

The DUS Health Screening Test strips are plastic strips onto which several separate reagent pads are affixed. The strips are intended for testing urine in the home for Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic Acid), Specific Gravity, Blood, pH, Protein, Nitrite and Leukocytes.

READ INSTRUCTIONS COMPLETELY BEFORE USING THE TEST

SUMMARY

Urine testing is a useful procedure as an indicator of health or disease as the composition of urine can change markedly when a wide variety of diseases or infections are present. Because urine testing is simple to carry out, it can be part of routine health screening in the home. The DUS Health Screening Test can be used to give a general indication of health and helps in the detection of diseases and infections that can affect the kidneys, urinary tract, liver and heart. The pack contains six strips so that routine testing can be carried out at regular intervals.

PRINCIPLE AND EXPECTED VALUES

Nitrite: Nitrite is not detectable in normal urine. Positive nitrite can be indicative of urinary tract infection.
Protein: Up to 14 mg/dL of protein may be excreted by a normal kidney. Higher than normal levels of protein in urine may indicate a variety of disorders including diseases of the kidney and urinary tract. In older patients, high protein levels may occasionally indicate heart problems.
Urobilinogen: Urobilinogen is normally present in low concentrations in urine. High levels of urobilinogen can indicate liver disease or conditions associated with increased breakdown of red blood cells.
Blood: The presence of red blood cells or haemoglobin in urine can indicate diseases or damage to the kidneys or urinary tract.
Specific Gravity: Urine collected at different times of day may vary in specific gravity from 1.003-1.035. Specific gravity equal or less than 1.010 indicates dilute urine and readings equal or greater than 1.025 indicate concentrated urine. Low readings may simply be due to excessive liquid intake and high readings may be due to insufficient drinking causing dehydration. However, persistent low readings can be due to kidney problems and continuous high readings can be indicative of underlying clinical problems relating to the kidney and possibly the heart.
Bilirubin: Bilirubin is not found in normal urine. The presence of bilirubin in urine is an early indicator of liver disease such as obstruction of the bile duct or hepatitis.
Glucose: The kidney normally excretes small amounts of glucose. Concentrations of 100mg/dl may be considered as abnormal if found consistently and may indicate diabetes.
Ketones: Ketone bodies should not be detected in normal urine specimens with this reagent. A positive result may indicate diabetes.
pH: Urine values generally range from pH 5 to 9. Results that are either too high or low can indicate that your body will form kidney stones.
Leukocyte: Normally no leukocytes are detectable in urine. A positive result for leukocytes is indicative of a urinary tract infection.

WARNING AND PRECAUTIONS

For in vitro diagnostic use only.
 All test strips within each foil will need to be used immediately once that foil has been opened.

STORAGE AND HANDLING

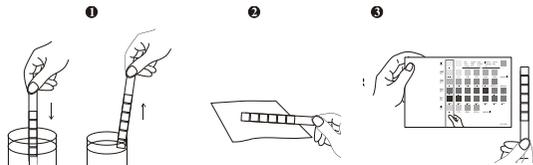
Store in a cool, dry place at temperatures between 2°C ~ 30°C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. As long as the foil pouch has not been opened, the product is stable up to the expiry date printed on the foil. Do not touch test areas of urine reagent strips. Do not open foil pouch until ready to use. All test strips will need to be used immediately once the foil has been opened. Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, confirm that the product is within its expiration date and is reacting properly using known negative and positive control materials. Do not use after the expiry date.

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen 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 used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination. If cleanly voided specimens are not collected from females, positive results for leukocytes may be found due to contamination from outside the urinary tract. Skin cleansers containing chlorhexidine may affect protein test results if specimen contamination occurs.

VISUAL TEST PROCEDURE

The procedure must be followed exactly to achieve reliable results. Do not compare strips with colour chart before the strip is dipped in urine.
 1) Dip the strip into the urine up to the test area, ensuring all reagent pads are fully immersed. Dip for no more than two seconds.
 2) Draw the edge of the strip along the brim of the vessel to remove excess urine; be careful not to allow the test areas to 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 colours of the reagent pads exactly after 60 seconds (Leukocytes after 90~120 seconds) with the colour 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.



INTERPRETATION OF RESULTS

Results are obtained and interpreted by comparing the colour of the test pads on the strip with the colour blocks printed on the colour chart. In the event of unexpected or questionable results, confirm that the strips have been used before the expiry date printed on the pack then repeat the test using a new strip.

If the results are outside the normal levels (see overleaf), consult your doctor.

NOTE: DO NOT MAKE ANY MEDICAL DECISION WITHOUT CONSULTING YOUR DOCTOR.

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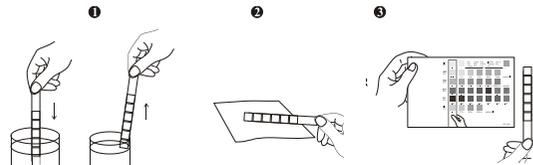
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If the results are outside the normal levels (see overleaf), consult your doctor.

NOTE: DO NOT MAKE ANY MEDICAL DECISION WITHOUT CONSULTING YOUR DOCTOR.

Nitrite: Any degree of uniform pink to red colour should be interpreted as a positive result and you should consult your doctor. Viewing the test against a white background may help the detection of low levels of nitrite, which might otherwise be missed. Pink spots or pink edges should not be interpreted as a positive result.

Protein: If your result is 30mg/dL (0.3g/L) or more, consult your doctor.

Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. If your result is 2mg/dL (35µmol/L) or more, consult your doctor.

Blood: A positive (+) result may be seen as either a uniform colour change of the test pad or the appearance of green spots on the test pad (see colour chart). If either type of positive result is obtained, consult your doctor.

Note: Strenuous exercise can cause blood to appear in urine and blood is often found in the urine of menstruating women. A uniform colour change indicates the presence of haemoglobin or broken red blood cells in the urine. Green spots on the test pad indicate the presence of intact red blood cells (erythrocytes).

Specific Gravity: A single low reading or a single high reading does not indicate a problem (see Principle and Expected Values). However, persistent low or high readings over a period of time should be checked by your doctor. High protein levels in urine (more than 300mg/dL) can cause high specific gravity results.

Bilirubin: Bilirubin is absent in normal urine, so any positive result should be investigated further by your doctor. If you are taking drugs containing chlorpromazine or rifampen, colour reactions may occur on the test pad that might be mistaken for positive bilirubin.

Glucose: The results comparison chart for glucose shows a line of 6 colours starting with a negative result (pale blue) and then five positive ranges which get darker the higher the levels detected through to dark brown. If you get a positive result, consult your doctor.

Ketones: The results comparison chart for ketones shows a line of 6 colours starting with a negative result (pale pink) and then five positive ranges which get darker the higher the levels detected through to deep burgundy. If you get a positive result, consult your doctor.

pH: Urine values generally range from pH 5 to 9. If you receive a highly acidic or highly alkaline result, consult your doctor.

Leukocytes: If leukocytes are found in your urine sample the colour of the test strip will change colour and go dark pink or purple. If you get a positive result, consult your doctor.

LIMITATIONS OF PROCEDURE

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result of method. Substances that cause abnormal urine colour may affect the readability of test pads in urinalysis reagent strips.

Nitrite: Ascorbic acid (>30mg/dL) may cause false negative result with low level of nitrite containing (<0.03mg) urine. 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 result 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.

Protein: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens.

Urobilinogen: The absence of urobilinogen in the specimen 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 colour. The test is not reliable method for the detection of porphobilinogen.

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 the low level of blood.

Specific Gravity (SG): High-buffered alkaline urine may cause diminished result, whereas high-buffered acidic urine may cause slightly elevated result.

Bilirubin: Metabolites of drugs, such as pyridium and selenium, which give a colour at low pH, may cause false positives. Indican (indoxyl sulphate) can produce a yellow-orange to red colour response, which may interfere with the interpretation of negative or positive bilirubin readings. Ascorbic acid (> 30mg/dl) may cause false negative result.

Glucose: High SG (>1.020) with high pH urine and ascorbic acid (more than 40mg/dl) may cause a false negative for specimen containing small amount of glucose (100mg/dl). Reactivity may be influenced by urine SG and temperature.

Ketones: Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Some high SG and low pH urine may give false positive result. Phenosulphonphthalein may cause false positive result.

pH: If the excessive urine is remain on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affect the pH portion, then pH result may be decreased than the actual. This phenomenon is called "run-over effect."

Leukocytes: The test result may not always be consistent with the leukocyte cell number by the 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 be due to contamination of the specimen by vaginal discharge.

PERFORMANCE CHARACTERISTICS

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of colour 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 specimen and reading variability, specimens 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, lesser concentrations may be detected under certain conditions.

TEST PAD AND SENSITIVITY (SPECIFICITY)

Glucose:	75-125mg/dL (Glucose)	Protein:	15-30mg/dL (albumin)
Bilirubin:	0.8-1.0mg/dL (Bilirubin)	Nitrite:	0.05-0.1mg/dL (Nitrite ion)
Ketones:	5-10mg/dL (Acetoacetic acid)	Leukocytes:	20-25 WBC/µl (Intact and lysed WBCs)
Blood:	10-15 RBC/µl (haemoglobin)		

BIBLIOGRAPHY

- NCCLS (National Committee for Clinical Laboratory Standard) GP 16-A/ ROUTINE URINALYSIS AND COLLECTION TRANSPORTATION AND PRESERVATION OF URINE SPECIMENS; TRNTATIVE GUIDELINE VOL 12-NO 26, EC.1992

NOTES ON SYMBOLS

 Consult instructions for use	 IVD	 In vitro diagnostic	 Keep away from sunlight	 Number of test strips
 Use By /Expiry Date	 Do not reuse	 Store at		

 DFI CO., Ltd, 388-25, Gomo-ro, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, Republic of Korea
Tel: 82-55-346-1882 Fax: 82-55-346-1883, Web-site: www.dfi-dus.com

DISTRIBUTED BY: HOME HEALTH UK Ltd, Unit 11 Peerglow Industrial Estate, Olds Approach, Watford, Herts, WD18 9SR, UK
TEL: (+44)1923 711511, FAX: (+44)1923 711550, Website: www.homehealth-uk.com

EU AUTHORISED REPRESENTATIVE: DONGBANG ACUPRIME, 1 The Forrest Units, Hennock Road East, Exeter, EX2 8RU, UK
TEL: 0044-1392-829500, FAX: 0044-1392-823232

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