HumaCombina 13

Urine Test Strips

Package Size 100 tests/bottle
REF 22130
IVD

Intended Purpose

HumaCombina 13 is a urine strip for the semi-quantitative determination of urobilinogen (UBG), bilirubin (BIL), ketones (KET), creatinine (CRE), blood (ERY/Hb), protein (PRO), microalbumin (ALB), nitrite (NIT), leucocytes (LEU), glucose (GLU), specific gravity (SG), pH, ascorbic acid (VC). The strip is intended for screening patients for diseases such as diabetes, liver diseases, hemolytic diseases, urogenital disorders, kidney disorders, and metabolic abnormalities. The urine strips are intended for evaluation by reflectometric reading or by visual reading. This assay is intended for professional use only.

Reagents Composition

Urobilinogen	Diazonium salt	0.3%
Bilirubin	Diazonium salt	0.6%
Ketones	Sodium nitroprusside	5.9%
Creatinine	3,5-Dinitrobenzoic acid	4.5%
Blood	Diisopropylbenzene-dihydroperoxide	26.0%
	Tetramethylbenzidine	1.6%
Protein	Tetra bromophenol blue	0.2%
Microalbumin	Sulfone phthalein	2.4%
Nitrite	p-Arsan Ilic acid	1.4%
	Tetrahydroquinoline	0.9%
Leucocytes	Pyrrole amino acid ester	4.3%
	Diazonium salt	0.5%
Glucose	Glucose oxidase	1.8%
	Peroxidase	0.4%
	Potassium iodide	0.3%
Specific Gravity	Bromothymol blue	4.8%
	Poly (methyl vinyl ether/maleic anhydride)	90.6%
	Sodium hydroxide	4.6%
pH	Bromocresol green	3.6%
	Bromothymol blue	55.1%
Ascorbic acid	2,6-Dichlorophenolindophenol	1.0%

Applicable instrument

REF	
17600	Combilyzer[13]
17630	HumaCombilyzer

Storage and Stability

Store the bottle containing the strips in a cool and dry place at 2...30°C, but not in the refrigerator. Keep diagnostic test strips protected from direct sunlight and humidity. Under proper conditions test strips are stable up to the stated expiry date. Use the strips within 1 month after first opening. The cap must be closed tightly subsequently after taking out the strips. Do not remove the desiccant from the bottle.

Specimen collection and preparation

Mid-stream first morning urine is recommended. The urine should incubate in the bladder for at least 4 hours. Collect specimens in clean, well rinsed containers, free from detergents or disinfectants. Do not add any preservatives. Protect the samples from light. For women: the analysis should not be performed while a woman is menstruating or having a vaginal discharge. After clinical samples are collected, the test should be completed within 2 hours.

Procedure and Notes

1. Use only well mixed, non-centrifuged urine. After clinical samples are collected, the test should be completed within 2 hours at room temperature of 25±5°C.
2. Collect specimen in clean, well rinsed containers, free from detergents or disinfectants. Do not add any preservatives.
3. Do not touch test areas of the reagent strip.
4. Immediately after removing the required number of strips, close the container securely using the original cap.
5. Immerse the test strip in the urine (approx. 2 sec), so that all reagent areas are covered. Remove excess urine from the strip by wiping the edge of the strip on the urine container or on absorbent paper.
6. For reflectometric reading with HumaCombilyzer or Combilyzer 13, please carefully read the detailed instructions for use of the instrument.

Visual reading

To prevent interaction from adjacent test areas, hold the strip in a horizontal position during incubation.

Compare the reagent areas on the strip with the corresponding charts of color fields on the container 60 seconds after immersion. Coloration only on the rim of the test pad or after more than 2 minutes after immersion is not relevant and should not be used for interpretation.

As a result of the differing spectral sensitivities of the human eye and the optical system of the instrument, it is not always possible to obtain precise agreement between the values obtained by visual and by automated reading.

Test Principles, Expected Values, Limitations

Urobilinogen (UBG): - The test is based on the coupling of urobilinogen with stabilized diazonium salts. The normal concentration of urobilinogen in urine ranges from 3.4 - 17 µmol/L (0.2 – 1 mg/dL). Concentrations of ≥ 34 µmol/L (2 mg/dL) may be clinically significant. Such patient specimens should be further evaluated.
The color fields correspond to the following urobilinogen concentrations: Norm./3.4 µmol/L (0.2 mg/dL), Norm./17 µmol/L (1 mg/dL), 1+/34 µmol/L (2 mg/dL), 2+/68 µmol/L (4 mg/dL), 3+/≥135 µmol/L (≥8 mg/dL).

Bilirubin (BIL): - A red azo compound is obtained in the presence of acid by coupling bilirubin with a diazonium salt.
The color fields correspond to the following values: Neg., 1+/17 µmol/L (1 mg/dL), 2+/51 µmol/L (3 mg/dL), 3+/≥103 µmol/L (≥6 mg/dL).
Normally, no bilirubin is detectable in urine. A positive result requires further investigation. False low or negative results may be caused by large amounts of ascorbic acid or by longer exposure of the sample to direct light. Different urine contents (e.g. urine indican) can lead to atypical coloration.

Ketones (KET): - Acetone and acetoacetic acid react with sodium nitroprusside in alkaline solution to give a pink to violet colored complex (Legal's test). Normally the urine is free of ketones. Detectable concentrations of ketones can originate from physiological stress (fasting, pregnancy, excessive sport).
The color fields correspond to the following acetoacetic acid values: Neg., ±/0.5 mmol/L (5 mg/dL), 1+/1.5 mmol/L (15 mg/dL), 2+/3.9 mmol/L (39 mg/dL), 3+/7.8 mmol/L (78 mg/dL), 4+/≥16 mmol/L (≥160 mg/dL).
Phenyl ketones in higher concentrations will produce variable colors. β-Hydroxybutyric acid is not detected. Phthalein compounds and derivatives of anthraquinones interfere by producing a red coloration in the alkaline range which may mask the coloration of ketones.

Creatinine (CRE): - The test is based on a reaction of creatinine with 3,5-dinitrobenzoic acid in alkaline medium.
The color fields correspond to the following values: 0.9 mmol/L (10 mg/dL), 4.4 mmol/L (50 mg/dL), 8.8 mmol/L (100 mg/dL), 17.7 mmol/L (200 mg/dL), 26.5 mmol/L (300 mg/dL).
Creatinine is present in urine at concentrations of 10 – 300 mg/dL. First morning urine may have creatinine concentration of >200 mg/dL, whereas high liquid intake may cause concentrations <50 mg/dL. Falsely elevated results are possible in visibly bloody urine samples.

Blood (ERY/Hb): - The detection is based on the pseudo peroxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator producing a green color.
The minimum sensitivity of the test strip is approximately 10 red cells /µL urine. In case of green patches (intact erythrocytes) or green coloration (free hemoglobin, myoglobin) of the test pad, proceed to further clinical investigations of the patient.
The color fields correspond to the following values: Neg., ±/ca.10, 1+/ca.25, 2+/ca.80, 3+/≥ca.200 Ery/µL.
Microbial peroxidase associated with urinary tract infections may cause a false positive reaction. The sensitivity of the test may be decreased in specimens with high specific gravity and by elevated ascorbic acid concentrations (≥88 mg/dL (5.0 mmol/L)). Pay attention to the ascorbic acid field.

Protein (PRO): - The test is based on the "protein error" principle of the indicator. The test pad is not specific for a particular protein and proteins other than albumin can cause a positive result. A visibly bloody urine (blood: +++) may cause falsely elevated results.
The color fields correspond to the following values: Neg., ±/Trace, 1+/0.3 g/L (30 mg/dL), 2+/1.0 g/L (100 mg/dL), 3+/3.0 g/L (300 mg/dL), 4+/≥20.0 g/L (≥2000 mg/dL).
Normally, no protein is detectable in the urine of healthy individuals. Falsely positive results are possible in highly alkaline urine samples (pH > 9), in visibly bloody urine samples and after infusions with polyvinylpyrrolidone (blood substitute), after intake of drugs containing quinine and also by disinfectant residues containing quaternary ammonium groups in the urine sampling vessel.

Microalbumin (ALB): - The test is based on the "protein error" principle of the indicator, which is caused by the presence of albumin. Sulfonephthalein has a high sensitivity for albumin.
The color fields correspond to the following values: 10, 30, 80 and ≥150 mg/l urinary albumin. Normally, albumin is present in urine at concentrations of <20mg/l. Concentrations of >20-200 mg/l indicate microalbuminuria; even higher concentrations indicate clinical albuminuria. For further information refer to "albumin-to-creatinine ratio". Falsely positive results may be caused for instance by visibly bloody urine samples and disinfectant residues containing quaternary ammonium groups in the urine sampling vessel.

Nitrite (NIT): - The color test is based on the Griess reaction. Any degree of pink coloration should be interpreted as a positive nitrite test. The presence of nitrite is a sign of bacteriuria caused by gram-negative nitrite-forming bacteria in the urine when their

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number is greater than 105/ml (0.075 mg/dL nitrite ion or greater). Negative results do not necessarily exclude significant bacteriuria and can be caused by insufficient incubation of the urine in the bladder, urinary tract infections due to bacteria not containing nitrate reductase, low dietary nitrate intake, use of diuretics. False positive results may occur in stale urines, in which nitrite has been formed by contamination of the specimen.

Leucocytes (LEU): - The test is based on the esterase activity of granulocytes. This enzyme splits heterocyclic carboxylic acid esters, and the resulting hydroxy-pyrrole derivative reacts with a diazonium salt producing a violet color. Urines of healthy subjects do not contain any leucocytes. Positive results, even when constantly varying from "normal" to "15", may be clinically relevant.

The color fields correspond to the following values: Neg., ±/ca.15, 1+/ca.70, 2+/ca.125, 3+/≥ca.200 Leu/µL.

High glucose concentration (≥160 mmol/L or 3019 mg/dL) or high specific gravity may cause decreased test results. False positive results may be caused by contamination with vaginal secretion.

Glucose (GLU): - The detection is based on the glucose oxidase-peroxidase-chromogen reaction. Apart from glucose, no other compound in urine is known to give a positive reaction.

Normally, glucose cannot be detected in the urine although small amounts are secreted also by the healthy kidney. Changes in the coloration corresponding to less than 50 mg/dL (2.8 mmol/L) are to be considered normal.

The color fields correspond to the following ranges of glucose concentrations: Neg., ±/2.8 mmol/L (50 mg/dL), 1+/5.6 mmol/L (100 mg/dL), 2+/14 mmol/L (250 mg/dL), 3+/28 mmol/L (500 mg/dL), 4+/≥56 mmol/L (≥1000 mg/dL).

High concentrations of ascorbic acid (≥2.8 mmol/L or 50 mg/dL) or ketones (≥1 mmol/L or 10 mg/dL) in specimens with low glucose concentration (up to 7 mmol/L or 126 mg/dL) may lead to false negative results. Pay attention to the ascorbic acid field.

Specific Gravity (SG): - The test is based on a color change of the reagent from blue green to greenish yellow depending on the concentration of ions in the urine. The test permits the determination of urine density between 1.000 and 1.030. For better correlation with the refractive index method 0.005 should be added to all visual readings from urines with pH ≥6.5. Strips read with HumaCombilyzer and Combilyzer[13] are automatically adjusted for pH. Highly alkaline (pH >8) urine specimens lead to slightly decreased results. Urine specimens with protein concentrations of 1.75 g/L may lead to elevated readings.

pH: - The test paper contains indicators which change color between pH 5.0 and pH 9.0. For visual reading, the color fields correspond to the following pH values: 5.0, 6.0, 6.5, 7.0, 7.5, 8.0 and 8.5. The instrument could recognize two more gradients, 5.5 and 9.0.

The pH value of fresh urine of healthy people varies between pH 5 and pH 6.5. Bacterial contamination may cause false results.

Ascorbic Acid (VC): - The detection is based on discoloration of the blue 2,6-dichlorophenolindophenol.

The color fields correspond to the following values: 0 mmol/L (0 mg/dL), 0.6 mmol/L (10 mg/dL), 1.4 mmol/L (25 mg/dL), 2.8 mmol/L (50 mg/dL), ≥5.7 mmol/L (≥100 mg/dL).

Ascorbic acid (Vitamin C) can interfere with the tests for glucose, blood, bilirubin, and nitrite. Repetition of testing is recommended at the earliest 10 hours after the last vitamin C intake (medication, fruit, vegetable). Mid-stream first morning urine is recommended. The urine should incubate in the cartridge.

Albumin-to-Creatinine Ratio (A:C)

Albumin is normally present in urine at concentrations of < 3.4 mg albumin/mmol creatinine (< 30 mg albumin/g creatinine).

Microalbuminuria is indicated as a ratio result of 3.4 - 33.9 mg/mmol or 30 - 300 mg/g (flagged by HumaCombilyzer and Combilyzer13 as "abnormal"). Results > 33.9 mg/mmol or > 300 mg/g can be defined as proteinuria (flagged by HumaCombilyzer and Combilyzer13 as "high abnormal").

		Microalbumin (ALB) mg/L			
		10	30	80	150
Creatinine (CRE) mg/dL	10	*New specimen	High Ab	High Ab	High Ab
	50	N	Ab	Ab	High Ab
	100	N	Ab	Ab	Ab
	200	N	N	Ab	Ab
	300	N	N	N	Ab

N = normal; Ab = abnormal; High Ab = high abnormal
*Urine specimen is too diluted. Retest with a new specimen.

Nitrite and leucocytes

If both parameters are negative (NIT and LEU), a urine tract infection (UTI) is very unlikely. If one or both parameters are positive (NIT and LEU) the patient might have a UTI and further analysis is required.

Quality Control

The performance of the reagent strips should be confirmed when a new test is performed, or a new bottle is opened. For quality control, use the corresponding quality control products recommended by HUMAN.

Performance Characteristics

Typical performance data and potentially interfering substances test results can be found in the Verification Report, accessible via:
www.human.de/data/gb/vr/us-hc13.pdf or
www.human-de.com/data/gb/vr/us-hc13.pdf

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

Notes

1. Please refer to the description of each parameter for limitations and interferences.
2. To establish a final diagnosis and prescribe an appropriate therapy, the results obtained with urine test strips should be verified with other medical results.
3. Drugs and their metabolic products may interfere with the test. Uptake of drugs should therefore be considered and if possible, the test should be repeated after discontinuation of drug therapy.
4. All materials contaminated with patient specimens should be inactivated by validated procedures according to applicable regulations.

Safety Notes

All patient specimens and controls should be handled as potentially infectious. All materials of animal origin avoid many risks associated with the use of human serum (e.g. Hepatitis B and C, HIV). Nevertheless, all material of animal origin should still be treated as potentially infectious material.

For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

P234 Keep only in original packaging.
P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.
P401 Store in accordance with local/regional/national/ international regulations.
P501 Dispose of contents/container in accordance with local/regional/national/inter-national regulations.

References

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2. Burtis, C.A. et al., Tietz Textbook of Clinical Chemistry and Molecular Diagnosis, 4th ed., Elsevier Saunders; 2006.
3. 1.Burtis, C.A. and Ashwood, E.R.: "Reference Information for the Clinical Laboratory " in Tietz, N.W. (ed.): Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 798-801, 1218, 483-484, 1799-1839.

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Version: HD/CE 22130 202501 V004

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