

# RHEONIX URINE SPECIMEN COLLECTION KIT

For *in vitro* diagnostic use

For Prescription Use Only

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Part Number: M22357 AX2

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## Intended Use

The Rheonix Urine Specimen Collection Kit is for use with the Rheonix STI TriPlex™ Assay. The Rheonix Urine Collection Kit is intended to be used for the transport and storage and testing of male urine specimens. The Rheonix Urine Specimen Collection Kit is not intended for home use.

## Summary and Explanation of the Procedure

The Rheonix Urine Collection Kit consists of a Rheonix Urine Specimen Transport/Storage/Testing Tube, containing 1 ml of Rheonix Urine Specimen Transport Buffer and a sterile, disposable graduated transfer pipette. After collection of a urine specimen, a sample of urine is transferred directly from the collection cup into the Specimen Transport/Storage/Testing tube using the graduated pipette. This sample is ready to be tested with the Rheonix Encompass MDx® workstation using the Rheonix STI TriPlex Assay.

## Materials Provided

Each individually packaged Rheonix Urine Specimen Collection Kit contains the following:

Component	Quantity	Description
Pipette	1	Disposable transfer pipette, graduated, individually wrapped
Urine Specimen Storage/Transport/Testing Tube	1	Tube containing 1 ml of Rheonix Urine Specimen Transport Buffer for urine storage/transport/testing

### Equipment and materials required but not provided

- Sterile, preservative-free urine collection cup
- Disposable gloves
- Labels with patient identification information

## Warnings and Precautions

- **WARNING: Do not use bleach** on spilled liquid from the collection device as the liquid contains guanidine hydrochloride. Bleach and guanidine hydrochloride can react to produce harmful gases.  
First, wipe the liquid with a dampened cloth.  
After wiping, clean the spill using a disinfectant, such as a 10% bleach solution.
- Do not apply the Rheonix Collection Buffer to the skin or mucus membranes or take internally.
- Always handle urine specimens as if they were infectious and in accordance with safe laboratory procedures. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- Take care during the urine specimen collection and handling steps to avoid cross-contamination of samples.
  - a) The transfer pipette should only be used to transfer one specimen. Do not use again for any other specimen.

- b) Avoid touching the tip of the transfer pipette to any surfaces before, during or after transferring the urine.
  - c) Do not allow the specimen containers to contact one another.
  - d) Discard any used materials in the appropriate waste containers without passing them over the urine specimen transport tube.
  - e) Change gloves that come in contact with the urine specimen and before handling other specimens.
- If the contents of the transport tube are spilled at any time during the collection procedure, use a new Rheonix Urine Specimen Collection Kit. Failure to use a new kit may invalidate the results.
  - Maintain proper storage conditions following specimen collection and during specimen shipping to ensure specimen integrity (Table 1).
  - Optimal performance of the Rheonix STI TriPlex Assay requires proper specimen collection, transport and handling (described below).
  - Dispose of the unused reagents and waste in accordance with local, state, and federal regulations.

## Urine Specimen Collection and Handling

### Instructions for male urine specimen collection (neat urine)

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Direct patient to provide a first-catch urine [approximately 20 mL to 30 mL (1 ounce) of the initial urine stream] into a sterile, preservative-free urine collection cup (required, but not provided). Collection of larger volumes of urine may result in target dilution that may reduce test sensitivity.
3. Cap and label the urine collection cup with patient identification and date/time collected.

## Instructions for Transferring the Male Urine specimen to the Rheonix Urine Specimen Transport/Storage/Testing Tube

**NOTE: Neat urine must be transferred from the collection cup to the Rheonix Urine Specimen Transport/Storage/Testing Tube immediately after collection.**

1. Open the package of the disposable transfer pipette included in the Rheonix Urine Specimen Collection Kit. Do not touch the tip of the sterile pipette to any surfaces.
2. Remove the cap from the transport tube.
3. Using the disposable transfer pipette, transfer approximately 3 mL of urine into the transport tube. The correct volume of urine has been added when the fluid level is in between the two arrows on the transfer tube label, as shown in Figure 1.
4. Discard the transfer pipette in a biohazard waste container. Each transfer pipette is intended for use with a single specimen.
5. Re-cap the transport tube and tighten the cap securely.
6. Invert the transport tube 3-4 times to ensure that the urine specimen and reagent are well-mixed.



The urine collection tube must be filled to the level indicated between the two arrows

7. Label the Rheonix Urine Specimen Transport Tube with the patient identification and date/time collected.
8. This is now known as the urine processed specimen (urine sample) and should be tested with the Rheonix STI TriPlex Assay within the stability period indicated in Table 1.

## Storage and Stability

Each package is labeled with an expiration date. Do not use the collection kit past the expiration date.

Fresh (neat) urine must be transferred from the original collection cup to the transport tube immediately after collection. Once added to the transport buffer, the specimens are stable for up to 120 days when stored at 2 to 8°C or up to 75 days when stored at 30°C.

**Note:** Urine samples must be shipped in accordance with all applicable national and international transport regulations.







**Table 1.** Urine sample stability when used with the Rheonix Urine Specimen Collection Kit and Rheonix STI TriPlex Assay

Specimen Type	Transport and/or Storage Temperature	
	2-8 °C	30 °C
Male urine	120 days	75 days










### Limitations

- Use this collection kit only with the Rheonix STI TriPlex Assay and the Rheonix Encompass MDx<sup>®</sup> workstation; performance has not been established with other assays or platforms.
- The performance of urine specimen collection kit has not been evaluated in teenage men less than 14 years of age.
- The Rheonix Urine Specimen Collection Kit is not intended for home use.

### Labeling symbology

Symbol	Title of symbol	Explanatory Text	Standard Reference
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2016 Reference no. 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2016 Reference no. 5.4.3 ISO 7000:2014 Reference no.1641
	Temperature limits	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2016 Reference number 5.3.7 ISO 7000:2014 Reference no. 0632
	Do not use if damaged	Indicates a medical device that should not be used if the package has been damaged or opened	ISO 15223-1: 2016 reference number 5.2.8 ISO 7000:2014 Reference no. 2606
	Single use only; do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1:2016 Reference no. 5.4.2 ISO 7000:2014 Reference no. 1051
	Caution, consult accompanying documents	Indicates the need for the user to consult the instructions for use for important cautionary information	ISO 15223-1:2016 Reference no. 5.4.4 ISO 7000:2014 Reference no. 0434

## Rheonix Urine Specimen Collection Kit

	Contains sufficient contents for <n> tests	Indicates the total number of IVD tests that can be performed with the IVD	ISO 15223-1:2016 Reference no. 5.5.5 ISO 7000:2014 Reference no. 0518
	<i>In vitro</i> diagnostic medical device	Indicates a control material that is intended to verify the performance characteristics of another medical device	ISO 15223-1:2016 Reference no. 5.5.2 ISO 7000:2014 Reference no. 2494
	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
	Catalog Number	Indicates the manufacturer's catalogue number to identify the medical device	ISO 15223-1:2016 Reference no. 5.1.6 ISO 7000:2014 Reference no. 2493
	Lot Number	Indicates the manufacturer's batch code to identify the batch or lot	ISO 15223-1:2016 Reference no. 5.1.5 ISO 7000:2014 Reference no. 2492
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1:2016 Reference no. 5.2.4 ISO 7000:2014 Reference no. 2502
	Environmental or aquatic toxicity	Indicates a potential of environmental or aquatic toxicity	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 09
	Use by	Indicates the date after which the medical device is not to be used	ISO 15223-1:2016 Reference no. 5.1.4 ISO 7000:2014 Reference no. 2607
	Skin Irritation, category 2 Eye Irritation, category 2	Indicates a potential for health risk to the user of the medical device	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 07

**Manufactured by Puritan Medical Prod. LLC for Rheonix:**

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