Urine 1-10 parameters
REF:
Urine-2GK: **Glucose and Ketones**
Urine-2GP: **Glucose and Protein**
Urine-3: **Protein, pH and Glucose**
Urine-4SG: **Protein, Glucose, Specific Gravity and pH**
Urine-10: **Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Nitrite and Leukocytes**

100 tests

IVD

Store at 2 - 30ºC

CYPRESS DIAGNOSTICS

CE

URINE 1 – 10 PARAMETERS

Reagent strips for urinalysis

Intended use

Reagent Strips for the rapid determination of Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic Acid), Specific Gravity, Blood, pH, Protein, Nitrite and Leukocytes in urine. These instructions describe all the tests using CYPRESS DIAGNOSTICS reagent strips. The combination of the test items differs per product.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

CYPRESS DIAGNOSTICS Urine Strips are dip-and-read test strips for testing the above items in urine. The test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection.

Principle

The urine strip contains different test pads, each of them with different reagents for testing a specific item in the urine. Depending on the concentration of the item in the urine, a different color will be obtained. The items are measured by comparing the formed color on the pads with the color chart blocks printed on the vial label. The strips may be read visually. They can also be read instrumentally, using CYANStrip or CYANStrip Mini Analyzers.

Kit composition

Each kit contains the items to perform 100 tests:
- 100 strips in a bottle with desiccant
- 1 instruction leaflet

The test pads contain the following reagents:
Urobilinogen: The test is based on the Ehrlich's reaction. The color changes from white to dark pink.
Ingredients: 4-Methoxybenzenediazonium 2,9mg
Glucose: Glucose oxidase catalyzes the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the test pad by the action of peroxidase. The color changes from blue to dark brown.
Ingredients: Glucose oxidase 430U, Peroxidase 200U, Potassium Iodide 12mg
Bilirubin: The test is based on an azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. The color changes from light tan to beige or light pink.
Ingredients: Sodium nitrite 0,733 mg, 2,4-dichlorobenzene diazonium 2,3mg, Sulfosalicylic acid 25mg
Ketones: The test is based on a Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricanide to produce a color change from beige to purple.
Ingredients: Sodium nitroprusside 23,0mg
pH: Double indicator system. Indicator's methyl red and bromothymol blue are used to give distinct color changes from orange to green to blue. (pH 5,0 to 9,0).
Ingredients**:** Methyl red 0.05mg, Bromothymol blue 0,5 mg
Blood: The test is based on the Pseudo-peroxidase activity of the haem moiety of hemoglobin and myoglobin. The chromogen is oxidized by hydroperoxide in the presence of haem and changes color from yellow (or greenish yellow) to blue.
Ingredients: Cumene Hydroperoxide 12mg, o-Tolidine 35 mg
Specific Gravity (SG): Ionic solutes present in the urine cause protons to be released from a polyelectrolyte. As the protons are released, the pH decreases and produces a color change of bromothymol blue from blue-green to yellow-green.
Ingredients: Bromothymol blue 0,5 mg, Polyvinyl ether-ALT-maleic acid anhydrous 140,5 mg
Protein: Protein "error of indicators." When the pH is held constant by a buffer, the indicator dyes release H^+ ions because of the protein present and change color from yellow (or greenish yellow) to blue-green.
Ingredients**:** Tetrabromophenol blue 0,34 mg
Nitrite: The test is based on the diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the test pad. The azo dye produced causes a color change from white to pink.
Ingredients**:** P-arsanilic acid 4,5 mg
Leukocyte: This test pad contains an indoxyl ester and diazonium salt. It induces an azo-coupling reaction of the aromatic amine formed by leukocytes esterase with a diazonium salt on the test pad. The azo dye produced causes a color change from beige to violet**.**
Ingredients: Induced Indole amino acid ester 1,3 mg

Preparation

The strips are ready for use.

Storage and stability

Store in a cool, dry place at temperatures between 2°C ~ 30°C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. When stored in the original bottle, the product is stable up to the expiry date printed on the label and (or) vial box.
Reseal the bottle cap immediately and tightly after removing test strips, and keep the vial tightly closed between tests. Do not remove desiccant from the bottle. Do not touch test areas of urine reagent strips. Do not open the bottle until ready to use.
Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with the expected finding, confirm that the product is within its expiry date and is reacting properly using known negative and positive control materials. Do not use after the expiry date. Note that once the bottle has been opened, the remaining strips remain stable for up to 6 months.

Additional materials required but not provided

- Timer
- Sample collection container

Precautions

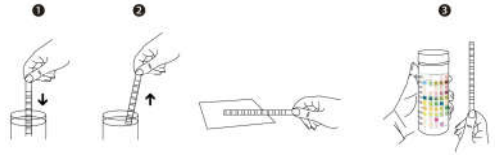
- The strip is intended for single use. Do not reuse.
- Keep away from sunlight.

Samples

Collect urine in a clean, dry container that allows a complete immersion of all the fields on the test strip. Do not add preservatives. Test the sample as soon as possible, with the sample well mixed but not centrifuged. The use of fresh morning urine is recommended for optimal nitrite tests, as well as for the valid determination of bilirubin and urobilinogen, since these compounds are unstable when exposed to light. If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before use in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination. Voided samples from females that are not collected cleanly, may give positive results for leukocytes due to contamination from outside the urinary tract. Skin cleansers containing chlorhexidine may affect protein test results if sample contamination occurs.

Visual test procedure and interpretation of the results

The procedure must be followed exactly to achieve reliable results**.** Do not compare strips with the color chart before the strip is dipped in urine.
1) Dip the strip into the urine up to the test area for no more than two seconds.
2) Draw the edge of the strip along the brim of the vessel to remove the excess urine. At this time, don't make the test areas touch the brim of the vessel.
Turn the strip on its side and tap once on a piece of absorbent material to remove any remaining urine. Excessive urine on the strip may cause the interaction of chemicals between adjacent reagent pads, so that an incorrect result may occur.
3) Compare the colors of the test pads after exactly 60 seconds (leukocytes after 90~120 seconds) with the color chart on the vial label under good light. While comparing, keep the strip horizontally to prevent possible mixing of chemicals when excessive urine is present.



Remark:
The strips can also be read instrumentally, using CYANStrip or CYANStrip Mini Analyzers. If using an instrument, refer to the appropriate instrument manual for detailed instructions.

Quality control

For best results, performance of reagent strips should be confirmed by testing known negative and positive sample or controls (e.g., **Quantimetrix** Dipper Urine Dipstick, Dropper Urine Dipstick, Dip&Spin Urine Dipstick; **Bio-Rad** qUAntify Plus Control; **Thermo SCIENTIFIC** MAS UA Control) whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that he complies with government and local requirements.

Reference values

Urobilinogen: The normal urobilinogen range is 0,1 to 1,0 Ehrlich unit /dl (0,1 to 1,0 mg/dl). If results exceed the concentration of 2,0 Ehrlich unit /dl (2,0 mg/dl), the patient and the urine sample should be evaluated further.
Glucose: The kidney normally excretes small amounts of glucose. Concentrations of 100 mg/dl may be considered as abnormal if found consistently.
Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.
Ketones: Ketone bodies should not be detected in normal urine samples with this reagent.
pH: Urine values generally range from pH 5 to 9.
Blood: Normally, no hemoglobin is detectable in urine (0,010 mg/dl; 3 RBC/µl). When hemoglobin appears in urine it indicates a kidney disease or a urinary tract disorder. Blood may often be found in the urine of menstruating females.
Specific Gravity (SG): The normal SG of urine ranges from 1,001 to 1,035.
Protein: Normal urine samples ordinarily contain some protein (<20 mg/dl). Therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace levels or higher indicate significant proteinuria and thus further clinical testing is needed to evaluate the significance of the results.
Nitrite: Normally no nitrite is detectable in urine.
Leukocyte: Normally no leukocytes are detectable in urine**.**

Limitations of the test

Clinical diagnosis should not be made on a single test result. It should integrate clinical and other laboratory data.
Substances that cause an abnormal urine color may affect the readability of test pads in urinalysis reagent strips.
Urobilinogen: The absence of urobilinogen in the sample cannot be determined. The test area will react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid. Drugs containing azo-gantrisin may give a masking golden color. The test is not a reliable method for the detection of porphobilinogen.
Glucose: High SG (>1,020) with high pH urine and ascorbic acid (more than 40mg/dL) may cause false negative results at low levels of glucose. Ketones reduce the sensitivity of the test. Moderately high ketone level (> 40 mg/dl) may cause a false negative for samples containing small amount of glucose (100 mg/dl). Reactivity may be influenced by urine SG and temperature.
Bilirubin: Metabolites of drugs, such as pyridum and selenium, which give a color at low pH, may cause false positives. Indican (indoxyl sulfate) can produce a yellow-orange to red color response, which may interfere with the interpretation of negative or positive bilirubin readings. Ascorbic acid (> 30 mg/dl) may cause false negative results.
Ketones: Positive results (trace or less) may occur with highly pigmented urine samples or those containing large amounts of levodopa metabolites. Some high SG and low pH urine may give false positive results. Phenosulfonphthalein may cause false positive results.
pH: If excessive urine remains on the strip because of an improper test procedure, it is possible that the acidic buffer in the protein portion comes out and affects the pH portion. Then, the pH result may be lowered. This phenomenon is called "run-over effect."
Blood: Elevated specific gravity or protein in urine may reduce the reactivity of the blood test portion. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations (>30 mg/dl) may cause false negatives at low concentrations of blood.
Specific Gravity (SG): High-buffered alkaline urine may cause diminished result, whereas high-buffered acidic urine may cause slightly elevated results.
Protein: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine samples.
Nitrite: Ascorbic acid (>30 mg/dl) may cause false negative result with urine containing a low level of nitrite (< 0,03 mg). The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as a positive result. Negative results may occur when urinary tract infections are caused by organisms which do not contain nitrate reductase, when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite occur, or when dietary nitrate is absent.
Leukocyte: The test result may not always be consistent with the leukocyte cell number found by microscopic examination. High concentration of glucose, high specific gravity, high level of albumin, high concentration of formaldehyde or presence of blood may cause decreased test results. False positive results may occasionally occur due to contamination of the sample by vaginal discharge.

Performance characteristics

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of color perception, the presence or absence of inhibitory and matrix factors typically found in urine and the laboratory conditions in which the product is used (e.g., lighting, temperature and humidity). Each colour block represents a range of values. Because of sample and reading variability, samples with analyte concentrations that fall between normal levels may give results at either level. Results will usually be within one level of the true concentration. The following list shows the generally detectable levels of the analytes in contrived urines. However, because of the inherent variability of clinical urines, lower concentrations may be detected under certain conditions.

Test pad sensitivity (specificity)

Urobilinogen: 2 mg/dl (2 Ehrlich unit /dl, Urobilinogen)
Glucose: 100 mg/dl (Glucose)
Bilirubin: 1 mg/dl (Bilirubin)
Ketones: 5 mg/dl (Acetoacetic acid)
Blood: 10 RBC/µl (0,03mg/dL hemoglobin, intact RBC)
Protein: 15 mg/dl (Albumin)
Nitrite: 0,05 mg/dl (Nitrite ion)
Leukocytes: 20-25 WBC/µl (Intact and lysed WBCs)

Bibliography

1. NCCLS (National Committee for Clinical Laboratory Standard) GP 16-A/ Routine urinalysis and collection transportation and preservation of urine specimens, Tentative guideline vol 12, no 26, ec 1992

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Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium • www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be