



Technical Bulletin

North Carolina State Laboratory of Public Health | Laboratory Improvement Unit

Testing at a Glance: Urinalysis

Urinalysis Testing

A routine urine chemistry test with a reagent test strip is a fast, simple and inexpensive tool used to aid in the diagnosis of many medical conditions or diseases related to carbohydrate metabolism, urinary tract health, kidney disease and pregnancy related disorders.

For the urine chemistry test to be accurate and reliable, good quality control (QC) and quality assurance (QA) must be in place that complies with CLIA regulations and manufacturer's instructions.

Policies must be in place that address both the laboratory and manufacturer's requirements for specimen type, collection method, proper labeling and transporting. Procedures must follow manufacturer's guidelines for QC, environmental conditions and step-by-step instructions on how to perform the test.

Urine chemistry analyzers have helped to standardize the test. The type of analyzer used in the laboratory should be determined by the FDA classification of the instrument and the type of CLIA certificate under which the laboratory is operating.

Urine Chemistry Reagent Strips

Urine chemistry reagent test strips are classified as a waived test and provide qualitative and semi-qualitative detection of the following analytes: leukocytes, nitrite, urobilinogen, protein, pH, blood, ketones, bilirubin, glucose and specific gravity. The strips are designed for single use and can be used in a centralized laboratory or for point of care testing. Test strip results, along with other diagnostic testing, can be used to screen patients for diseases such as diabetes, urinary tract infections (UTI), kidney disease and pregnancy related disorders. As with all waived tests, procedure and QC requirements can be referenced from the manufacturer's package inserts.

Test strips can be read manually (visually) or with a compatible urine chemistry analyzer.

Clinical Significance of Urine Chemistry

A routine urine chemistry test can have clinically relevant information that can be used to screen for the following diseases or conditions:

- **Urinary tract infection (UTI)**
 - Nitrite - detects nitrate reducing Gram negative bacteria
 - Leukocytes - detects leukocyte esterase found in white blood cells
 - Protein - may indicate damage to urinary tract
 - pH - high alkaline if UTI is present
- **Kidney Disease**
 - Protein - detects the presence of proteinuria possibly caused by kidney damage
 - Leukocytes - indicator of a UTI that can lead to kidney damage
 - Blood - may indicate damage to kidneys
- **Diabetes**
 - Glucose - may detect undiagnosed diabetes
 - Ketones - May detect early ketoacidosis in diabetics
- **Pregnancy related disorders**
 - Glucose - may indicate gestational diabetes
 - Protein - may indicate pre-eclampsia during pregnancy

As with any laboratory test, a diagnosis or treatment should not be based on one single test result or method.

Urine Chemistry Analyzers

Urine chemistry analyzers read every test the same way every time. This standardizes the testing of urine chemistry by eliminating variables from one testing personnel to another. Using a urine chemistry analyzer will reduce transcription errors and increase productivity. Most analyzers read and print results in minutes.

There are two types of urine chemistry analyzers—automated and semi-automated. Both types use the principle of percent reflectance to determine the concentration of the measured analyte. When a particular analyte is present at or above the level of detection, a chemical reaction occurs and causes a color change on the dipstick pads. The color change is proportional to the concentration of the analyte. At specific time intervals, light is transmitted at a particular wavelength and depending on the concentration of the analyte measured, some light will be absorbed and some will be reflected. The reflected light is measured at specific wavelengths and concentration calculations are reported.

- **Automated chemistry analyzers** – Hands-off operation. These analyzers mix the specimen, transfer the specimen to the testing strip and determine specimen color, clarity and specific gravity using a refractometer.
- **Semi-automated chemistry analyzers** – Hands-on operation. The operator must manually dip the urine strip into the urine and place on the urine dipstick reader.

When a laboratory is considering purchasing an analyzer, they need to pay close attention to the FDA testing complexity classification and choose an analyzer that is appropriate for their laboratory's CLIA certificate type. For example, if the laboratory has a CLIA certificate of waiver, they will need to choose an analyzer that is FDA classified as waived.

Specimen Types and Collection Methods

A urine chemistry test is only as good as the specimen collected. No matter how well trained the testing personnel are at performing the test, improperly collected specimens or incorrect specimen types can cause invalid or erroneous results. The laboratory must have policies and procedures in place that state the collection method and specimen type based on manufacturer's recommendations and purpose of test. Specimen types include:

- **Random urine** – urine collected at any time of the day. It is the most common and easiest to collect. However, it can be the least concentrated specimen and is associated with the most false negatives.
- **First morning** – the specimen voided immediately in the morning before breakfast and other activities. It is the most concentrated urine and is the best specimen to test for nitrite and protein.

- **Postprandial** – a specimen collected 1-2 hours after a meal. This is the best specimen for testing glucose.

Mid-stream, clean-catch urine is the most common collection method and is the specimen of choice for determining UTIs.

Regardless of the specimen type or collection method, the specimen must be sent to the laboratory in a timely manner for testing.

Summary

A urine chemistry test is a fast and inexpensive way to screen patients for diabetes, UTIs, kidney disease and pregnancy related disorders. Reagent strips can be read manually or with an automated or semi-automated analyzer. Using a urine analyzer standardizes the test and is the preferred method of choice for reading the test strips. When purchasing a urine analyzer, a laboratory needs to pay close attention to the FDA complexity classification of the analyzer. The type of analyzer used to read the waived reagent test strip can change the complexity of testing from waived to moderate complexity.

April Hill, BS, MLS (ASCP)^{cm}

References

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