

DUS pH REAGENT STRIPS FOR URINALYSIS



PRODUCT NAME: DUS pH

Reagent Strips for the rapid determination of pH in urine.

SUMMARY AND EXPLANATION

DUS Reagent Strips are dip-and-read test strips for In Vitro Diagnostic Use only for testing above items in urine. Test result may provide information regarding the status of carbohydrate metabolism. 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

pH: This test is based on a double indicator principle that gives a board range of colours covering the entire urinary pH range. (pH 5.0 to 8.5)
Ingredients: Methyl red 0.05mg, Bromothymol blue 0.5mg

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. 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. Note once the canister has been opened, the remaining strips remain stable for up to 6 months.

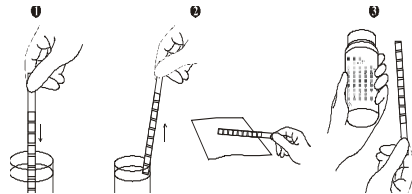
SPECIMEN COLLECTION AND PREPARATION

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. 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.

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 seconds.
- 2) Draw the edge of the strip along the brim of the vessel to remove excess urine; at this time, don't make the test areas touched to 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., MAS UA Control, BIO-RAD Liquichek Urinalysis 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.

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 the "run-over effect."

EXPECTED VALUES

pH: Urine values generally range from pH 5 to 9.

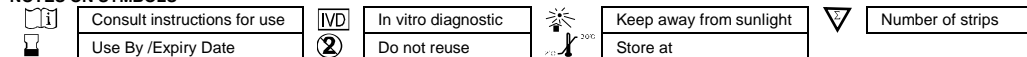
PERFORMANCE CHARACTERISTICS

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.

BIBLIOGRAPHY

- 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

NOTES ON SYMBOLS



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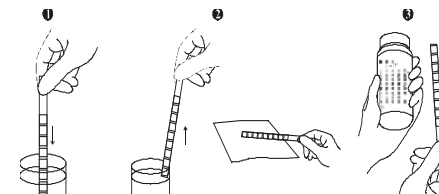
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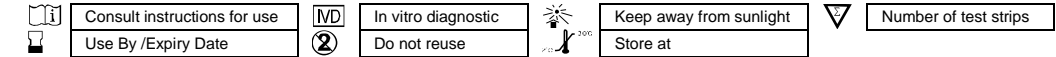
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