

SURESIGN	Health Check-Up
	Urinary Analysis Test Strips
	Package Insert For Self-Testing Only
	REF SG10100 English

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 check-up in the home. The Health Check-Up Urinary Analysis Test can be used to give general indication of health and helps in the detection of diabetes, diseases and infections that can affect the kidneys, urinary tract, liver and heart. General information on urine tests can be obtained from: www.patient.co.uk/patientplus & www.labtestsonline.org.uk

INTENDED USE

The Health Check-Up Urinary Analysis Test Strips are plastic strips onto which ten separate reagent pads are affixed. The test strips are intended for testing urine in the home to provide semi-quantitative determination of Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone (acetoacetic acid), Bilirubin and Glucose. For self-testing and *in vitro* diagnostic use only.

MATERIALS

Material Provided	Materials Required but Not Provided
<ul style="list-style-type: none"> • 1 or more Test Strips • Colour Card • Package Insert 	<ul style="list-style-type: none"> • Timer • Urine Sample Collection Container • Absorbent Sheet

PRECAUTIONS

- For *in vitro* diagnostic use only. Not for internal use. For external use only.
- Do not use after the expiry date printed on the labelling.
- Keep the strip in the sealed pouch until use.
- Before using the test strip check if the colour of the test pads are darker than the lowest block on the chart (except for specific gravity and pH), if they are then the strip is unusable. Discard the strip and obtain a new test.
- All urine specimens should be handled with care. Wash hands thoroughly after using the test.
- Each strip can only be used once.
- Do not touch the test pads on the strip.
- The used strip should be discarded hygienically with normal household waste.

SPECIMEN COLLECTION AND PREPARATION

A urine sample must be collected in a clean and dry container. Mix the urine sample well before testing it. Test the urine as soon as possible (for bilirubin or urobilinogen) and no more than four (4) hours after voiding. The container should allow for complete dipping of all reagent strip areas. Do not contaminate the urine sample with antiseptics, detergents, or skin cleansers containing chlorhexidine as this may affect test results.

WHEN TO READ THE TEST

The table below indicates the read time for each parameter that should be used when following the DIRECTIONS FOR USE in step 3 in the next section.

Reagent	Read Time
Leukocytes (LEU)	120 Seconds (2 minutes)
Nitrite (NIT)	60 Seconds
Urobilinogen (URO)	60 Seconds
Protein (PRO)	60 Seconds
pH	60 Seconds
Blood (BLO)	60 Seconds
Specific Gravity (SG)	45 Seconds
Ketone (KT)	45 Seconds
Bilirubin (BIL)	45 Seconds
Glucose (GL)	45 Seconds

DIRECTIONS FOR USE

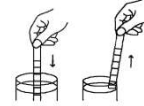


Do not touch the test pads on the test strip.



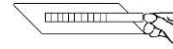
Before using the test strip check if the colour of the test pads are darker than the lowest block on the chart (except for specific gravity and pH), if they are then the strip is unusable. Discard the strip and obtain a new test.

1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Hold the end of the strip farthest away from the test pads. Dip the test strip pads completely into the collected fresh urine sample for 1-2 seconds and remove immediately.



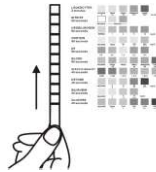
Start the timer.

3. Run the edge of the test strip against the rim of the urine container to remove excess urine. Place the test strip onto the absorbent sheet (e.g. paper towel) with the test strip pads facing upwards.



Wait for the required time on the colour card before reading a specific test, see previous WHEN TO READ THE TEST section.

4. In good lighting conditions and after the exact specified times shown on the colour card for each parameter, vertically align the test strip pads to the colour card blocks. Then for each parameter compare the colour of the test strip pad with the horizontal colour blocks on the colour card and match carefully, record the result.



Do not read any result after two (2) minutes.

5. Dispose of the test strip in household waste.

INTERPRETATION OF RESULTS

Results are obtained and interpreted by comparing the colour of the test pads on the test strip with the colour blocks printed on the colour card for each specific test. 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.

Interpretation of visual results is dependent on several factors: the variability of colour perception, the presence of any interfering substances, and the lighting conditions when the strip is read. Each colour block on the colour card corresponds to a range of concentrations of the test substance.



Deterioration of the test strip may result in discoloration or darkening of the test pads on the strip. If this happens when the test is removed from the pouch, or the test results are questionable or inconsistent with expected results, discard the test, check and make sure the strips are within the expiration date.

For the Nitrite parameter, comparison of the test pad area against a white background may aid in the detection of low levels of nitrite.

Expected results or values for a "normal" healthy population and abnormal populations are provided in the table below for each test parameter. If you are concerned about the results of your test for one or more parameters consult your doctor.

NOTE: DO NOT TAKE ANY MEDICAL DECISION WITHOUT CONSULTING YOUR DOCTOR



If you have questions about the instructions or your results, please contact our UK Helpline on 0800 0430318 or R.O.I Helpline on 0818 333 181.

Parameter	Expected Results
Leukocytes	Normal urine specimens generally yield negative results. Positive results are clinically significant. Individual 'TRACE' results are clinically questionable, it is very important that 'TRACE' results be confirmed in a repeated test. The presence of leukocytes in urine is an important symptom of an inflammation of the kidneys and the urinary tract. Consult your doctor if you have a positive result.
Nitrite	Nitrite is not detectable in normal urine. Any degree of uniform pink colour development should be taken as a positive result. Positive nitrite can be indicative of urinary tract infection. A negative result does not necessarily mean you do not have a urinary tract infection. Negative results may be obtained if your urine has not been in the bladder for at least four (4) hours or if the bacteria present are unable to produce nitrite. Consult your doctor if you have a positive result or if you are concerned about the test result.
Urobilinogen	A level of 2mg/dL in urine is the critical value, representing the transition from normal to abnormal, A positive result of four (4) or above is abnormal. Consult your doctor if you have a positive result.
Protein	Normally protein is not detectable in urine with conventional methods, although a minute amount of protein is excreted through normal kidney function. Therefore, a NEGATIVE result is not sufficient to indicate that protein is not present. Protein in urine is indicated when the colour is darker than the plus/minus mark on the chart. In older patients, high protein levels may occasionally indicate heart problems. If your result is 30mg/dL (0.3g/L) or more, consult your doctor.
pH	The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment, or some calculi (stones). Consult your doctor if you are concerned about the test result.
Blood	The 'TRACE' reaction may vary among patients. The presence of green spots or green colour on the reagent area within 60 seconds indicates the need for a further diagnostic check. Green spots are often, but not always, found in the urine of menstruating females. Consult your doctor if the test pad changes colour.
Specific Gravity	The normal specific gravity of urine ranges from 1.003-1.035. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal. 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 kidney and possibly the heart. If you are concerned about your test result consult your doctor.
Ketone	Normal urine specimens usually produce negative results in the test. In ketoacidosis, starvation, fasting, pregnancy and frequent strenuous exercise, ketones may appear in urine and may produce positive results. If you are concerned about your test results consult your doctor.
Bilirubin	Normally, even the most sensitive method cannot detect bilirubin in healthy urine. It is abnormal to have even a little bilirubin in urine, which requires further inspection. Bilirubin in urine indicates liver disease before any clinical signs are usually evident. If you have a positive result consult your doctor.
Glucose	Normally, a small amount of glucose may be excreted through the kidneys. The amount is usually below the sensitivity level of the test. Results at the first positive level trace may be significantly abnormal if found consistently. If the colour appears somewhat mottled at the higher glucose concentrations, match the darkest colour to the blocks. If you have a positive result consult your doctor.

PLEASE SEE OVERLEAF FOR FURTHER INFORMATION.

PERFORMANCE CHARACTERISTICS

The table below indicates the performance characteristics for each parameter.

Reagent	Description
Leukocytes (LEU)	Urinary tract infection in up to 90% of all patients can be detected by analysis of random urine specimens. A positive reaction (small or greater) at less than the two (2) minutes reading time may be regarded as a positive indication of leukocytes in urine.
Nitrite (NIT)	The test has a sensitivity of 0.08-0.1 mg/dL nitrite ion in urine of normal excreted in urine. Comparison of the test pad area against a white background may aid in the detection of low levels of nitrite.
Urobilinogen (URO)	This test can detect urobilinogen in concentrations as low as 0.2mg/dL (approximately 0.2 EU/dL). Therefore, most normal urines will give a slightly pink reaction. The absence of urobilinogen in the specimen cannot be determined.
Protein (PRO)	In 90% of urines tested, albumin concentrations of 0.1 g/L or greater will produce a colour change. The test pad is more sensitive to albumin than globulin, Bence-Jones proteins, and mucoproteins.
pH	Strip tests for pH measure pH values from 5.0 – 8.5 visually. And to 9.0 by machine read.
Blood (BLO)	The test is specific for haemoglobin and myoglobin. In 90% of urines tested, haemoglobin or erythrocytes concentrations of 5 Ery/ μ L will produce a positive result.
Specific Gravity (SG)	The reagent strips test urine specimens for specific gravity between 1.000 and 1.030. In general, the mean error between the results of the strip test and results from the refractive index method is only 0.005. For increased accuracy 0.005 may be added to readings from urine samples with pH equal to or greater than 6.5.
Ketone (KT)	In 90% of urines tested, acetoacetate acid at 5.0 mg/dL will produce a positive reaction. The strip does not react with hydroxybutyric acid.
Bilirubin (BIL)	The test has a sensitivity of 0.5mg/dL.
Glucose (GL)	In 90% of urines tested, glucose concentrations of 4.4 mmol/L (80 mg/dL) or greater will produce a positive result. Sugars other than glucose will not react with the reagent.

The sensitivity of the strips on clinical urine specimens may vary depending upon several factors, such as the variability of colour perception, specific gravity, pH value, and the lighting conditions when the strips are read visually. Please refer to the Limitations section in this package insert for further details.

PRINCIPLE

Leukocytes	Granulocytic leukocytes contain esterases that catalyse the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product. The reagent area of the strip reacts with esterase in leukocytes (granulocyte leukocytes).
Nitrite	This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram-negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin-3-ol to produce a pink colour. Gram-negative bacteria in urine converts nitrate (derived from foods) into nitrite. The reagent strip is specific to nitrite and will not react with other substances in urine. The degree of colour development and the number of bacteria is not in direct proportion.
Urobilinogen	This test is based on the Ehrlich reaction in which p-diethyl-aminobenzaldehyde in conjunction with a colour enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red colour. Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL (1 Ehrlich unit/dL). Evaluation of both the bilirubin and urobilinogen results helps in the differential diagnosis of jaundice, as well as other liver and biliary disorders.
Protein	This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green colour is due to the

	presence of protein. Colours range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.
pH	This test is based on a double indicator principle that gives a broad range of colours covering the entire urinary pH range. Colours range from orange through yellow and green to blue.
Blood	This test is based on the peroxidase-like activity of haemoglobin, which catalyses the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting colour ranges from orange through green; very high levels of blood may cause the colour development to continue to blue.
Specific Gravity	This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colours range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
Ketone	This test is based on the development of colours ranging from buff-pink, for a negative reading, to maroon when acetoacetic acid reacts with nitroprusside.
Bilirubin	This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The colour ranges through various shades of tan.
Glucose	This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyses the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, per-oxidase, catalyses the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colours ranging from green to brown.

STORAGE AND STABILITY

Store in the sealed foil pouch in temperature range 2-30 °C (35.6 °F to 86.0 °F). **DO NOT FREEZE.**

Keep out of direct sunlight and moisture. Protect against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.

LIMITATIONS















Leukocytes	A high glucose concentration (2000mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of oxalic acid may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction.
Nitrite	A negative result does not rule out significant bacteriuria. False negative results may occur (1) when urine does not contain the organism that caused the conversion from nitrate to nitrite, (2) when urine has not remained in the bladder long enough (up to four hours) for the nitrate to convert into nitrite, or (3) when nitrate in foods is absent. A high specific gravity of urine may reduce the sensitivity of the test. A 17mg/dL concentration of Vitamin C (Ascorbic Acid) or less will not affect the test result.
Urobilinogen	The reagent area may react with interfering substances, such as sulfonamides. Atypical colour reactions may be obtained in the presence of high concentrations of p-aminosalicylic acid. False negative results may be obtained if formalin is present, and the specimen has been in direct sunlight. The test is not a reliable method for the detection of porphobilinogen.
Protein	False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with cleansers containing chlorhexidine may also produce false positive results.
pH	Bacterial growth in a specimen may cause a marked alkaline shift (>8.0), usually because of urea conversion to ammonia.
Blood	Some urinary tract infections may cause a false positive reaction in this test. False negative results may be obtained if moderate to high concentrations of Vitamin C (Ascorbic Acid) are present in the urine sample or if the urine is alkaline.

Specific Gravity	Urine non-ionic constituents such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (100mg/dL). The reagent strip is not suitable for testing newborn babies because of their low specific gravity (1.002-1.004).
Ketone	False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites.
Bilirubin	Medicines that dye urine red and anything that shows red in an acid medium (e.g., phenazopyridine) may affect the test result. A high concentration of Vitamin C (Ascorbic Acid) (49mg/dL) may cause a false negative result.
Glucose	Vitamin C (Ascorbic Acid) concentrations of 4.9 mg/dL and/or acetoacetic acid concentrations of 19.4mg/dL or lower will not influence the test.
General	Large amounts of Vitamin C (Ascorbic Acid) may affect the test for glucose, bilirubin, nitrite, and blood.

BIBLIOGRAPHY

- "Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline"; NCCLS Document GP16-A (ISBN 1-56238-282-9); 1995. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA19087, USA.
- "Operating Rules Of Clinical Test" (Rev.2), The Ministry of Health of P.R.C. Publishing. Yingwu Ye, Yusan Wang.
- "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editors; 1998; pp.37-81, 96-97.
- "Compendium-Urinalysis with Test Strips" Roche Diagnostic, Combur(R) Reagent Strips.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse		Importer
	For <i>in vitro</i> diagnostic use only		Use by		Catalogue #		Authorized Representative
	Store between 2-30°C		Lot Number		Attention, see instructions for use		
	Do not use if package is damaged		Consult Instructions For Use		Keep away from sunlight		



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