One Step® CE IVD

DUS 12AC
REAGENT STRIPS FOR URINALYSIS

PRODUCT NAME: Urine Reagent Strip

ONE+STEP® DUS 12AC

Reagent Strips for the rapid determination of Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic Acid), Specific Gravity, Blood, pH, Protein, Nitrite, Leukocytes, Microalbumin and Creatinine 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.

Microalbuminuria, an abnormal elevation of the urinary albumin excretion rate, is often one of the first signs of renal disease or damage that can lead to renal failure. Patients with hypertension or diabetes have the highest risk of renal disease where microalbumin may be present. Microalbuminuria refers to small detectible amounts of albumin in the urine.

Creatinine is a byproduct of muscle metabolism and creatinine excretion into the urine is usually constant. Creatinine measurement is used in the diagnosis and treatment of renal diseases, to monitor renal dialysis, and as a calculation basis for measuring other urine analytes. Though the concentration (or dilution) of urine varies throughout the day, the urinary creatinine level is relatively stable which allows its measurement to be used as a corrective factor in random/spot urine samples. When albumin and creatinine are measured simultaneously from a single-void / random urine sample, the albumin to creatinine ratio (ACR) can be determined. The ACR is the preferred test for screening of microalbuminuria recommended by the American Diabetes Association.

WARNING AND PRECAUTIONS

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

CHEMICAL PRINCIPLES OF PROCEDURE AND INGREDIENTS

Urobilinogen: The test is based on the Ehrlich's reaction
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 reaction pad by the action of peroxidase.
Ingredients: Glucose oxidase 430U, Peroxidase 200U, Potassium Iodide 12mg.
Bilirubin: Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye.
Ingredients: Sodium nitrite 0.733 mg, 2,4-dichlorobenzene diazonium 2.3mg, Sulfosalicylic acid 25mg
Ketones: Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricanide.
Ingredients: Sodium nitroprusside 23.0mg
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
Blood: The peroxidase-like action of haemoglobin and myoglobin specifically catalyzes the oxidation of the indicator by means of the organic hydroperoxide contained in the test paper to give a blue colouration.
Ingredients; Cumene Hydroperoxide 12mg, o-Tolidine 35mg
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 colour change of bromothymol blue from blue-green to yellow-green.
Ingredients: Bromothymol blue 0.5mg
Poly vinyl ether-ALT-maleic acid anhydrous 140.5mg
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
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 reaction pad. The azo dye produced causes a pink colour change.
Ingredients: P-arsanilic acid 4.5mg
Leukocyte: This test reveals the presence of granulocyte esterases. These esterases cleave an indoxyl ester, and the indoxyl so liberated reacts with a diazonium salt to produce a violet dye.
Ingredients: Induced Indole amino acid ester 1.3mg
Microalbumin: This test is based on dye binding using sulfonephthalein dye. At a constant pH, albumin binds with sulfonephthalein dye to develop a blue colour. The resulting colour ranges from pale green to aqua blue.
Ingredients: sulfonephthalein dye 0.1mg, Citric acid 30mg
Creatinine: This test is based on the reaction of creatinine with a dye-metal complex. At an alkaline condition, creatinine reacts with a dye-metal complex to form a purplish-brown colour complex.
Ingredients: picric acid 0.3mg, Borax 20mg

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.

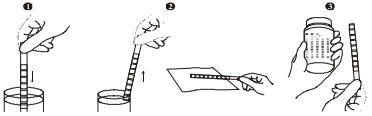
SPECIMEN COLLECTION AND PREPARATION

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.

TEST PROCEDURE

The procedure must be followed exactly to achieve reliable results.
1) Dip the strip into the urine up to the test area for no more than two seconds, making sure all reagent pads are fully immersed in the urine.
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) Read the result

a. **If reading visually:** 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 horizontall to prevent possible mixing of chemicals when excessive urine is present.



b. **If using a DUS instrument,** carefully follow the directions given in the appropriate instrument operating manual. The instrument will automatically read each test pad result at a specified time.

Microalbumin to Creatinine Ratio
The following table is used to obtain the Microalbumin to creatinine ratio.

		Creatinine mg/dl(mmol/L)				
		10(0.9)	50(4.4)	100(8.8)	200(17.7)	300(26.5)
Microalbumin mg/dl(mg/L)	1(10)	*			Normal	
	3(30)					
	8(80)	High Abnormal		Abnormal		
	15(150)					

* Specimen is too dilute to accurately determine the ratio result. Repeat test with a new specimen, preferably a first-morning collection.

Examples:

Reading	Reported Result	Creatinine Result	Micoralbumin-to-Creatinne Ratio
Microalbumin =15mg/dL Protein=30mg/dL	30mg/dL	100mg/dL	Abnormal
Microalbumin =8mg/dL Protein=Negative	8mg/dL	300mg/dL	Normal

Microalbumin/Creatinione ratio Interpretation

	Normal	Abnormal	High Abnormal
Conc. (mg/g)	<30	30-300	>300
Conc.(mg/mmol)	<3.4	3.4-33.9	>33.9

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 or method. Substances that cause abnormal urine colour may affect the readability of test pads in urinalysis reagent strips.

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 a reliable method for the detection of porphobilnogen.

Glucose: High SG (>1.020) with high pH urine and ascorbic acid (more than 40mg/dl) may cause false negative result at the low level of glucose. Ketones reduce the sensitivity of the test. Moderately high ketone level (> 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.

Bilirubin: Metabolites of drugs, such as pyridum and selenium, which give a colour at low pH, may cause false positives. Indican (indoxyl sulfate) 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.

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.

pH: If 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."

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.

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

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.

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

Microalbumin: The following substances may cause false positive results: a large amount of haemoglobin(≥5mg/dl), visibly bloody urine, highly alkaline urine(pH>8), disinfectants including quaternary ammonium compound.

Creatinine: Visibly dark brown colour urine may affect the results. Substances that cause abnormal urine colour, such as drugs containing azo dyes, nitrofurantoin, riboflavin may affect the results.

Microalbumin to Creatinine Ratio: A low microalbumin result(10mg/L) in combination with strongly diluted urine (creatinine result of 10mg/dl) could indicate a microalbumin concentration below the sensitivity limit.In this case, consider testing a new specimen, preferably a first morning collection, for greater confidence in the result.

EXPECTED VALUES

Urobilinogen: The normal urobilinogen range is 0.1 to 1.0 Ehrlich unit /dl. If results exceed the concentration of 2.0 mg/dl, the patient and the urin e specimen should be evaluated further.

Glucose: The kidney normally excretes small amounts of glucose. Concentrations of 100mg/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 specimens with this reagent.

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

Blood: Normally, no haemoglobin is detectable in urine (0.010mg/dl; 3 RBC/μl). When haemoglobin appears in urine it indicates 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 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 significance of results.

Nitrite: Normally no nitrite is detectable in urine.

Leukocyte: Normally no leukocytes are detectable in urine.

Microalbumin: Normal albumin levels in urine are under 2mg/dl. Microalbuminuria is indicated by results of 3~30mg/dl.

Creatinine: The urine of healthy individuals contains 10~300mg/dl of creatinine. Very low creatinine results can be caused by adulteration of the urine specimen or by severe renal failure.

Microalbumin to Creatinine Ratio: Microalbumin is normally present in urine at concentrations of less than 30mg albumin / g creatinine. Microalbumina is indicated at a ratio result of 30~300mg/g(Abnormal) and clinical albuminuria at a ratio result of >300mg/g (High Abnormal)

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 urine; however, because of the inherent variability of clinical urine, lesser concentrations may be detected under certain conditions.

TEST PAD AND SENSITIVITY (SPECIFICITY)

Glucose: 75-125mg/dL (Glucose)
Bilirubin: 0.8-1.0 mg/dL (Bilirubin)
Ketones: 5-10mg/dL (Acetoacetic acid)
Blood: 10-15 RBC/μl (hemoglobin)
Protein: 15-30mg/dL (albumin)
Nitrite: 0.05-0.1mg/dL (Nitrite ion)
Leukocytes: 20-25 WBC/μl (Intact and lysed WBCs)
Microalbumin: 3mg/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
	Store at
	Keep away from sunlight
	Number of test strips
EC REP	EU Authorized Representative

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