



Urinalysis for HPTN 035

- Urinalysis will only be done if clinically indicated.
- Only Nitrite and Leukocytes will be recorded.



Test kit

- Use only the Quidel UrinChek 10+SG



Specimen

- Patient should not use a cleanser prior to specimen collection.
- Collect the 1st 20ml into a sterile container
- If CT/GC are to be tested, transfer a small amount to a tube.
- Use the urine in the tube for urinalysis and pregnancy
- Refrigerate the remaining sample for CT/GC immediately.
- If urinalysis can not be done within an hour, refrigerate.



External Quality Control

- CLIA requires testing on each new lot number, and shipment.
- Recommend additional testing weekly.
- Use a commercial QC kit.
- If QC is not acceptable after repeat testing, do not run patient specimens.
- Document the QC on a log sheet.



Urinalysis Test Procedure

- Urine should be at room temperature and mixed well.
- Completely immerse the test strip into the urine.
- Remove the reagent strip immediately.
- While removing, drag the underside of the strip across the urine container to remove excess urine.
- Hold the strip horizontal to prevent possible mixing of the chemicals from adjacent reagents.



Urinalysis Test Procedure

- Read at the specified times:
 - Nitrite 30-60 seconds
 - Leukocytes: 60-120 seconds



Reporting

- Record the results for the Leukocytes and Nitrite only for the 035 study in the lab note book.
- Record the lot number and expiration date.



Limitations

- Nitrite: A negative test with symptoms of bacteriuria can be caused by bacteria that do not reduce nitrate, antibiotic therapy, or insufficient urinary retention time in the bladder. False positive tests can be caused by dyes in the urine (beets).



Limitations

- Leukocytes: False positive results can occur if the specimen is not a clean void.