CE

REF CM-374-009

MEDITAPE™ UC-11A

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Identification of the IVD reagent
MEDITAPE™ UC-11A

Intended use
For in vitro diagnostic use only
MEDITAPE UC-11A is a urinalysis test strip with reagent pads for the determination of diagnostic parameters in human urine.

Principles of the examination method[1)]
[Urobilinogen] Azo coupling method: The reaction of urobilinogen in urine with 3,4-Methylene dioxybenzenediazonium tetrafluoroborate develops a color change from light pink to red.
[Blood] Peroxidase-like reaction of the hemoglobin: Peroxidase-like hemoglobin releases oxygen, oxidizing tetramethylbenzidine causing the color change from white to blue.
[Protein] Protein error of pH indicator: A reaction between tetrabromophenol blue and protein induces a color change from yellow to blue-green.
[Glucose] Enzyme method (GOD, POD): Glucose in the urine is determined by the glucose oxidase-peroxidase reaction. The action of glucose oxidase on glucose produces gluconic acid and hydrogen peroxide. The peroxidase then catalyzed the reaction of hydrogen peroxide and chromogen to form a blue dye. The basic color on the test pad is yellow and the color will change from yellow to blue-green according to the glucose concentration.
[Ketones] Nitroprusside method: Acetone and acetoacetic acid react with sodium nitroprusside in an alkaline medium. A color change from buff pink to lavender occurs.
[Bilirubin] Azo coupling method: 2,4-dichlorobenzene diazonium tetrafluoroborate reacts with bilirubin in the presence of acid medium. A color change from light tan to light pink occurs.
[Nitrite] Griess method: Nitrite forms a diazonium compound by reacting with an aromatic amine and further coupling yield a purple azo dye. Therefore, the color on the test pad changes from light green to purple.
[Leukocytes] Measurement of Leukocyte esterase activity: The 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.
[pH] pH indicator method: The pH reaction area is impregnated with methyl red and bromothymol blue as indicators. A color change from orange to green indicates pH between 5 and 9.
[Creatinine] Benedict–Behre method[2)]
[Albumin] Protein error of pH indicator: A reaction between tetrabromophenol blue and protein induces a color change from yellow to blue-green.

Parameters: Urobilinogen (URO), Blood (BLD), Red blood cell (RBC), Hemoglobin (Hb), Protein (PRO), Glucose (GLU), Ketones (KET), Bilirubin (BIL), Nitrite (NIT), Leukocytes (LEU), pH, Creatinine (CRE), Albumin (ALB).

Components
Reactive ingredients (per test pad 1 cm²)
[Urobilinogen] Metaphosphoric acid: 4.16 mg, 3,4-methylenedioxybenzene diazonium tetrafluoroborate: 0.042 mg
[Blood] Cumen hydroperoxide: 0.223 mg, 3,3',5,5'-tetramethylbenzidine: 0.286 mg
[Protein] Tetrabromophenol blue: 0.015 mg
[Glucose] Glucose oxidase: 0.059 mg, peroxidase: 0.023 mg, 3,3',5,5'-tetramethylbenzidine: 0.088 mg
[Ketones] Glycine: 6.64 mg, sodium nitroprusside: 0.188 mg
[Bilirubin] 2,4-dichlorbenzene diazonium tetrafluoroborate: 0.022 mg
[Nitrite] Sulfanilamide: 0.26 mg, N-(1-Naphytylamino)-3-propanesulfonic acid: 0.076 mg
[Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy)-indole: 0.020 mg, 2-methoxy-4-(N-morpholino) -benzenediazonium salt: 0.007 mg
[pH] Methyl red: 0.002 mg, bromothymol blue: 0.038 mg
[Creatinine] 3,5-dinitrobenzoic acid: 0.48 mg
[Albumin] Tetrabromophenol blue: 0.010 mg
The blank pad is used for correcting the influence of urine color, not for the analysis.

Warnings and precautions
1. Before use, please read the analyzer's Instructions for Use carefully.
2. Diagnosis should not be made based on the analysis using the MEDITAPE UC-11A test strip alone; use other test results and clinical symptoms for comprehensive diagnosis.
3. Use the test strips as directed in this Instructions for Use, otherwise the product quality and safety will not be guaranteed.
4. Use disposable powder free gloves to prevent infection during the analysis and disposing the test strips.
5. Do not use a product that is suspected to have been frozen.
6. Reagents must not be used after its expiry date.
7. Avoid refrigeration as much as possible. If the test strip is refrigerated for long-term storage, take it out and wait until it returns to 20 - 25 °C before use.
8. Do not use deteriorated, discolored or blackened test strips.
9. Do not touch the test pads. Make sure the test strip is free of dirt before use.
10. Minimally handle test strips after opening as test strips deteriorate in humid conditions.
11. Do not take the desiccant out of the test strip container except when a strip is placed to the analyzer.
12. The test strips are for single use only. Do not reuse.
13. Do not put test strips in other container except when placing a strip to the analyzer and storing.
14. Do not put more than 100 test strips in the test strip receptacle of the analyzer.
15. When the power of the analyzer is turned off after the analysis, remove test strips from the analyzer and store them in accordance with the following method.
    [Cases where a test strip container is used] Please put a desiccant back in the test strip container and seal the bottle with a cap tightly.
    [Cases where a test strip receptacle (for device installation) is used] Put test paper and desiccant back in a test strip container and seal the bottle with a cap tightly.
16. Handle samples as biohazardous material.

Examination procedure
1. By using powder free gloves remove only the number of test strips required for testing and close the bottle immediately after removing the test strips.
2. Place the test strip to the analyzer as directed in the analyzer's Instructions for Use.
3. Place the urine samples on the sample rack and place it to the analyzer as directed in the analyzer's Instructions for Use.
4. Press the start key. The analyzer will automatically start the following process.
5. The test strip is set on the strip holder.
6. Sampled urine is applied to the test pads.
7. The test strip is guided to the detection part to measure the reflectivity at the specific time and wavelength.
8. The urine color is corrected by the blank pad. The result is determined based on the prearranged respective working curves and output.

Storage and shelf life of unopened product
Store the test strips at 1 – 25 °C. Keep away from humidity, direct sunlight and heat. When the product is properly stored in its sealed container, it is stable until the expiration date printed on the label.

Storage and shelf life after first opening
Once placed to the analyzer and stored, the test strip should be used within 1 week.

Control procedure
Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.
For quality control, use of at least two levels urine control which are commercially available is recommended.

Biological reference intervals

Parameter	Standard range
URO	0.03 – 0.97 mg/dL[3)]
BLD	< 5 cells/HPF[4)]
PRO	< 30 mg/dL[4)]
GLU	2 - 20 mg/dL[1)]
KET	≦ 2 mg/dL[1)]
BIL	≦ 0.05 mg/dL[4)]
NIT[6)]	
LEU	< 12 cells/μL[4)]
pH	4.5 – 7.5[4)]
CRE	0.5 – 1.5 g/day[1)]
ALB	≦ 23.8 mg/L[1)]

Interpretation of results

Parameter		Assessment								
URO		normal			1+ 2.0 (34)	2+ 4.0 (68)	3+ 8.0 (135)	4+ 12.0 (202)		mg/dL (μmol/L)
BLD	RBC	-		± 10	1+ 20	2+ 50	3+ 250			c/μL*
BLD	Hb	-		± 0.03	1+ 0.06	2+ 0.15	3+ 0.75			mg/dL
PRO		-		± 15 (0.15)	1+ 30 (0.3)	2+ 100 (1.0)	3+ 300 (3.0)	4+ 1000 (10)		mg/dL (g/L)
GLU		-		± 50 (2.8)	1+ 100 (5.6)	2+ 250 (14)	3+ 500 (28)	4+ 2000 (111)		mg/dL (mmol/L)
KET		-			1+ 10 (0.93)	2+ 30 (2.8)	3+ 80 (7.4)			mg/dL (mmol/L)
BIL		-			1+ 0.5 (8.6)	2+ 1.0 (17)	3+ 2.0 (34)			mg/dL (μmol/L)
NIT		-			+					
LEU		-			1+ 25	2+ 75	3+ 500			c/μL*
pH		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
CRE		10 (0.1)		50 (0.5)	100 (1.0)	200 (2.0)	300 (3.0)			mg/dL (g/L)
ALB		10 (0.01)		30 (0.03)	80 (0.08)	150 (0.15)	over			mg/L (g/L)

* c/μL=cells/μL
Ketones are measured using lithium acetoacetate as standard reference material.
Nitrite (+), sodium nitrite 0.1 to 0.3 mg/dL.

The protein/creatinine ratio (P/C ratio) and the albumin/creatinine ratio (A/C ratio) are automatically computed according to the settings in the analyzer.

Parameter	Assessment								
P/C ratio	dilute*1	normal	1+ 0.15		1+ 0.30		2+ >=0.50		g/gCr
A/C ratio*2	dilute*1	normal	1+ 30	1+ 80	1+ 150	>=1+ >=80	>=1+ >=150	2+ >=300	mg/Cr

*1 The "dilute" represents that urine is too dilute for accurate calculation of the P/C ratio and the A/C ratio.
Therefore, another urine sample should be obtained for retest.
*2 For A/C ratio, when albumin is "over" and creatinine is 200 or 300 mg/dL, the qualitative value and the semiquantitative value shall be computed as >=1+ and >=150 or >=80, respectively.

[Note 1] Urobilinogen (-) cannot be confirmed with this method[4)].
[Note 2] Bacteriuria cannot be denied even if nitrite is negative because some bacteria do not reduce nitrate, and in a case where urine lacks nitrate, the test pad will show nitrite negative since nitrate-reducing bacteria cannot produce nitrite[5)].
[Note 3] The test pad for leukocytes measures esterase activity in leukocytes. Therefore, an assessment may be different from a result from urinary sediment depending on extent of disintegration of leukocytes in urine[5)].

Performance characteristics
1. Sensitivity
(1) For the test pads for urobilinogen, blood, protein, glucose, ketones, bilirubin, nitrite, leukocytes, creatinine and albumin, when the following 2 reference urine levels are measured, the resulted assessment is consistent with the preset assessment grades and then may be clearly differentiated.
(2) For the test pad for pH, when a test is performed by using reference urine with pH at 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5 or 9, the resulting values as outcome are those in the preset assessment grade ±0.5.

Parameter		Reference urine level
URO		≦ 0.2 mg/dL and 2.0 mg/dL
BLD	RBC	0 cells/μL and 10 cells/μL
BLD	Hb	0 mg/dL and 0.03 mg/dL
PRO		0 mg/dL and 15 mg/dL
GLU		≦ 10 mg/dL and 50 mg/dL
KET		0 mg/dL and 10 mg/dL
BIL		0 mg/dL and 0.5 mg/dL
NIT		0 mg/dL and 0.1 mg/dL
LEU		0 cells/μL and 25 cells/μL
CRE		10 mg/dL and 50 mg/dL
ALB		10 mg/L and 30 mg/L

Ketones are measured using lithium acetoacetate as standard reference material.

2. Accuracy
(1) For the test pads for urobilinogen, blood, protein, glucose, ketones, bilirubin, nitrite, leukocytes and albumin, when a test is performed by using reference urine in which levels are equivalent to those in each assessment grade, outcome is consistent with the preset assessment grades.
(2) The test pad for pH shows outcome in a same manner in **1. Sensitivity.**
(3) For the test pad for creatinine, when a test is performed by using reference urine in which levels are equivalent to those in each assessment grade, outcome is consistent with the preset assessment grades in 10, 50 and 100 mg/dL. The assessment grade may be indicated as higher by 1 grade than the preset one in 200 mg/dL, and the assessment grade may be indicated as lower by 1 grade than the preset one in 300 mg/dL.

3. Repeatability
The test pads show the following outcome, when reference urine with known levels is tested simultaneously for 5 times.
(1) The test pads for urobilinogen, protein, glucose, ketones, bilirubin, nitrite, leukocytes and albumin show a consistent outcome.
(2) The test pad for blood (hemoglobin) shows a consistent outcome. The test pad for blood (RBC) shows a consistent outcome. However, with reference urine with RBC level of 10 cells/μL, RBC level is indicated at 20 cells/μL in no more than one situation.
(3) The test pad for pH shows the value in the preset assessment grade ±0.5 as outcome.
(4) At creatinine level of 10 to 100 mg/dL, the test pad for creatinine shows a consistent outcome. At creatinine concentration of 200 to 300 mg/dL, it shows 200 mg/dL or 300 mg/dL.

4. Measuring range

Parameter		Measuring range
URO		2.0 - 12.0 mg/dL
BLD	RBC	10 - 250 cells/μL
BLD	Hb	0.03 - 0.75 mg/dL
PRO		15 - 1000 mg/dL
GLU		50 - 2000 mg/dL
KET		10 - 80 mg/dL
BIL		0.5 - 2.0 mg/dL
NIT		0.1 - 0.3 mg/dL
LEU		25 - 500 cells/μL
pH		5.0 - 9.0
CRE		10 - 300 mg/dL
ALB		10 - 150 mg/L

Ketones are measured using lithium acetoacetate as standard reference material.

5. Correlation

Parameter	Number of patients	Concordance rate (%)
URO	254	98.4
BLD	279	98.6
PRO	224	92.0
GLU	286	98.6
KET	281	99.3
BIL	299	98.7
NIT	288	99.7
LEU	266	99.6
pH	233	94.8
CRE	60	91.7
ALB	108	95.4

6. Interferences[4), 6)]

Parameter	Interfering substance
URO	• Not affected by porphobilinogen, indole, para-aminosalicylic acid, sulfonamide[7)] and urea[8)] that react to Ehrlich's aldehyde reagent.
BLD[9)]	• The test may be false negative in the presence of a large amount of reducing agent such as ascorbic acid and nitrite in the urine. The in-house study showed that sodium nitrite concentration ≦ 10 mg/dL displayed no false negative results when the measured hemoglobin concentration was 0.06 mg/dL. • The test may be false positive if affected by oxidizing agents such as hypochlorous acid and bleaching powder. The in-house test was false positive in the presence of sodium hypochlorite ≧ 1.2 mg/dL. • The reactivity may be inhibited in baruria. • Reaction to myoglobin may occur[10)]. • The test may be false positive if drugs containing -SH groups (e.g., glutathione agents and bucillamine, etc.) have been taken.
PRO[11)]	• The test may be false positive in urine of pH ≧ 8 or urine having strong buffering action. • The test may be false positive if detergent or disinfectant (quaternary ammonium compound or chlorhexidine) is left in the container. • The reaction to globulin and mucoprotein, etc. is weaker compared with albumin. It has been reported that although the reactivity of Bence Jones protein is lower than that of albumin, they often exhibit similar sensitivity[12)].
GLU[13)]	• False negative test results are possible in the presence of high levels of ascorbic acid. Investigations found that ascorbic acid concentrations ≦ 200 mg/dL display no false negative results when the measured glucose concentration is 100 mg/dL. • The in-house test showed no effect of sodium chloride (3 %), uric acid (150 mg/dL) or sodium nitrite (10 mg/dL). • The test may be false positive if affected by oxidizing agents such as hypochlorous acid and bleaching powder. The in-house test was false positive in the presence of sodium hypochlorite ≧ 6 mg/dL. • The test pad reacts to galactose. • The reactivity may be inhibited in baruria.
KET	• The test may be false positive or an abnormal color may be shown in the presence of a large amount of phenylpyruvic acid, pyruvic acid, oxaloacetate, α-ketoglutaric acid or phenolsulfonphthalein (PSP)[14)]. • The test pad does not react to β-hydroxybutyric acid. • The test may be false positive if drugs containing -SH groups (e.g., glutathione agents and bucillamine) have been taken[15)].
BIL	• The test may be false negative in the presence of a large amount of ascorbic acid or nitrite. • The test may be false positive in the presence of a large amount of urobilinogen or 5-hydroxyindoleacetic acid (5-HIAA)[14)]. • When etodolac has been taken, the test may be false positive showing pink (unlike the usual color of bilirubin) due to the reaction to its metabolite phenol derivative[7)].
NIT	• The test may be false negative in the presence of a large amount of ascorbic acid. The in-house study showed that ascorbic acid concentrations < 100 mg/dL displayed no false negative results when the measured nitrite concentration was 0.1 mg/dL.
LEU[16)]	• The test may be false positive in the presence of formaldehyde (urine preservative)[14)]. • The test may be false negative under the presence of protein ≧ 500 mg/dL. • The test may be false negative under the presence of cephalexin, gentamicin or boric acid (urine preservative).
pH	• Use of volatile materials such as acid and alkali may affect the test.
CRE	• The assessment value may be lower in urine containing ketones. However, the inhouse test showed no effect of lithium acetoacetate ≦ 30 mg/dL.
ALB[17)]	• The assessment value may be higher in urine of pH ≧ 8, urine having strong buffering action, or urine containing alkaline mucus. The test may be false positive if detergent or disinfectant (a quaternary ammonium compound or chlorhexidine) remains in the container. • The test may be false positive in the presence of a large amount of hemoglobin or myoglobin or macroscopically-obvious hematuria. The test may be positive in urine containing semen. • With regard to the following proteins, no impact was observed up to the concentration level shown in parentheses[6)]: Lysozyme (50 mg/L), α1-microglobulin (25 mg/L), β2-microglobulin (15 mg/L), prealbumin (200 mg/L), immunoglobulin (500 mg/L), α1-acidic glycoprotein (300 mg/L), haptoglobin (25 mg/L), transferrin (25 mg/L), α1-antitrypsin (25 mg/L), Bence Jones protein (100 mg/L) and retinol-binding protein (15 mg/L)

Limitations of the examination procedure
Severely discolored urine and urine discolored by medication may affect the analysis because of abnormally colored test pads.[6), 7)]
Use of volatile materials (e.g., acid, alkali, and organic solvent) or heating appliances such as oil heaters may affect the analysis.
The use of this product is validated on specific analyzers to optimize product performance and meet product specifications. Please refer to the Instructions for Use of your analyzer to confirm that the use of this product is authorized by Sysmex.
Sysmex cannot take the responsibility for patient results received from the use of Sysmex products on unauthorized analyzers. It is the responsibility of the user to validate modifications to these instructions or use of the product on analyzers other than those specified by Sysmex.

Primary sample collection, handling and storage[4)]
1. Fresh urine (within 1 hour of sampling) should be used in principle since urobilinogen[3)] and bilirubin[18)] are unstable when exposed to light or heat.
2. Frozen or refrigerated urine samples should be returned to 20 °C to 25 °C before use.
3. Urine should be collected in a rinsed container free of detergent and disinfectant.
4. Do not add highly acidic preservatives or organic solvents to store urine samples. Organic solvent such as toluene, xylene, and chloroform may adversely affect the analyzer (e.g., cell deterioration).
5. Urobilinogen level in the urine is generally the highest between 14:00 and 16:00[3)]. Although urine sampling during this time frame is ideal, samples collected at other times may also be used for analysis.
6. The first urine sample collected in the early morning or urine retained in the bladder for at least 4 hours should be used for nitrite analysis.
7. The protein and albumin test pads may show a false positive result or may be colored unevenly due to alkaline urine (pH ≧ 8)[11)]. Make the urine sample acidic with dilute acetic acid for retesting based on the result shown by a pH test pad.
8. Agitate the urine sample well before putting it on the sample rack.

Disposal procedures
Disposal procedures should meet requirements of applicable local regulations.

Literature references

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Product information
MEDITAPE UC-11A (MEK-200A) 100pcs.x10

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REF Catalogue number
Use by
IVD In vitro diagnostic medical device
LOT Batch code
Manufacturer
Keep away from sunlight
EC REP Authorised Representative in the European Community
Do not reuse
Consult instructions for use
CONT Contents
Temperature limitation
DESICCANT Desiccant