

Avoiding Rejections with the ExoDx[™] Prostate (EPI) Test



| Category | Examples | What to Do |
|--|---|--|
| Sample Collection and Transport Issues | | |
| Labeling Issue/ Missing Information | Samples are required to have two unique identifiers we can verify to ensure we have the correct sample for the correct patient. | Ensure the sample collection container and associated paperwork are clearly marked with the patient's full name and date of birth. |
| Sample Delayed in Transit | Samples should not be in transit for more than 2 days. | Store samples immediately in refrigerated conditions until they are packed on frozen ice packs for shipping overnight. |
| Visible Blood or Other Contaminant in the Sample | Urine with blood or other visible contamination will be rejected. | Instruct your patients to immediately notify medical staff if there is blood in the urine. |
| Quantity not Sufficient (QNS) | Less than 15 mL of urine was received. | Encourage your patients to follow the specimen collection directions to obtain a full 15 mL "first catch" urine sample. |
| Sample Preparation Failure | | |
| Filter Failures (>5 filters, concentration failure, elution error) | This most often occurs when extracellular material in the urine clogs the specimen preparation devices. | Instruct patients to notify staff if the urine has other visible contamination before submission. |
| Improper collection device | This occurs when the Colli-Pee® is not utilized. | Prompt patients to use the proper collection device to mitigate the chances for a diluted sample. |
| Test Failure | | |
| Indeterminate test result | Not enough prostate exosome material was in the collected sample to give an interpretable result. | Even with the best intentions, sometimes there is not enough testable material in the sample. A repeat sample most often works. |

Successful Testing Benefits Everyone

The ExoDxTM Prostate Test (EPI) result is a crucial piece of information which informs the biopsy decision-making discussion between patient and physician. Several factors contribute to a successful testing outcome, and this table gives examples of how to mitigate possible testing process errors.

General Guidance:

- Do not send a sample if your patient has an active urinary tract infection
- Do not collect a larger volume of urine in a standard container first, then pour into the Colli-Pee. The prostate exosome material will be diluted, and the test result becomes unreliable, even if a result is reported
- Do not ship when there are expected significant weather delays
- Avoid shipment on days that back up to a holiday
- If collection is necessary on Friday, refrigerate over the weekend and ship on Monday

If a rejection occurs, please contact us at 844-396-7663, option 3 then option 2, to receive a new At-Home Collection Kit.

Questions?

Contact us at 844-EXOSOME (844-396-7663)