



UROVYSION

INDICATIONS:

The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion Kit are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

SPECIMEN:

Urine (at least 35 to 40 ml.)

SUPPLIES:

- 1. Specimen Requisition
- 2. Specimen Bag with a biohazard label
- 3. PreservCyt preservative collection vial
- 4. Sterile Collection cup

COLLECTION PROCEDURE:

Note: The specimen is stable for 24 hours

The specimen can be sent fresh, refrigerate and transport to the laboratory as soon as possible.

Or

- 1. Collect a minimum of 33 ml of urine. If urine exceeds 40 ml, pour off excess volume.
- 2. Add PreservCyt in 2:1, urine to PreservCyt ratio immediately:

| Urine | PreservCyt | Total |
|-------|---------------------|-------|
| 35 ml | 17 ml (7/8 of vial) | 52 ml |
| 40 ml | 20 ml (entire vial) | 60 ml |

- 3. Total PerservCyt volume equals 20 ml and the mixture of urine and PerservCyt should not exceed 60 ml.
- 4. Label the vial with patient's name and date of birth.
- 5. Place urine / preservative mixture in original packaging and store immediately in the refrigerator until ready for transport. Decomposition of urine begins within 30 minutes.



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6. Transport to cytology lab ASAP on same day. Preferred shipping conditions are on ice packs. Do not allow direct contact of ice pack with specimen container. A foam divider or paper towels should be used to separate.

Submit all patient information following the procedure for "Completing a Gynecologic Cytology Requisition".

Complete test requisition including last and first name of patient, patient's date of birth and social security number, body site and source of specimen collected. Label specimen container (using the labels provided on the requisition) with patient's first name and last name, and body site/source. The container must have at least two (2) unique identifiers. Examples of unique identifiers: patient name, DOB, unique bar code, etc. Include pertinent clinical information, i.e., previous malignancy, radiation therapy, drugs, etc. Place container in a specimen bag with a biohazard label. Place the requisition in the side pocket of the specimen bag.