COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER # 26

Urinalysis

INTRODUCTION

Urinalysis is a common examination which normally includes three parts:

1. Visual Evaluation
2. Chemical Analysis
3. Microscopic Examination

SPECIMEN COLLECTION AND HANDLING

A properly collected urine specimen is crucial for accurate results. A freshly voided random specimen is acceptable for a routine urinalysis. Specimens should be collected in a clean dry container with a tight fitting lid, and detailed instructions for proper urine specimen collection should be given to the patient and posted in the bathroom. All specimens must have two patient identifiers on the collection cup, either handwritten or with a patient label. Never label the lid with the patient information as the lid will be removed during specimen handling and testing, leaving the specimen itself with no identification.

If a freshly voided urine specimen cannot be tested within 2 hours, it will need to be refrigerated. Prolonged storage at room temperature contributes to bacterial overgrowth, decomposition of formed elements, and chemical changes that can alter dipstick and microscopic results.

Please note that if a urine culture is also ordered, then a **sterile container** must be used for collection and specimens for culture should be collected by the clean catch method. Any sterile sampling of the specimen for culture purposes should be done prior to sampling the specimen for urinalysis, to prevent contamination of the specimen prior to culture.

VISUAL EXAMINATION

For a visual examination, the color and clarity of the specimen are assessed and recorded.

DIPSTICK OR CHEMICAL ANALYSIS

A chemical analysis is usually performed using urine test strips covered in reagent test pads. Analytes tested usually include pH, specific gravity, protein, glucose, ketones, bilirubin, urobilinogen, hemoglobin, leukocyte esterase, and nitrites. These test strips must be stored in the original packaging according to the manufacturer's instructions. Room temperature and humidity monitoring may be required to ensure proper storage conditions. Always recap the container after removing test strips. These test pads are susceptible to light and moisture damage, which can lead to inaccurate test results. Always date the bottle when it is opened, and note that the manufacturer's stated expiration date for the strips may change once the bottle has been opened: if this is the case, write the new expiration date on the open bottle

and do not use the test strips after the expiration date. Always check the manufacturer's instructions for specific storage and shelf life.

WAIVED DIPSTICK METHODS

Visual interpretation of urine test strips – manually comparing the test pads to the printed key on the bottle label – is a CLIA-Waived test. Some automated test strip readers are also classified as Waived. For Waived readers, you must follow all manufacturer's instructions for use and perform quality control as stated in the package insert. Note that the quality control ranges can vary between different lots of test strips; always check the ranges when starting new lots of test strips.

Perform and document required maintenance on the instrument, according to the instrument's user manual.

NON-WAIVED DIPSTICK METHODS

For non-Waived (Moderate Complexity) automated strip readers, the performance of the test system must be verified prior to patient testing. This can be done by testing known normal and abnormal control materials; please see COLA Primer 13 on Verifying Performance Specifications for more detail about this process.

Follow all manufacturer's instructions for use of the strips and reader, performance of controls (type, number, and frequency) and any confirmatory procedures. Record quality control results daily and ensure they are in range prior to performing patient testing. Out of range results require documented corrective action. Perform and document required maintenance on the instrument, according to the instrument's user manual.

MICROSCOPIC EXAMINATION

While the chemical analysis of urine can give some indication of a potential problem, microscopy allows for a deeper urine analysis, which can help diagnose the patient.

In microscopy, a urine specimen is centrifuged to obtain some sediment, which can then be examined for the presence of crystals, casts, blood cells, or microorganisms. It is good practice for a laboratory to have a photographic atlas to use as a reference during microscopic examination of urine sediment.

Some of the basic steps are as follows:

Start with a well-mixed specimen that is fresh or has been adequately preserved.

• Spin 10 to 15 ml of specimen in a conical tube. The spin time and centrifugal force should be established and written into your procedure. Consult the manufacturer of your centrifuge for recommendations.

• After the urine is centrifuged, pour off the excess supernatant, leaving about 0.5 to 1.0 ml of urine. Gently re-suspend the sediment and perform the microscopic exam using a drop of this sediment under a coverslip.
• Observe at least 10 fields under low (10x) power. Scan for casts, especially around the edges of the coverslip. Have an atlas available to aid in identification of casts. Report your results as an average from fields examined per low power field (lpf). **Your procedure manual should specify how your lab will quantitate and report casts.

**NOTE When observing the slide under low power, a low light source should be used. Cellular and crystalline elements are difficult to resolve in bright light.

• Observe approximately 20 fields under high (40x) power for cells, crystals, etc. Refer to your atlas for their proper identification. Report your results for each formed element as an average range from fields examined per high power field (hpf). These can be reported as 0-2/hpf, 2-5/hpf, 5-10/ hpf, etc. Your procedure manual should specify how you quantitate these elements.

Be consistent in reporting semi-quantitative results for elements such as bacteria or mucus, where an actual number per field is not reported. The terms rare, few, moderate, many, or 1+, 2+, 3+, 4+ are often used, and your procedure manual should specify how your lab will quantify these elements.

Compare microscopic results with other urine findings, such as appearance, specific gravity, and dipstick results. If there is not a good correlation, recheck the specimen. However, there are instances when dipstick results may not correlate with what is found under the microscope. For example, the dipstick may read as 4+ blood, and there will be little or no RBCs found microscopically. This may be due to the specimen having a high pH or not being fresh. RBCs can disintegrate and release hemoglobin into the specimen causing free hemoglobin to be detected on the dipstick, while intact RBCs are not seen microscopically.

QUALITY CONTROL

Some form of quality control is required for the preparation and examination of urine sediment. The laboratory is required to have procedures that detail how accuracy and precision will be monitored. Commercial liquid QC material is available for purchase. If purchasing QC material is not an option, the laboratory must implement other means of assuring the quality of the test. Other examples of quality control for urine microscopics that can be used are:

- Use of standardized systems for specimen preparation and microscopic examination such as KOVA and UriSystem.
- Maintenance and upkeep of the microscope.
- Availability of reference slides or photographic atlas at the bench.
- Proficiency testing.

- Centrifuge maintenance and RPM checks.
- Routine competency assessment.
- Have a second person confirm results.

PROFICIENCY TESTING OR SPLIT SAMPLE REQUIREMENTS

All moderate complexity tests require either proficiency testing (PT) enrollment or regular split sample testing with another laboratory. If your urinalysis test system is Waived, then this is not required, but COLA recommends proficiency testing for all tests, as good laboratory practice.

Urinalysis, including microscopic examination of urine sediment, are *unregulated* tests, which means split sample analysis is theoretically acceptable in lieu of proficiency testing enrollment; however, urine specimens are labile in nature and impractical to split between laboratories for comparisons. Formed elements degrade quickly and chemical composition changes upon storage and transport, making lab-to-lab comparisons very difficult. Proficiency testing modules are available for urinalysis, and COLA recommends that laboratories perform PT rather than perform split-sample testing.

If the laboratory chooses not to enroll in PT, then some type of internal comparison to assure the accuracy and reliability of results for this test must be performed. A minimum of 5 comparisons, twice a year, would be acceptable along with a written procedure, acceptable scoring, and corrective actions to be taken in the event of failures. All documentation for proficiency testing, split sample testing or internal comparisons must be maintained.

See COLA Primer 9 for more information on split-specimen testing or internal comparisons.