Weerink Maud A S; Struys Michel M R F; Hannivoort Laura N; Barends Clemens R M; Absalom Anthony R; Colin Pieter. Journal | [J] Clinical pharmacokinetics. Volume 56 , Issue 8 . 2017. PP 893-913

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
	Do not reuse		Use by