

AssureMDx Urine Collection & Transportation Kit

Instructions for Use by HealthCare Personnel: Specimen Collection, Labeling, Preparation, and Transportation

One AssureMDx Urine Collection & Transportation Kit contains:

- (1) 125 mL (Orange Lid) Sterile Disposable Urine Collection Cup wrapped individually
- (1) 50 mL (Blue Lid) Polypropylene Urine Transport Tube containing 1.4 mL of DNA Preservative
- (1) 6x6 inch Absorbent Sheet
- (1) 8x8 inch Biohazardous Safety Bag
- (1) AssureMDx Clinical Study Form
- (1) AssureMDx Urine Collection Kit Instructions
- (1) FedEx Clinical Pak with FedEx Express Saver Shipping Label

Intended Use

This AssureMDx Urine Collection & Transportation Kit is intended for the collection of male and female urine specimens. The Kit provides the necessary components to collect, store, and transport a urine specimen at ambient temperature (15-30°C or 59-86°F) utilizing a DNA preservative (1.4 mL) provided in the Urine Transport Tube (Blue Lid).

Important: The urine specimen must be transferred from the Urine Collection Cup (Orange Lid) into the Urine Transport Tube (Blue Lid) containing the DNA preservative within 15 minutes.

Specimen Collection, Labeling, Handling, and Preparation Requirements

Labeling instructions for the Urine Collection Cup and the Urine Transport Tube

Step 1. 125 mL Urine Collection Cup (Orange Lid):

- Remove the plastic wrap from around the Urine Collection Cup and dispose of the plastic wrap in regular trash.
- Place a barcode label containing the Subject ID number, Patient DOB, and Patient Initials and apply it to the side of the Urine Collection Cup. (**Do not** put the barcode label on the lid of the Cup).
- Using a permanent marker, draw a 2-3" line at the 30 mL mark on the Urine Collection Cup.

Step 2. 50 mL Urine Transport Tube (Blue Lid) containing 1.4 mL of DNA preservative:

- Place a barcode label containing the Subject ID number, Patient DOB, and Patient Initials and apply it to the side of the Urine Transport Tube. (**Do not** put the barcode label on the lid of the Tube).

Patient Urine Collection Instructions

- Step 1.** Instruct the patient to remove the lid from the 125 mL Urine Collection Cup (Orange Lid) and to set it aside for recapping.
- Step 2.** Instruct the patient to urinate into the Urine Collection Cup (Orange Lid) and that they must fill the cup to the 30 mL line (as marked) which is the minimum fill line. Once they have collected 30 mL of urine, they should finish urinating in the toilet. (**Important:** Instruct the patient **not** to overfill the urine cup).
- Step 3.** Instruct the patient to replace the Orange Lid on the Urine Collection Cup and securely tighten the lid to prevent the urine from leaking from the container.
- Step 4.** Instruct where the patient is to return the specimen for processing.



Important Note: Urine Volume Requirements

- A minimum of 20 mL of urine is required to generate valid test results.
- If less than 20 mL is collected, the specimen is considered Quantity Not Sufficient (QNS) and is invalid for testing.
- The patient will need to resubmit a new specimen.

Instructions for the Preparation of the Urine Transport Tube (Blue Lid)

Note: To prevent cross-contamination or mishandling of specimens, only process one patient sample at a time.

- Step 1.** It is recommended that gloves and protective clothing be worn when handling urine specimens.
- Step 2.** *Compare the barcode, Subject ID number, Patient DOB, and Patient Initials and apply on the Urine Collection Cup (Orange Lid) to the Barcode, Subject ID number, Patient DOB, and Patient Initials and apply on the Urine Transport Tube (Blue Lid) to ensure they match.*
- Step 3.** Ensure the Orange Lid on the Urine Collection Cup is securely closed. Mix well by inverting at least 10 times.
- Step 4.** Immediately after mixing, remove the Orange Lid from the Urine Collection Cup and carefully open the Blue Lid from the Urine Transport Tube. Pour 20 mL of urine from the Urine Collection Cup into the Urine Transport Tube. The total volume should be filled (measured) between the 21 mL and 25 mL line.
- Step 5.** Tightly screw on the Blue Lid of the Urine Transport Tube and mix vigorously for 10 seconds. **Note:** *Foaming may occur, this is normal.*
- Step 6.** Properly discard the Urine Collection Cup and remaining urine, in accordance with your local, state, or federal regulations.

Instructions for Packaging the AssureMDx Urine Transportation Kit

- Step 1.** Check to ensure the Urine Transport Tube (Blue Lid) contains the correct Subject ID number, Patient DOB, and Patient Initials on the label are correct.
- Step 2.** Wrap the Urine Transport Tube with the absorbent sheet provided.
- Step 3.** Insert the Urine Transport Tube and the absorbent sheet into the Biohazardous Safety bag labeled with a biohazard symbol.
- Step 4.** Close the biohazardous safety bag and ensure it is completely sealed. (If leakage should occur, it will be contained in the bag.)
- Step 5.** Place the biohazardous safety bag (with the tube within) into the AssureMDx Urine Specimen Collection Kit.
- Step 6.** *Place the completed AssureMDx Clinical Data Form in the box.*
- Step 7.** Fold the inner flap over the contents, then fold the outer lid over the box and insert the two tabs into the front of the box.
- Step 8.** Ensure the box is tightly closed.

Instructions for Shipping the AssureMDx Urine Transportation Kit by FedEx

- Step 1.** Insert the AssureMDx Urine Transportation Kit into the FedEx Clinical Pak labeled with the pre-filled **FedEx Express Saver Shipping** label addressed to Vesica Health and seal the packaging.
- Step 2.** Contact FedEx to request a pickup: 800-GO-FEDEX or (800-463-3339).
- Step 3.** Ship at ambient temperature on the same day of collection.
- Step 4.** Specimens must be received at Vesica Health within 5 days of the specimen collection date.

Shipping Exceptions: If unable to ship the specimen on the same day of collection, maintain it at room temperature (do not expose it to extreme temperatures) and ship it the following business day. ***In the event a patient specimen has been held over a weekend, please mark the shipping label for FedEx Express Standard Overnight delivery.***

For Questions please contact:

Customer Service

Vesica Health

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