One Step® CE IVD

DUS K / DUS G / DUS pH / DUS PRO
REAGENT STRIPS FOR URINALYSIS

PRODUCT NAME: Urine Reagent Strip

The strips you have will test either Ketones, Glucose, pH or Protein in urine. Please check the label on the test tub to see which test you have (DUS K, DUS G, DUS pH or DUS P).

- **ONE+STEP® DUS K**
  Reagent Strips for the rapid determination of Ketones (Acetoacetic Acid), in urine.
- **ONE+STEP® DUS G**
  Reagent Strips for the rapid determination of Glucose in urine.
- **ONE+STEP® DUS pH**
  Reagent Strips for the rapid determination of pH in urine.
- **ONE+STEP® DUS Pro**
  Reagent Strips for the rapid determination of Protein in urine.

SUMMARY AND EXPLANATION

ONE+STEP® DUS Reagent Strips are dip-and-read test strips for In Vitro Diagnostic Use only for testing the above items in urine. Test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. It is measured by comparison of test paper attached to a plastic strip with the colour chart blocks printed on the vial label. The strips may be read visually. They can also be read instrumentally, using urine chemistry analyzers.

WARNING AND PRECAUTIONS

For in vitro diagnostic use only.
For professional use only.

CHEMICAL PRINCIPLES OF PROCEDURE AND INGREDIENTS

ONE+STEP® DUS K
Ketones: Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricanide.
Ingredients: Sodium nitroprusside 23.0mg

ONE+STEP® DUS G
Glucose: Glucose oxidase catalyzes the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.
Ingredients: Glucose oxidase 430U, Peroxidase 200U, Potassium Iodide 12mg.

ONE+STEP® DUS pH
pH: This test is based on a double indicator principle that gives a broad range of colours covering the entire urinary pH range. (pH 5.0 to 9.0)
Ingredients: Methyl red 0.05mg, Bromothymol blue 0.5mg

ONE+STEP® DUS Pro
Protein: This test is based on the principle of the protein error of pH indicators. At a constant pH, the development of any green colour is due to the presence of protein.
Ingredients: Tetrabromophenol blue 0.34mg

STORAGE AND HANDLING

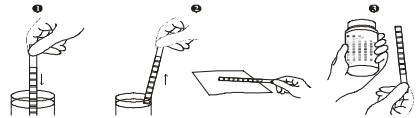
Store in a cool, dry place at temperatures between 2℃ ~ 30℃. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. When stored in the original container, the product is stable up to the expiry date printed on the **label and (or) vial box.** Replace the bottle cap immediately and tightly after removing test strips, and keep the vial tightly closed between tests. Do not remove desiccant from bottle. Do not touch test areas of urine reagent strips. Do not open container until ready to use.
Discolouration 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. Please note that once the canister has been opened, the remaining strips remain stable for up to 6 months.

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 for no more than two second.
2) Draw the edge of the strip along the brim of the vessel to remove excess urine, but make sure the reagent pads do not come into contact with 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 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.



QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimen 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 it complies with government and local requirements.

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.

ONE+STEP® DUS K
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. Phenosulfonphthalein may cause false positive result.

ONE+STEP® DUS G
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 amounts of glucose (100mg/dl). Reactivity may be influenced by urine SG and temperature.

ONE+STEP® DUS pH
pH: If the excessive urine remains on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affects the pH portion, so pH result may be more than the actual. This phenomenon is called "run-over effect."

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

EXPECTED VALUES

ONE+STEP® DUS K
Ketones: Ketone bodies should not be detected in normal urine specimens with this reagent.

ONE+STEP® DUS G
Glucose: The kidney normally excretes small amounts of glucose. Concentrations of 100mg/dl may be considered as abnormal if found consistently.

ONE+STEP® DUS pH
pH: Urine values generally range from pH 5 to 9.

ONE+STEP® DUS Pro
Protein: Normal urine specimens ordinarily contain some protein (<20mg/dL) therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace level or over indicate significance proteinuria and thus further clinical testing is needed to evaluate the significant of results.

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)

Ketones: 5-10mg/dL (Acetoacetic acid)
Glucose: 75-125mg/dL (Glucose)
Protein: 15-30mg/dL (albumin)

BIBLIOGRAPHY

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

NOTES ON SYMBOLS

	Consult instructions for use
IVD	In vitro diagnostic
	Use By /Expiry Date(YYYY-MM)
	Do not reuse
2°C 30°C	Store at
	Keep away from sunlight
	Number of test strips
EC REP	EU Authorized Representative

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