SelectMDx™ for Prostate Cancer

SelectMDx for Prostate Cancer Urine Collection Kit

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Instructions for Use

Kit for the collection, stabilization and transportation of post-DRE first void urine samples.

Specimen collection, handling and preparation

Samples collected with the SelectMDx Urine collection kit should be handled according to the specifications in Table 1. This kit enables transport and storage of urine samples at ambient temperatures by preserving nucleic acids using the stabilizing buffer provided in the urine transport tube. First-void urine samples should be collected directly following DRE and immediately transferred (within 15 minutes) into the urine transport tube and the cap should be closed tightly to prevent leaking. The samples should be shipped to MDxHealth at room temperature on the day of collection.

Table 1. Collection media and specimen storage conditions

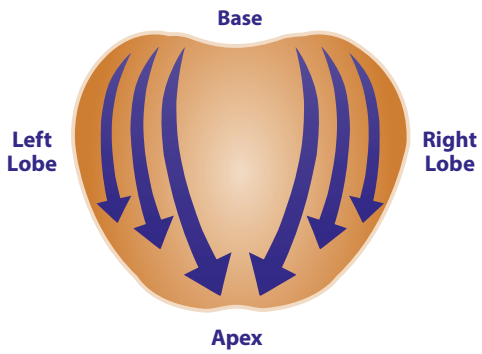
Specimen medium type:	Clinical specimen:	Storage duration of stabilized urine in transport tube prior to RNA extraction:
SelectMDx stabilization buffer	Post-DRE first void male urine	Up to 6 days at room temperature
		Up to 6 months at <-20 degrees Celsius

Physician instructions

- Prior to urination, digital rectal examination (DRE) of the prostate is required. DRE is necessary to mobilize the prostate cancer cells and exosomes, towards the urethra, and consequently increase the urinary target mRNA levels.
- Avoid cross-contamination during the urine sample handling steps. Urine samples can contain high levels of RNA. When handling more than one container, ensure the urine sample containers do not contact one another. To avoid cross-contamination, change gloves after handling a urine sample and avoid handling across multiple opened samples.
- Transfer the unprocessed urine samples immediately after collection into the urine transport tube. Do not freeze the unprocessed samples.

Urine collection

- Conduct a DRE immediately prior to urine collection. Apply enough pressure to slightly depress the prostate surface. Perform exactly three strokes per lobe from the base to the apex and from the lateral to the median line for each lobe as shown in the figure below. (This is not intended to be a prostatic massage.)
- Immediately following DRE, instruct the patient to collect approximately 30 ml of the first void urine stream in the collection cup provided. Make sure the collection cup is labelled appropriately for patient identification.
- When a patient is unable to provide the requested volume of urine, at least 8 ml is required to perform SelectMDx testing.
- Urine volumes >30 ml in the collection tube can lower the analyte concentrations, and may result in an invalid specimen. Thus, the patient should try to avoid filling the urine collection cup >30 ml. Please note the amount of urine on the patient request form.
- If more than 30 ml is collected, note the volume on the patient request form. Do not discard excess voided urine.



MDxHealth

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Urine sample handling procedure

1. Tightly screw on the cap of the urine collection cup and swirl the urine in the collection cup 5 times.
2. Carefully open the transport tube without spilling contents of the transport tube.
3. Transfer 8 ml of urine from the collection cup into the transport tube using the pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the transport tube label. (The urine must be transferred into the tubes within 15 minutes.)
4. Label the urine transport tube and the patient request form with the barcode labels provided.
5. Complete the patient request form with all required data.
6. Tightly screw on the cap of the tube and invert the transport tube five times to mix the contents.
7. Place the tube and the absorbent sheet in the safety bag. Seal the safety bag and place it together with the patient request form inside the cardboard insert in the blue shipping envelope.
8. Place the sealed blue shipping envelope into the mail on the same day as collection.

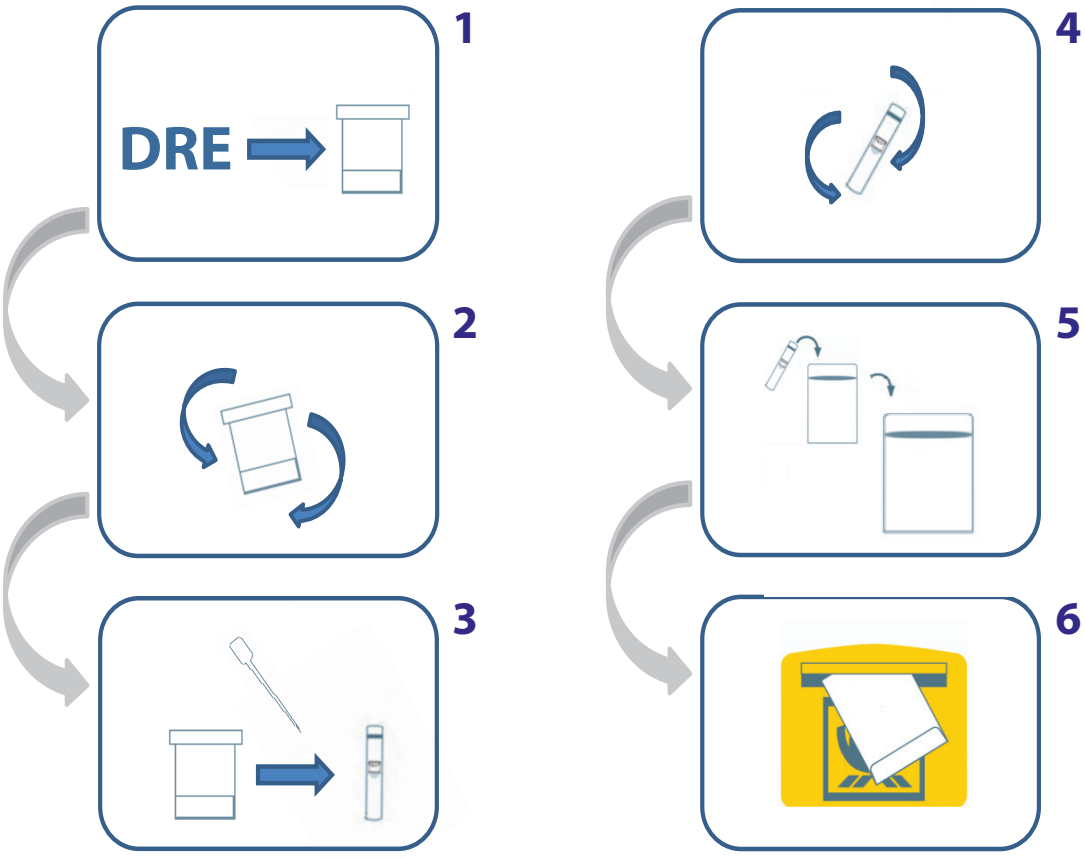
Transport and storage instructions

- Sample should be shipped at ambient temperature on the same day of collection.

Limitations of the procedure

- The product should only be used by personnel trained in DRE. The recommendations on laboratory design and procedures must be followed to avoid false results and contamination.

Summary of the collection, stabilizing and transport procedure



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