# EM-COMBINA Test

IVD

**Strip Tests for the rapid determination of Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Nitrite, Leukocytes and Ascorbic Acid.**

**INTENDED USE**

EM-Combina tests 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, kidney and liver function, acid-base balance, and urinary tract infection.

**PACKAGE SIZE**

| REF | Contains | Quantity |
|---|---|---|
| **E22092** | **EM-Combina G**<br>Glucose | **100 tests** |
| **E22093** | **EM-Combina K**<br>Ketones | **100 tests** |
| **E22094** | **EM-Combina P**<br>Protein | **100 tests** |
| **E22095** | **EM-Combina Hemo**<br>Blood | **100 tests** |
| **E22022** | **EM-Combina 2GK**<br>Glucose, Ketones | **100 tests** |
| **E22023** | **EM-Combina 2GP**<br>Glucose, Protein | **100 tests** |
| **E22024** | **EM-Combina 2BU**<br>Bilirubin, Urobilinogen | **100 tests** |
| **E22032** | **EM-Combina 3**<br>Protein, pH, Glucose | **100 tests** |
| **E22033** | **EM-Combina 3GK**<br>Glucose, Protein, Ketones | **100 tests** |
| **E22042** | **EM-Combina 4**<br>Glucose, Protein, pH, Blood | **100 tests** |
| **E22043** | **EM-Combina 4SG**<br>Glucose, Protein, pH, Specific Gravity | **100 tests** |
| **E22052** | **EM-Combina 5**<br>Glucose, Ketones, Protein, pH, Blood | **100 tests** |
| **E22072** | **EM-Combina 7L**<br>Blood, Specific Gravity, pH, Glucose, Protein, Nitrite, Leukocytes | **100 tests** |
| **E22082** | **EM-Combina 8**<br>pH, Protein, Glucose, Blood, Nitrite, Ketones, Bilirubin, Urobilinogen | **100 tests** |
| **E22083** | **EM-Combina 8SG**<br>Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein | **100 tests** |
| **E22002** | **EM-Combina 9SG**<br>Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Nitrite | **100 tests** |
| **E22102** | **EM-Combina 10**<br>Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Nitrite, Leukocytes | **100 tests** |
| **E22112** | **EM-Combina 11**<br>Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Nitrite, Leukocytes and Ascorbic Acid. | **100 tests** |

**STORAGE AND STABILITY**

1. Tests should be stored in original tube. Do not remove desiccant from tube.
2. Replace the tube cap immediately and tightly after removing test strips.
3. Do not touch test area of reagents strips.
4. Store in a cool (15℃ - 30℃) and dry place.
5. Do not store the strips on sunlight, in a refrigerator or freezer.
6. Do not use after expiration date indicated on tube.

**TEST PROCEDURE**

1. Collect fresh urine in a clean and dry vessel free from detergents.
2. Mix well just before test and do not centrifuge. Early morning collection of urine is recommended. If refrigerated urine is use, allow it to return to room temperature before testing.
3. Dip the strip into the urine up to the test area for not longer than two second.
4. Draw the edge of the strip along to brim of the vessel to remove excess urine.
5. 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.
6. Exactly after 60 second (except of Leukocytes 90-120 second) compare the test results carefully with the color 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.

**REAGENT AREA INFORMATION**

**1. Urobilinogen**

Chemical Principle: Modified Ehrlich's reaction. Urobilinogen present reacts with Ehrlich's reagent to form a red-colored compound. Colour changes from light orange-pink to dark pink.

Reagents: 4-Methoxybenzenediazonium 2.9mg

Expected Values: 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.

Detection Limits: The test will detect urobilinogen in concentration as low as 0.1 Ehrlich unit/dl. However, the absence of urobilinogen in the specimen cannot be determined. In patients with elevated urobilinogen excretion, urobilingen test results correlate closely with Watson-Schwartz spectrophotometer procedures.

Limitation of Test: 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.

**2. Glucose**

Chemical Principle: 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.

Reagents: Glucose oxidase 430U, Peroxidase 200U
Potassium Iodide 12mg

Expected Values: Normally no glucose is detectable in urine although the normal kidney excretes a small amount. The kidney normally excretes small amounts of glucose. Approximately 50mg Glucose /dl urine is detectable with this strip. Concentrations of 100mg/dl may be considered as abnormal if found consistently.

Detection Limits: Approximately 50mg/dl of glucose is detectable. The test is highly specific for glucose. The reagent area does not react with lactose, galactose, fructose or reducing metabolites of salicylates and nalidixic acid.

Limitation of Test: Ascorbic acid (more than 50mg/dl) and ketone bodies (more than 40mg/dl) may cause a false negative for a specimen containing a small amount of glucose (100mg/dl). But the combination of such ketone levels and low glucose levels is methobolically improbable in screening. Reactivity of the test decreases as the specific gravity and pH of urine increases and may also vary with tem perature.

**3. Bilirubin**

Chemical Principle: 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.

Reagents: Sodium nitrite 0.733 mg, 2,4-dichlorobenzene diazonium 2.3mg, Sulfosalicylic acid 25mg

Expected Values: 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.

Detection Limits: The test has a sensitivity of 0.5mg/dl bilirubin.

Limitation of Test: Metabolites of drugs, such as pyridum and serenium, which give a color 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. False positive results may be obtained in the presence of diagnostic or therapeutic dyes in test urine. Ascorbic acid concentrations of 25mg/dl or greater may cause false negatives

**4. Ketones**

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

Reagents: Sodium nitroprusside 23.0mg

Expected Values: Ketone bodies should not be detected in normal urine specimens with this reagent.

Detection Limits: Some high specific gravity and low pH urines may give reactions up to and including trace level. Clinical judgment is needed to determine the significance of reactions at trace level.

Limitation of Test: Positive results (trace or less) may oc cur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Detectable levels of Ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise in ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, Ketones may appear in urine in large amounts before serum Ketone is elevated.

**5. pH**

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

Reagents: Methyl red 0.05mg, Bromothymol blue 0.5mg

Expected Values: Urine values generally range from pH 5 to 9. The pH of urine

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is an important indicator of certain metabolic, kidney, gastrointestinal and respiratory factors.
Detection Limits: The test measures pH values generally to within 1 unit in the range of 5-9.
Limitation of Test: Excessive urine on the test strip may move the acid buffer from the neighbouring protein reagent onto the pH area and change the pH reading to an acid pH although the urine being tested is originally neutral or alkaline. This is called the "run-over" phenomenon.

**6. Blood**

Chemical Principle: 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 colour from yellow to blue.
Reagents; Cumene Hydroperoxide 12mg, o-Tolidine 35mg
Expected Values: The significance of trace reaction may vary among patients and clinical judgment is required for assessment in individual cases. When hemoglobin appears in urine it indicates kidney disease or a urinary tract disorder. This test is highly sensitive to hemoglobin (it is slightly less sensitive to intact erythrocytes) and thus complements the microscopic examination. Blood may often be found in the urine of menstruating females.
Detection Limits: The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes. The sensitivity may be reduced in urines with high specific gravity and those containing ascorbic acid. The appearance of green spots on the reagent test area indicates the presence of intact erythrocytes in the urine.
Limitation of Test: Elevated specific gravity or elevated protein may reduce the reactivity of the blood test. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations of 40 mg/dl or greater may cause false negatives at trace levels.

**7. Specific Gravity (SG)**

Chemical Principle: 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.
Reagents: Bromothymol blue 0.5mg
Poly vinyl ether-ALT-maleic acid anhydrous 140.5mg
Expected Values: Adults random urines vary in SG from 1.003 to 1.040. The first morning specimen should have a SG between 1.015 and 1.025. Newborns random specimen vary between 1.002 ~1004. In severe renal damage the SG is fixed at 1.010, the value of the glomerulus's filtrate.
Detection Limits: The SG test permits determination of urine SG between 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, and 1.030. Highly buffered alkaline urines may cause low reading of result.
Limitation of Test: Elevated SG readings may be obtained in the presence of moderate quantities of protein. SG is also increased with glucose in the urine.

**8. Protein**

Chemical Principle: Protein "error of indicators." When pH is held constant by a buffer, indicator dyes release $H^+$ ions because of the protein present and change colour from yellow to blue-green.
Reagents: Tetrabromophenol blue 0.34mg
Expected Values: Normal urine specimens ordinarily contain some protein 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.
Detection Limits: This test has detection limit of 10 ~15 mg/dl protein.
Limitation of Test: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens

**9. Nitrite**

Chemical Principle: 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 colour change form white to pink.
Reagents: P-arsanilic acid 4.5mg
Expected Values: Normally no nitrite is detectable in urine and the presence of nitrute indicates the presence of bacteria that may be caused by infection of the kidneys, ureter, and bladder of urethra.
Detection Limits: Comparison of the reacted reagent area against a white background may aid in the detection of low levels which may otherwise be missed. The test is specific for nitrite and will not react with any other substance normally excreted in urine.
Limitation of Test: Any degree of uniform pink colour development should be considered positive; however, pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as suggesting the presence of $10^5$/ml, but colour development is not proportional to the number of bacteria present. The specimen should not be more than 4 hours old at the time of the test. Urine that has been stored for longer periods of time is likely to give a false negative or a false positive result. The latter can be shown to be due to bacteria contamination.

**10. Leukocyte**

Chemical Principle: 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 colour change from beige to violet.
Reagents: Induced Indole amino acid ester 1.3mg
Expected Values: Normally no leukocytes are detectable in urine. Individually observed trace results may be questionable clinical significance.
Detection Limits: The test is generally capable of detecting 20~25 ca Cells /µl as a trace.
Limitation of Test: The test result may not always be consistent with the leukocyte cell number by the microscopic examination. High concentration of glucose, high specific gravity, and high level of albumin, high concentration of formaldehyde or presence of blood may cause decreased test results. High concentration of oxalic acid of trace of oxidizing agents may cause false negative results.

**11. Ascorbic acid**

Chemical Principle: 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.
Reagents: 2,6-dichloro indophenol sodium salt 0.8mg
Expected Values: Urinary ascorbic acid concentrations as low as 50mg/dl can cause interference in specimens with low concentrations of glucose, blood and bilirubin. Concentrations of and above 200mg/dl can be expected to cause strong interference. If detect ascorbic acid in urine, once again test after 24 hours do not take ascorbic acid.
Detection Limits: The test has a sensitivity of 20mg/dl ascorbic acid. False positive reaction with other reducing agent.
Limitation of Test: No interferences are known.

**NOTES**

1. Reagent strips should not be used for the analysis of body fluids other than urine.
2. Reagent strips are only for professional use in vitro diagnostic.
3. All patient samples should be treated as potentially infectious.
4. As with all laboratory tests, definitive diagnostic decisions should not be based on any single result of method.
5. The effect of medicaments or their metabolic products on the test is not known in all cases. In case of doubt it is recommended not to take the medicaments and than repeat the test.
6. Removing of residues should be performed according to local law regulation.
7. Keep out of reach of children.

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**Explanation of symbols**

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|---|---|---|---|---|---|
| ⚠ | Caution, consult accompanying documents | 📖 | Consult instructions for use | 🏭 | Manufacturer |
| IVD | For in vitro diagnostic use | LOT | Batch code | REF | Catalog number |
| 🌡 | Temperature limitation | ⏳ | Use by | | |

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