URINOX-10

URINALYSIS TEST STRIPS

Instruction Manual

Diagnox

ABOUT THE PRODUCT

Urinox™–10 Urinalysis Test strips by DIAGNOX®, are multiparameter urine reagent dipstick tests (UA tests) that check ten different parameters in urine. These CLIA-waived urine test strips are intended for qualitative and semi-quantitative analysis of urine parameters as an aid for diagnosing various health conditions, such as kidney function, liver health, Urinary Tract Infections (UTIs), and various systematic and metabolic diseases.

Individual packing of each test strip ensures that each strip is fresh and not altered by atmospheric conditions so that you get a reliable result every time. The strips can be read visually or automatically by a machine.

ABOUT URINALYSIS

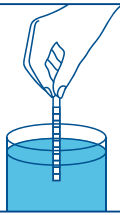
A urinalysis is a test of urine. Urine is produced by the kidneys. Kidneys filter wastes out of the blood, help regulate the amount of water in the body and conserve proteins, electrolytes, and other compounds that the body can reuse. Therefore, by examining the composition of urine, many disorders can be detected.

Urinox–10 Urinalysis Test strips are lined with ten different reagent test pads that change color in response to the chemical characteristics of the urine and can help in the general monitoring of health as well as the detection of a broad spectrum of abnormalities. This is the same kind of test medical professionals use to assist in diagnosis.

DIRECTIONS FOR USE

Start with a freshly collected urine sample in a clean, dry container. Tear open the sealed bag and remove the strip. Hold the strip without touching the test pads.

1



IMMERSE

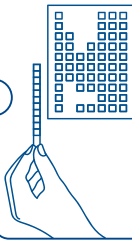
Immerse the strip into the urine sample and remove it immediately by dragging the edge of the strip against the container rim to remove excess urine. If reading the strip visually, start timing.

2

WAIT

Remove excess urine by blotting the side of the strip on a paper towel. Place the strip horizontally on a paper towel. Wait until the results are ready to be read. The first test is ready in 30 seconds.

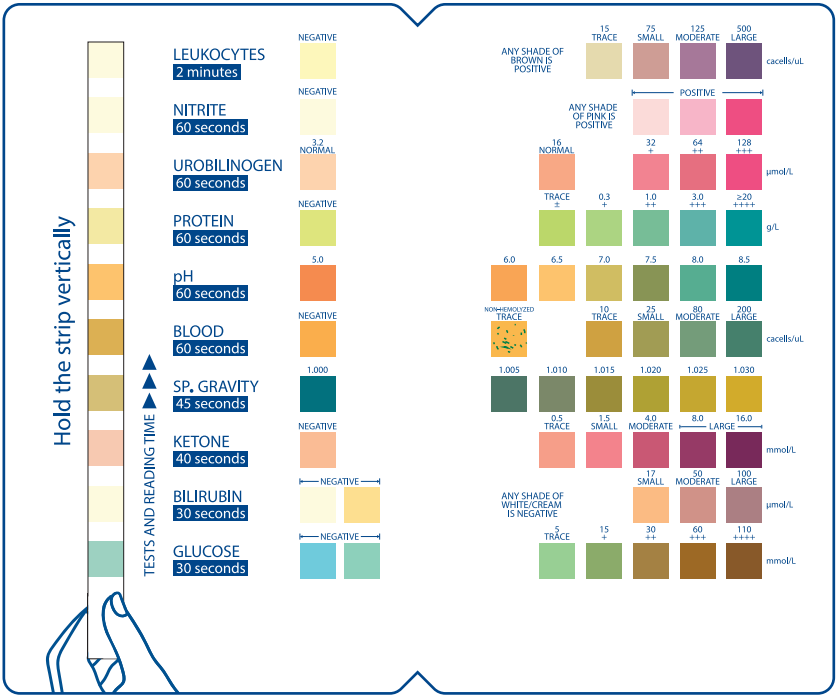
3



COMPARE

Compare the color of each test pad to the corresponding row of color blocks on the color key to find the closest match. Read the results carefully at the time listed for each parameter in a good light. The color changes that appear after two minutes are of no diagnostic significance.

COLOR KEY



STORAGE & HANDLING

- Store in a dry place at 2–30°C (36–86°F). Do not freeze. Keep out of direct sunlight.
- The strip should remain in the sealed pouch until use.
- Long-term exposure to air may cause inaccurate readings.
- Do not use if the pouch is torn or damaged.
- Do not touch the test pads of the strip.
- Discard any discolored strips that may have deteriorated.

INSTRUCTIONS

Please read all the information in this package insert before performing the test.

- For urine testing only.
- Do not use for blood testing.
- The used strip should be discarded according to local regulations after testing.
- Keep out of the reach of children.
- Do not use after the expiration date.
- For in vitro diagnostic use. Not to be taken internally.

INTERPRETATION OF RESULTS

LEUKOCYTES

Leukocytes (white blood cells) are the cells of the immune system that protect the body against both infectious diseases and foreign invaders. A few white blood cells are normally present in urine and generally yield negative results. When the number of WBCs in urine increases significantly, this screening test will become positive. The presence of leukocytes (>10 cacells/µL) in urine may indicate inflammation or infection in the urinary tract or kidneys.

NITRITES

Normal urine contains chemicals called nitrates. If bacteria enter the urinary tract, nitrates can turn into different, similar named chemicals called nitrites. Nitrites in urine may signify bacteria in urine (bacteriuria) and a urinary tract infection (UTI). To detect UTI, the presence of Leukocytes in urine is also considered. UTI can be present despite a negative Nitrite test.

UROBILINOGEN

Urobilinogen is formed from the reduction of bilirubin. Bilirubin is a yellowish substance found in the liver that helps break down red blood cells. Normal urine contains some urobilinogen (up to 1.0 mg/dL). If there is little or no urobilinogen in urine, it can mean the liver isn't working correctly. Too much urobilinogen (> 2 mg/dL) in urine may indicate a liver disease such as hepatitis or cirrhosis.

PROTEIN

A protein in urine test measures how much protein is in your urine. Proteins are substances that are essential for the body to function properly. Protein is normally found in the blood. If there is a kidney problem, protein can leak into the urine. While a small amount occasionally is normal, a large amount of protein in the urine may indicate kidney disease. When urine protein is elevated, a person has a condition called proteinuria. Persistently elevated protein levels in urine can result from urological and nephrological disorders and require medical intervention.

PH

A urine pH test measures the level of acid in urine. Normal urine is slightly acidic, with pH values ranging from 5 to 8. Urine under 5.0 is acidic, and urine higher than 8.0 is alkaline. A high urine pH (>8) may be due to UTI, kidney stones/failure, stomach pumping, or vomiting. A low urine pH may be due to strong diabetic ketoacidosis, diarrhea, too much acid in the body fluids (metabolic acidosis), or starvation. One of the major factors affecting urine pH is diet. A diet high in fruits and vegetables can increase your urine pH, while a diet high in meat products or cheese can decrease your urine pH. Certain medications can also alter normal urine pH.

BLOOD

Blood in the urine is not a normal finding, but it is not uncommon and not necessarily a cause for alarm. Your healthcare practitioner

will investigate further to determine the underlying cause. It may be a sign of kidney damage, infection, kidney or bladder stones, kidney or bladder cancer, or blood disorders. Blood is often, but not always, found in the urine of menstruating females.

SPECIFIC GRAVITY

The urine specific gravity is a measure of the concentration of all chemical particles in the urine. Healthy adults have urine specific gravity ranging from 1.003 to 1.030. Reduced specific gravity may indicate diabetes or other renal disorders, while elevated levels may be due to liver disease, excessive loss of free water, or congestive heart failure. A higher-than-normal concentration often is a result of not drinking enough fluids.

KETONES

Ketones are produced when the body burns fat for energy or fuel. They are also produced when you lose weight or if there is not enough insulin to help your body use sugar for energy. Ketones are not normally found in the urine. They can form when a person does not eat enough carbohydrates (for example, in cases of fasting, starvation, or high-protein diets) or when a person's body cannot use carbohydrates properly. When carbohydrates are unavailable, the body metabolizes fat to get the energy it needs to keep functioning. Diabetes, starvation, vomiting, digestive disorders, pregnancy, and febrile states can result in increased ketone levels in the urine. If you are on a ketogenic diet, ketones in the

urine indicate a metabolic state called ketosis, which is desirable for weight loss and fat burning.

BILIRUBIN

Bilirubin is a yellowish pigment found in bile, a fluid produced by the liver. Bilirubin is not present in the urine of healthy individuals. Increased bilirubin levels indicate different forms of liver disease, e.g., cirrhosis, hepatitis, gallstone, and biliary tract disease, and are an early indicator of jaundice development. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.

GLUCOSE

Glucose is normally not present in urine. When glucose is present, the condition is called glucosuria. This often happens if abnormally high glucose levels are present in the blood. The normal glucose range in urine is 0 to 0.8 mmol/L (0 to 15 mg/dL). Higher values may occur with diabetes, pregnancy, or renal glycosuria.

This information is not a substitute for professional medical advice, clinical diagnosis, or treatment.

SCAN THIS BARCODE WITH YOUR PHONE'S CAMERA TO READ IN DETAIL ABOUT EACH URINE PARAMETER AND HOW IT AFFECTS YOUR HEALTH.

ABOUT DIAGNOX

We believe that promoting and sharing knowledge is a form of care. With this mission, we make it easy for people to take charge of their own health.

Listen to your body and get to know yourself to own yourself.

Being the protagonist of your well-being is having information at the palm of your hand. With that in mind, we provide innovative health tests that provide accurate results along with simple-to-understand information and all the support needed for you to connect the dots and be aware of your health. After all, good decisions come from good information.

It is knowledge from the inside out that guides us to look after ourselves and others around us, raising awareness for better health for all.

Diagnox
Care to Know. Know to Care.

QUESTIONS?

For questions, please contact us at:
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