Medetomidine (MDE) Rapid Test (Urine)
Package Insert

ɜst for the qualitative detection of Dexmedetomidine in human urine.
ɪsic Use Only.

DED USE】

etomidine (MDE) Rapid Test (Urine) is a rapid chromatographic immunoassay tection of Dexmedetomidine in human urine.

ay provides only a qualitative, preliminary test result. A more specific alternate method must be used in order to obtain a confirmed analytical result. C/MS) is the preferred confirmatory method. Clinical consideration and nal judgment should be applied to any drug of abuse test result, particularly liminary positive results are used.

ARY】

ate is currently permitted in the United States for veterinary use, specifically for anesthesia and pain management in animals, with limited clinical applications in humans. The widely used dexmedetomidine can be administered via cular injection, intravenous infusion, or nasal drops, effectively reducing the propofol, isoflurane, and fentanyl during surgeries. As a highly selective ergic receptor agonist, dexmedetomidine demonstrates unique sedative, ;, and anti-sympathetic effects. It provides central antisympathetic and ty benefits, induces sleep-like sedation, and exhibits mild diuretic properties. aracteristics have led to its widespread adoption in critical care, perioperative ia, and day surgery procedures.[1-3]

gence of metomidate as a new adulterant in the U.S. illegal drug supply marks ing development in the growing multi-drug crisis. Metomidate, an α_2-adrenergic agonist approved only for veterinary use, is increasingly involved in overdose linked to the illegal fentanyl. Its potency is 200 to 300 times higher than that of and its rapid geographic spread underscores the need for enhanced clinical and coordinated intervention.[1]

etomidine (MDE) Rapid Test (Urine) is a rapid urine screening test that can be d without the use of an instrument. The test utilizes the antibody to selectively evated levels of Dexmedetomidine in urine. The Medetomidine (MDE) Rapid ne) yields a positive result when the Dexmedetomidine in urine exceed the e level.

IPLE】

etomidine (MDE) Rapid Test (Urine) is an immunoassay based on the principle titive binding. Drugs which may be present in the urine specimen compete ie drug conjugate for binding sites on the antibody.

sting, a urine specimen migrates upward by capillary action. Dexmedetomidine, in the urine specimen below the detectable level, will not saturate the binding ie antibody in the test. The antibody coated particles will then be captured by ed Medetomidine-protein conjugate and a visible colored line will show up in the region. The colored line will not form in the test line region if the tomidine level exceeds the detectable level because it will saturate all the tes of anti-Medetomidine antibody.

ositive urine specimen will not generate a colored line in the test line region of drug competition, while a drug-negative urine specimen or a specimen g a drug concentration less than the cut-off will generate a line in the test line) serve as a procedural control, a colored line will always appear at the control n indicating that proper volume of specimen has been added and membrane as occurred.

ENTS】

contains mouse monoclonal anti-Medetomidine antibody coupled particles and idine-protein conjugate. A goat antibody is employed in the control line system.

AUTIONS】

ensic Use Only.
use after the expiration date.
st should remain in the sealed pouch until use.
cimens should be considered potentially hazardous and handled in the same r as an infectious agent.
ed test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Package Insert

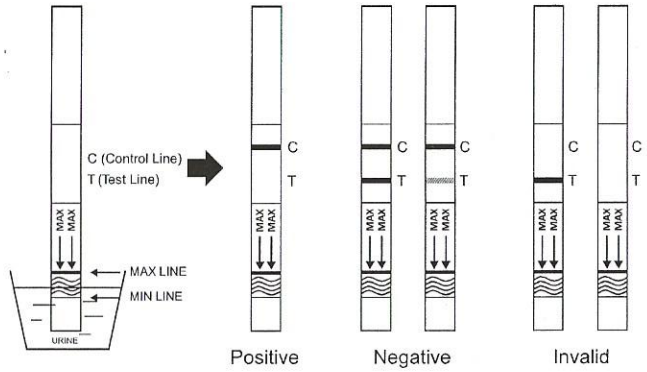
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch or closed canister to room temperature before opening it. Remove the Test Dipstick from the sealed pouch or closed canister and use it within one hour.
2. With arrows pointing toward the urine specimen, **immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.
3. Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Dexmedetomidine concentration is below the detectable level.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Dexmedetomidine concentration exceeds the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Medetomidine (MDE) Rapid Test (Urine) provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. GC/MS(LC/MS) is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Analytical Specificity

The following table lists compounds that are positively detected by the Medetomidine (MDE) Rapid Test (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Dexmedetomidine	1,000

【BIBLIOGRAPHY】

1. Palamar J J ,Krotulski J A .Medetomidine Infiltrates the US Illicit Opioid Market.[J].JAMA,2024,
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3. Grimsrud N K ,Mama R K ,Steffey P E , et al.Pharmacokinetics and pharmacodynamics of intravenous medetomidine in the horse[J].Veterinary Anaesthesia and Analgesia, 2012,39(1):38-48.

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