



INTENDED USE:

The **Liqui-PREP® Urine Preservative Solution** is both a transport and Preservative Solution. Immediately after urine collection, the **Liqui-PREP® Urine Preservative Solution** is added to the urine for transportation and preservation. The preserved urine specimen is processed using the **Liqui-PREP®** processing procedure. The results are a thin layer slide ready for staining and reading.

SUMMARY AND EXPLANATION:

The **Liqui-PREP®** System has 4 basic steps:

- **Specimen Collection:** After a urine specimen is collected, the specimen should be preserved immediately. The urine can be preserved by mixing the specimen and pouring it into a **Liqui-PREP® Urine Preservative Cup** containing **Liqui-PREP® Urine Preservation Solution** or approximately 55ml of **Liqui-PREP® Urine Preservation Solution** can be added to the Urine specimen (maximum of 100ml of urine) and mixed.
- **Specimen Preparation:** The urine specimen must be preserved for approximately 1 hour prior to specimen preparation. When the preserved urine specimen arrives in the laboratory, the specimen is mixed well and poured into 1 or 2-50ml centrifuge tubes. The specimen centrifuge tube is centrifuged at 1000xg for 10 minutes. After centrifugation, the supernatant is decanted leaving a cellular pellet. Aliquots of either **Liqui-PREP® Urine Preservative Solution** or **Liqui-PREP® Preservative Solution** are used to rinse the re-mixed cell pellet into a 15ml centrifuge tube. (Depending on the urine cellularity, it may take several concentrations of the urine to have good cellularity.)
- **Specimen Cleaning and/or Concentration:** The concentrated urine cellular pellet in the 15ml centrifuge tube is centrifuged at 800xg for approximately 10 minutes. Decant the supernatant, resulting in a preserved cellular pellet.
- **Cellular Encapsulation and Slide Production:** The preserved cellular pellet is mixed well. The cells are encapsulated using **Liqui-PREP® Cellular Base Solution**. The preserved cells and the **Liqui-PREP® Cellular Base Solution** are mixed well using either the "Working Tube" or In-centrifuge tube method of encapsulation (Method depends on the cellularity of the specimen) and an aliquot is applied to a microscope slide. The microscope slide is dried, stained and read.

PRINCIPALS OF THE PROCESS:

After the urine specimen is collected and preserved in the **Liqui-PREP® Urine Preservative Cup** or the urine specimen is preserved using **Liqui-PREP® Urine Preservative**, cell preservation begins and continues during its trip to the laboratory. (After approximately 1 hour, the urine specimen should be completely preserved.)

Because of the lower cellularity of urine specimens, the use of 50ml centrifuge tubes is suggested to ensure a good harvest of cells from the specimen. After the 50ml centrifuge tube is centrifuged, the supernatant is decanted leaving the cells in the 50ml centrifuge tube. The resulting cells are rinsed into a 15ml centrifuge tube for concentration. After concentration, agitation and centrifugation the supernatant is decanted and cells are encapsulated.

Encapsulation is performed with either "Direct In-Tube" or a "Working Tube" encapsulation method using **Liqui-PREP® Cellular Base Solution** to dilute and encapsulate the cells.

If the cellular pellet is very small <50µl Direct In-Tube encapsulation is used. Pipette 50µl to 100µl of **Liqui-PREP® Cellular Base Solution** into the centrifuge tube, mix the centrifuge tube well, aspirate ~50µl of the encapsulated cells and apply to a microscope slide. Dry, stain and read the slides.

If the cellular pellet is 50µl or larger, Mix the cells well to produce a homogenous suspension. Pipette 200µl to 400µl of **Liqui-PREP® Cellular Base Solution** into a "Working Tube" test tube. Aspirate 50µl of the well mixed cell suspension into the "Working Tube". Mix the "Working Tube" and aspirate 50µl from the "Working Tube" and apply it to a microscope slide. Dry, stain and read.

STABILITY:

- **Liqui-PREP® reagents**, stored properly, are stable until the labeled expiration date.
- Specimens collected in the **Liqui-PREP® Urine Preservative Solution** are stable for 60 days at 10° to 30°C.
- Store kit at 10° to 30°C and out of direct sunlight.

Materials Required But Not Provided

- Centrifuge - Swinging Bucket Model; capable of 1,000xg with both 50ml and 15ml tube adapters
- Vortex Mixer
- Pipettor (capable of dispensing 50 to 500µl) and Pipette Tips
- High quality, clean Microscope Slides
- 15ml Centrifuge tubes
- 50ml Centrifuge tubes
- Small test tube - if using the "Working Tube" method of encapsulation.

**PRODUCTS:
& AVAILABLE KITS**

| Quantity | Liqui-PREP® Urine Preservative Solution | | Liqui-PREP® Cellular Base Solution | Liqui-PREP® Microscope Slides |
|----------|---|-----------------------------|--|-------------------------------------|
| | 50 Cups (55ml Fill) | 4 Bottles (3,750ml Fill) | 1 Bottle (10ml Fill) | 1 Box (100 Slides) |
| 35-0050 | ✓ | | ✓ | |
| 35-0055 | ✓ | | ✓ | ✓ |
| 35-0100 | | ✓ | | |

WARNINGS: **Liqui-PREP®** Specimen Preservative Fluid contains a dilute mixture of denatured ethanol. It is not intended for human consumption.

Liqui-PREP® Urine Cytology

Processing Procedures



SPECIMEN COLLECTION:

Collection:

- Urine is collected from the patient in a urine cup with lid.
- Thoroughly mix the specimen.
- Pour off excess urine and retain approximately 50ml.

OR

- Add approximately 55ml of the **Liqui-PREP® Urine Preservative Solution** into the urine specimen cup. Cap tightly, mix and store out of direct sunlight at room temperature.
- Transport to the lab for further processing.

SPECIMEN PREPARATION:

- Mix the **Liqui-PREP®** preserved urine specimen well and pour approximately 50ml into a 50ml conical centrifuge tube.
- Centrifuge the 50ml centrifuge tube at 1,000xg for approximately 10 minutes.
- Decant the supernatant.
- Add the remaining **Liqui-PREP®** preserved urine specimen into the same 50ml conical tube.
- Centrifuge the 50ml centrifuge tube at 1,000xg for approximately 10 minutes.
- Decant the supernatant and mix well before rinsing into a 15ml centrifuge tube.
- Using either **Liqui-PREP® Urine Preservative Solution** or **Liqui-PREP® Preservative Solution** to rinse the resulting cellular pellet into a 15ml conical centrifuge tube.

SPECIMEN CLEANING AND/OR CONCENTRATION:

The concentrated urine cellular pellet suspension in the 15ml centrifuge tube is centrifuged at 800xg for approximately 10 minutes. Decant the supernatant, resulting in a preserved cellular pellet ready for encapsulation.

CELLULAR ENCAPSULATION AND SLIDE PRODUCTION:

There are two methods for encapsulating the urine cells.

Direct In-Tube Encapsulation: (cellular pellet very small <50µl) (**REFLEX Testing can not be performed on these specimens**)

- Pipette 50µl to 100µl of **Liqui-PREP® Cellular Base Solution** directly onto the cell pellet at the bottom of the centrifuge tube.
- Mix the specimen using a vortex
- Pipette 50µl onto a microscope slide. Use the pipette tip like a paint brush to spread the drop in a circle **or** hold the tip above the microscope slide and rapidly expel the 50µl on to the slide. (vortex the centrifuge tube immediately prior to making each slide).
- Allow the slide to dry, then stain and read the slides.

“Working Tube” Encapsulation: (cellular pellets over 50ul) (**This is the best method for having a cellular pool for REFLEX Testing**)

- Mix the cellular pellet well to produce a homogeneous suspension.
- Pipette 200µl to 400µl (based on pellet size) of **Liqui-PREP® Cellular Base Solution** into a small test tube (“Working Tube”)
- Aspirate 50µl of the well mixed cellular pellet and deliver the aliquot to the “Working Tube”.
- Mix the Working Tube Well.
- Pipette 50µl from the Working Tube onto a microscope slide. Use the pipette tip like a paint brush to spread the drop in a circle **or** hold the tip above the microscope slide and rapidly expel the 50µl on to the slide. (vortex the centrifuge tube immediately prior to making each slide).
- Allow the slide to dry.
- Stain, and read the slides.

NOTES:

- Encapsulated Cells are NOT available for use in REFLEX testing because the encapsulation does not allow exposure to cellular components.
- If REFLEX Testing is needed and going to be performed, use the “Working Tube” Encapsulation. **The residual cellular suspension in the 15ml centrifuge tube** has clean preserved cells that were not encapsulated and **can** be used for REFLEX Testing.
- The processed, dried **Liqui-PREP®** cytology slide is stable for up to 48 hours at ambient room temperature, prior to staining.
- Staining may need to be optimized (i.e. Staining times may need to be shortened due to the effects of encapsulation and fixation)
- Storage of residual cells after processing:
 - “Working Tube” Encapsulation: Storage of the residual cells in the 15ml centrifuge tube may be accomplished by Pipetting 2-3ml of **Liqui-PREP® Preservative Solution** into the 15ml centrifuge tube. Seal the centrifuge tubes with parafilm and/or a lid to reduce evaporation. Store at room temperature or between 10° to 30°C.
 - Direct In-Tube Encapsulation: These specimens can be stored for up to 12 hours by immediately sealing the centrifuge tube with parafilm and/or a lid to prevent drying. These specimens should **not** be used for REFLEX Testing.
- Visit www.liquiprepreagents.com for Technical Tips or other frequently asked questions.

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All Liqui-PREP® reagents are manufactured under an audited ISO 13485:2016 Quality System.
LGM International, Inc.'s Quality Management System is certified to ISO 13485:2016 by Orion Registrar, Inc.

**CLASS 1
REGISTRATION**



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