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.

Leukocyte
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.

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 organism 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.

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. Phenosulfonphthalein 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."

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 pyridum and selenium, which give a color at low pH, may cause false positives. Indican (indoxyl sulfate) can produce a yellow-orange to red color response, which may interfere with the interpretation of negative or positive bilirubin readings. Ascorbic acid (> 30mg/dl) may cause false negative result.

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 color. The test is not reliable method for the detection of porphobilinogen.

Ascorbic acid
No interferences are known.

QUALITY CONTROL
For best results, performance of reagent strips should be confirmed by testing known negative and positive specimen or controls (e.q., MAS Level1, Level2 control solution) 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.

EXPECTED VALUES
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.

Blood
Normally, no hemoglobin is detectable in urine (0.010mg/dl; 3 RBC/μl). When hemoglobin appears in urine it indicates kidney disease or a urinary tract disorder. Blood may often be found in the urine of menstruating females.

Leukocyte
Normally no leukocytes are detectable in urine.

Nitrite
Normally no nitrite is detectable in urine.

Glucose
The kidney normally excretes small amounts of glucose. Concentrations of 100mg/dl may be considered as abnormal if found consistently.

Ketones
Ketone bodies should not be detected in normal urine specimens with this reagent.

pH
Urine values generally range from pH 5 to 9.

Specific Gravity (SG)
The normal SG of urine ranges from 1.001 to 1.035.

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.

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 urine specimen should be evaluated further.

Ascorbic acid
The average daily intake ranges from 30-80mg, with an output of 20-30mg/day.

PERFORMANCE CHARACTERISTICS
Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of color 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 color 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.

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IVD : For *in vitro* diagnostic use
LOT : Lot number
REF : Catalogue number
: Consult instructions for use
: Store at 2~30℃
: Do not reuse
EC REP : Authorized Representative
: Manufactured by
EXP : Use by / Expiry date
: Keep away from sunlight
Σ : Number of test strips
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices

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U-AQS

REAGENT STRIPS FOR URINALYSIS

U-AQS Series
(U-AQS 11, U-AQS 10, U-AQS 5, U-AQS 4SG, U-AQS 4, U-AQS 3GK, U-AQS 3, U-AQS 2GP)
Tests for Protein, Blood, Leukocytes, Nitrate, Glucose, Ketone, pH, Specific Gravity, Bilirubin, Urobilinogen and Ascorbic acid (Vitamin C) in Urine.

- Please read the instructions carefully before use!
- In vitro diagnostic use

INTENDED USE

U-AQS series are designed to test for Protein, Blood, Leukocytes, Nitrate, Glucose, Ketone, pH, Specific Gravity, Bilirubin, Urobilinogen and Ascorbic acid (Vitamin C) in Urine.

SUMMARY AND EXPLANATION

U-AQS series are intended for use in at-risk patient group to assist diagnosis in the kidney function, urinary tract infections, carbohydrate metabolism (e.g., diabetes mellitus), liver function and physical characteristics such as acid-base balance and urine concentration. It is measured by comparison of test pads attached to a plastic strip with the color chart blocks printed on the bottle label. The strips may be read visually. They can also be read instrumentally, using urine chemistry analyzers U-AQ.

PRINCIPLE OF THE TEST

Protein
Protein "error of indicators." When pH is held constant by a buffer, indicator dyes release H+ ions because of the protein present and change color from yellow (or greenish yellow) to blue-green.

Blood
The test is based on the Pseudo-peroxidase activity of the haem moiety of hemoglobin and myoglobin. The chromogen is oxidized by a hydroperoxide in the presence of haem and changes color from yellow to blue.

Leukocyte
This test pad contains an indoxyl ester and diazonium salt. It is followed by an azo-coupling reaction of the aromatic amine formed by leukocytes esterase with a diazonium salt on the reaction pad. The azo dye produced causes a color change from beige to violet.

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 color change from white to pink.

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.

Ketones
Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricanide to produce a color change from beige to purple.

pH
Double indicator system. Indicator's methyl red and bromothymol blue are used to give distinct color changes from orange to green to blue. (pH 5.0 to 9.0)

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 color change of bromothymol blue from blue-green to yellow-green.

Bilirubin
Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. Color changes from light tan to beige or light pink.

Urobilinogen
The test is based on the Ehrlich's reaction. Color changes from light orange-pink to dark pink.

Ascorbic acid
The test field involves the decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from gray-blue to yellow.

MATERIALS PROVIDED

1. U-AQS: 100 strips/bottle
2. Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen container
2. External QC reagent
3. U-AQ instrument (optional)

STORAGE AND SHELF-LIFE

1. Store the strip in the original bottle at 2~30℃ (36~86℉). Do not freeze.
2. Shelf-life : 24 months from manufacturing date.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For use by healthcare professionals.
3. Handle all specimens as potentially infectious.
4. Do not reuse the strip that has already been used.
5. The test result should be used in conjunction with other clinical information such as clinical signs, symptoms and other test results

SPECIMEN COLLECTION AND PREPARATION

Collect freshly-voided urine in a clean container and test it as soon as possible. The container should allow for complete dipping of all reagent strip areas.

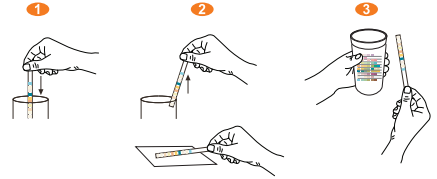
For professional use

A first-morning specimen is preferred but random collections are acceptable. Test the urine within two hours after voiding, sooner if testing for bilirubin or urobilinogen. If unable to test within the recommended time, refrigerate the specimen immediately and let it return to room temperature before testing. Work areas and specimen containers should always be free of detergents and other contaminating substances.

TEST PROCEDURE

1. Test preparation
1) Collect a fresh urine specimen in a clean, dry container.
2) Mix well just before testing.
3) Remove one strip from the bottle.
4) Replace the cap.

2. Test
1) Dip all the test pads of the strip into the urine.
2) Immediately remove the strip.
3) If reading the strip visually, start timing.
4) Drag the edge of the strip against the container rim to remove excess urine. 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 results
1) Reading visually
   (1) Compare each test pad to the corresponding row of color blocks on the bottle label.
   (2) Read each pad at the time shown on the label, starting with the shortest time.
   (3) Hold the strip close to the blocks and match carefully.
   (4) Read the pads in good light.
2) Using U-AQ instrument
   Carefully follow the directions given in the appropriate instrument operating manual. The instrument will automatically read each test pad at a specified time.

4. Report the results to the lab supervisor or physician.

LIMITATIONS

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 color may affect the readability of test pads in urinalysis reagent strips.

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