Instructions for Use

UTS-10 Cap™

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1. Introduction

A single-use push-fit testing cap that contains reagent pads for ten (10) parameters, Glucose, Blood, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Protein, Urobilinogen, Nitrite and Leukocytes intended for the *in vitro* diagnostic analysis of analytes in a urine specimen.

For *in vitro* diagnostic use by a Healthcare Professional only.

1.1 Intended purpose.

The UTS-10 Cap™ is a single-use push-fit testing cap for the *in vitro* diagnostic determination of analytes, Glucose, Blood, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Protein, Urobilinogen, Nitrite and Leukocytes in a urine sample. The UTS-10 Cap™ is intended for use in at-risk patient groups to aid in the diagnosis of renal, urinary, hepatic and metabolic disorders.

The UTS-10 Cap™ is designed to connect to the UTS Tube 5ml™ which is inserted into the UTS Digital Analyser™, a semi-automated in vitro diagnostic reflectance photometry device, designed to support the performance of the UTS-10 Cap™ that detects specific urine analytes by presenting the results as digital results on a display screen.

The UTS-10 Cap™ is intended for use by Healthcare Professionals in a near patient setting only.

1.2 Summary

The UTS-10 Cap™ is intended to be used in combination with the UTS Digital Analyser™ and UTS Tube 5ml™ for the *in vitro* diagnostic examination of analytes in a urine specimen.

The UTS Digital Analyser™ is a semi-automated *in vitro* diagnostic reflectance photometry device, designed to support the performance of the UTS-10 Cap™ that detects specific urine analytes by presenting the results as digital results on a display **– Product Name and Code: UTS Digital Analyser™ (UTSDA01)**

The UTS Tube 5ml™ is a non-sterile single-use specimen receptacle for the containment of a urine specimen during urinalysis **– Product Name and Code: UTS Tube 5ml™ (UTSTT02)**

2. Test Principle and Ingredients

Urinalysis using reagent pads is designed to provide a rapid and qualitative analysis of several analytes in a urine specimen. The UTS-10 Cap™ contains multiple reagent pads, each of which contains specific chemicals that react with the urine specimen. The reactions cause a colour change that can be analysed using the UTS Digital Analyser™ via automated reflectance photometry. Each reagent pad is tailored to detect a particular analyte through a specific chemical reaction:

Glucose: Glucose oxidase catalyses the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reagent test pad by the action of peroxidase. Ingredients: Glucose oxidase 430U, Peroxidase 200U, Potassium Iodide 12mg.

Blood: The peroxidase-like action of haemoglobin and myoglobin specifically catalyses 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

Bilirubin: Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azo dye. Ingredients: Sodium nitrite 0.733 mg, 2,4-dichlorobenzene diazonium 2.3mg, Sulfosalicylic acid 25mg

Ketone: Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide. Ingredients: Sodium nitroprusside 23mg

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.

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

Protein: This test is based on the principle of the protein error of a pH indicator. At a constant pH, the development of any green colour is due to the presence of protein. Ingredients: Tetrabromophenol blue 0.34mg

Urobilinogen: The test is based on the Ehrlich's reaction Ingredients: 4-Methoxybenzenediazonium 2.9mg

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 reagent test pad. The azo dye produced causes a pink colour change. Ingredients: p-Arsanilic acid 4.5mg

Leukocytes: 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

3. Device procedure

The UTS-10 Cap™ should be used with a urine specimen only.

Only open and place the UTS-10 Cap™ onto the UTS Tube 5ml™ if you are ready to run the test immediately - ensure that the UTS Tube 5ml™ has been appropriately filled with a urine specimen to the middle line on the UTS Tube 5ml™ and that the UTS™ Digital Analyser™ is ready for analysis before proceeding with the following procedure:

Step 1. Prior to opening a new UTS-10 Cap™, check the expiry date and ensure that the packaging is undamaged.

NOTE: Do not use the UTS-10 Cap™ if there is any damage to its packaging as this may compromise the performance of the test.

Step 2. Tear open the packaging and remove the UTS-10 Cap™.
Step 3. Place the UTS-10 Cap™ onto the top of the lid of the UTS Tube 5ml™ specimen.
Step 4. Press the UTS-10 Cap™ firmly down onto the lid of the UTS Tube 5ml™ specimen until the cap aligns with Bottom of the lid
Step 5. Once the UTS-10 Cap™ is connected to the UTS Tube 5ml™ lid, invert for 3 seconds and ensure that all the reagent pads are fully soaked.
Step 6. Revert the UTS-10 Cap™ and UTS Tube 5ml™ to the upright position.
Step 7. When all the above steps are complete, the UTS-10 Cap™, and UTS Tube 5ml™ should be immediately inserted into the UTS Digital Analyser™ by lifting the UTS Digital Analyser™ Top and inserting the UTS-10 Cap™ and UTS Tube 5ml™ into the Bottom and replacing the Top immediately to start the analysis.

NOTE: Do not lift the UTS Digital Analyser™ Top until the analysis has been completed. If the UTS Digital Analyser™ Top is lifted during the analysis, the test will be invalidated and will need to be repeated using a new UTS-10 Cap™ and UTS Tube 5ml™.

Step 8. Results will be shown on the UTS Digital Analyser™ display, record the results before lifting the UTS Digital Analyser™ Top.

NOTE: Do not lift the UTS Digital Analyser™ Top before the results are recorded. The results will be lost, and the test will need to be repeated using a new UTS-10 Cap™ and UTS Tube 5ml™.

Step 9. Lift the UTS Digital Analyser™ Top to remove the UTS-10 Cap™ and UTS Tube 5ml™, then immediately replace the UTS Digital Analyser™ Top.
Step 10. Dispose of the UTS-10 Cap™ and UTS Tube 5ml™ according to local policy.

Continue with test procedure detailed in the User Manual for the UTS Digital Analyser™ **– Product Name and Code: UTS Digital Analyser™ (UTSDA01)**

See Section 9 for additional Specimen Collection and Handling.

4. Interpretation of Results

Once the UTS Digital Analyser™ has completed evaluating the UTS-10 Cap™, both qualitative and semi-quantitative results will be shown on the UTS Digital Analyser™ display.

Analyte Units	**Results Shown** Analyte Concentration	
Leukocytes WBC/µL	**Negative**	**Trace**
		+ +70
		++ ++125
		+++ +++500
Nitrite mg/dL (mg/L)	**Negative**	**Trace** 0.3(3.0)
		Positive 10(100)
Blood (Hb) RBC/µL	**Negative**	**Trace**
		+ Haem +25
		++ Haem ++80
		+++ Haem +++200
		NH10 Non-Haem +10
		NH80 Non-Haem ++80
Glucose mg/dL (mmol/L)	**Negative**	**Trace** 100(5.5)
		Positive ≥250(14)
Ketone mg/dL (mmol/L)	**Negative**	**+-** ±5(0.5)
		+ +15(1.5)
		++ ++40(3.9)
		+++ +++80(8)
		++++ ++++160(16)
Protein mg/dL (g/L)	**Negative**	**Trace** 15(0.15)
		+ +30(0.3)
		++ ++100(1)
		+++ +++300(3)
		++++ ++++1000(10)
Specific Gravity	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030	
pH	5, 6, 6.5, 7, 7.5, 8, 8.5	

Analyte Units	**Results Shown** Analyte Concentration	
Bilirubin mg/dL (mg/L)	**Negative**	**+** +0.5(5)
		++ ++2(20)
		+++ +++4(40)
Urobilinogen mg/dL (µmol/L)	**Normal** 0.1(1.6), 1(16)	**2** 2(33)
		4 4(66)
		8 Positive 8(131)

Refer to the User Manual for the UTS Digital Analyser™ – **Product Name and Code: UTS Digital Analyser™ (UTSDA01)** for detailed instructions on interpreting fault messages or warnings shown on the UTS Digital Analyser™ display.

5. Materials

The UTS-10 Cap™ is intended for use in combination with the UTS Tube 5ml™ and UTS™ Digital Analyser™.

Contents of Individual packaging:
1 x UTS-10 Cap™

Devices required to perform a test:
Provided:
1 x UTS-10 Cap™

Not Provided:
1 x UTS Tube 5ml™
UTS Digital Analyser™

Specimen Collection Container
Consumables (i.e. Transfer Pipette, PPE/ gloves)

Please follow applicable internal procedures in accordance with local or national regulations.

The UTS-10 Cap™ is intended to be used in combination with the UTS Digital Analyser™ and UTS Tube 5ml™ for the *in vitro* diagnostic examination of analytes in a urine specimen.

The UTS Digital Analyser™ is a semi-automated *in vitro* diagnostic reflectance photometry device, designed to support the performance of the UTS-10 Cap™ that detects specific urine analytes by presenting the results as digital results on a display **– Product Name and Code: UTS Digital Analyser™ (UTSDA01)**

The UTS Tube 5ml™ is non-sterile single-use specimen receptacle for the containment of a urine specimen during urinalysis **- Product Name and Code: UTS Tube 5ml™ (UTSTT02)**

6. Storage

The UTS-10 Cap™ should be stored in a cool, clean and dry area, at a temperature within the range of 5 to 30°C.

Do not store the UTS-10 Cap™ in the refrigerator or freezer.
Store away from moisture and heat.

Storage outside of this temperature range may cause degradation of the UTS-10 Cap™ reagent pads, which may compromise the performance of the test.

The expiry date is printed on the UTS-10 Cap™ packaging; the UTS-10 Cap™ must not be used beyond the date of expiry.

If the UTS-10 Cap™ packaging is damaged and there is discolouration to the UTS-10 Cap™ do not use.

7. Warnings and Precautions

For *in vitro* diagnostic use by a Healthcare Professional only.
Single use.

NOTE: Testing should be performed immediately after opening the UTS-10 Cap™, as prolonged exposure to room temperature and humidity may result in a deterioration of the accuracy of the test results.

- Do not store the UTS-10 Cap™ in the refrigerator or freezer.
- Do not open the UTS-10 Cap™ packaging until you have the UTS Tube 5 ml™ appropriately filled with the specimen and are ready to perform the test.
- The UTS-10 Cap™ must be used with the UTS Tube 5ml™ and lid only.
- The Instructions for Use (IFU) must be read and understood completely before performing the test.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against handling of urine specimens throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear appropriate protective clothing such as disposable gloves when specimens are handled.
  Used specimen should be discarded according to local or national regulations.
- The urine specimen must be allowed to equilibrate to room temperature before testing.
- Store away from moisture and heat
- Do not use the UTS-10 Cap™ if there are any visible signs of damage to the device or packaging.
- Please ensure that an appropriate amount of specimen is used for testing. Ensure that the UTS Tube 5ml™ has been filled up to the middle line indicated on the UTS Tube 5ml™. Too much or too little specimen size may lead to invalid or no results.
- Substances that cause abnormal urine colour may affect the readability of urine testing reagent pads.

Please comply with applicable internal procedures in accordance with local or national regulations.

8. Limitations

As with all point of care 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 urine testing reagent pads.

Urinary ascorbic acid concentrations as low as 40mg/dl can cause interference in specimens with low concentrations of glucose, blood, nitrite and bilirubin.

Glucose: Ketones reduce the sensitivity of the test. Moderately high ketone levels (≥40 mg/dL), and ascorbic acid (≥40 mg/dL) may cause a false negative for specimens containing small amounts of glucose (100 mg/dL). Chlorine Bleach (≥1%), low SG (≤1.000) and formaldehyde (≥150 mg/dL) may cause false positive results.

Blood: Elevated specific gravity (≥1.040) or protein (≥1000 mg/dL) in urine may reduce the reactivity of the blood test pad leading to lower results. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations (>30 mg/dl) may cause false negatives at low levels of blood. Substances that cause abnormal urine colour, such as drugs containing azo dyes, nitrofurantoin and riboflavin may cause false positive result. Strong oxidizing cleaning agents such as chlorine bleach cause false positive results.

Bilirubin: Metabolites of drugs, such as Pyridium (≥220 mg/dL) 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 a false negative result.

Ketone: 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. Phenolsulfonphthalein may cause a false positive result.

Specific Gravity (SG): High-buffered alkaline (pH≥8) urine may cause a lower result, whereas high-buffered acidic urine may cause a slightly elevated result.

pH: If excessive urine remains on the reagent test pad because of an improper test procedure, it is possible that the acidic buffer from the protein testing pad will leach out and affects the pH testing pad, then the pH result may be lower than the actual. This phenomenon is called the "run-over effect."

Protein: False positive results may be found in strongly basic urine (pH≥9). Protein testing should not be performed using turbid urine specimens. Metabolites of drugs such as acetaminophen may cause false positives. Haemoglobin may also cause false positives. Pigments such as bilirubin and azo-containing compounds cause false positive results.

Urobilinogen: The absence of urobilinogen in the specimen cannot be determined. The reagent test pad will react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid. Drugs containing Azo Gantrisin (sulfamethoxazol) or high bilirubin may give a masking golden colour. Preservative formaldehyde may cause false negatives. The test is not reliable method for the detection of porphobilinogen.

Nitrite: Ascorbic acid (≥40mg/dL) may cause false negative results with urine containing low levels of nitrite (≤0.05mg/dL). The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as positive results. Medications such as phenazopyridine or other azo containing compounds or other dyes cause false positive results.

Leukocytes: The test result may not always be consistent with the leukocyte cell number observed by microscopic examination. High concentration of glucose, high specific gravity, high levels of albumin, high concentrations of formaldehyde or presence of arterial blood may cause decreased test results. False positive results may occasionally be due to contamination of the specimen by vaginal discharge.

9. Specimen Collection and Handling

The UTS-10 Cap™ should be used with a urine specimen only. There is no additive present in the UTS Tube 5ml™.

As per local policy, use an appropriate specimen collection receptacle to collect a freshly voided urine specimen and then using a Transfer Pipette, fill the UTS Tube 5ml™ with the urine specimen to the middle line indicated on the UTS Tube 5ml™ before securely screwing the lid onto the UTS Tube 5ml™.

For the most accurate results, a first of the day, mid-stream urine specimen collected at the point of care and tested within 2 hours is recommended. However, specimens taken at other times in the day are acceptable. Allow the test specimen to equilibrate to room temperature before testing.

See Section 7 for Warnings and Precautions before using the UTS-10 Cap™.

10. Performance Characteristics

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the presence or absence of inhibitory and matrix factors typically found in urine; and the conditions in which the product is used (e.g. temperature and humidity).

Each reagent test pad result represents a range of values. Because of specimen 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.

10.1 Analytical performance

a. Analytical Sensitivity (Detection limit)

A sensitivity study was performed to evaluate the limits of detection for each of the analytes. Negative urine was spiked with standard materials to obtain 3 levels across the measuring range for each analyte concentration. 90 replicates were obtained for each concentration (each specimen concentration was analysed 30 times using 3 reagent strip lots). Sensitivity was defined as the cutoff for which ≥95% of the contrived pooled measurements were trace or the first positive result:

Glucose:	100mg/dL (Glucose)
Bilirubin:	1.0mg/dL (Bilirubin)
Ketones:	5mg/dL (Acetoacetic Acid)
Blood:	10 RBC/µl (haemoglobin)
Urobilinogen:	2 mg/dL
Protein:	15mg/dL (Albumin)
Nitrite:	0.05mg/dL (Nitrite Ion)
Leukocytes:	20 WBC/µl (Intact and Lysed WBCs)

Detection Limit is not applicable to pH and Specific Gravity.

b. Analytical Specificity

Potential interferents and drugs were evaluated to assess their interfering effect on the performance. Urine specimen pools prepared at 3 analyte concentrations (negative, low positive and high positive) were spiked with potential interfering substances at various interference concentrations and analysed in 3 replicates using 3 lots. Interference was defined as change in output of ±1 colour block between the spiked and un-spiked control specimen.

The following table shows the substances that did interfere with one more of the analytes tested. Results are expressed as the lowest concentration of interfering substances that exhibit interference and the resulting change in output of colour block:

Analyte	Potential Interfering Substance	Concentration at which Interference was observed	Change in colour block output
Urobilinogen	Azo gantrinsin (Sulfamethoxazol)	≥105mg/dL	+1
	Bilirubin	≥4mg/dL	+1
	Formaldehyde	≥150mg/dL	-1
	Nitrofurantoin	≥40mg/dL	+1
	p-Amino salicylic acid	≥750mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Riboflavin	≥25mg/dL	+1
	Selenium	≥220mg/dL	+1
Glucose	Ascorbic Acid	≥40mg/dL	-1
	Bilirubin	≥6mg/dL	+1
	Chlorine Bleach	≥1%	+1
	Chlorine Bleach	≥150mg/dL	+1
	Lithium	≥40mg/dL	-1
	NaCl (Specific gravity)	≤1.000	+1
Nitrite	Ascorbic Acid	≥40mg/dL	-1
	Bilirubin	≥4mg/dL	+1
	Nitrofurantoin	≥20mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Riboflavin	≥50mg/dL	+1
	Selenium	≥300mg/dL	+1
	Urobilinogen	≥15mg/dL	+1
Bilirubin	Bilirubin	≥40mg/dL	-1
	p-Amino salicylic acid	≥1500mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Selenium	≥220mg/dL	+1
Ketones	Bilirubin	≥4mg/dL	+1
	Captopril	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	+1
Protein	Acetaminophen	50mg/dL	+1
	Bilirubin	≥6mg/dL	+1
	Haemoglobin	≥5mg/dL	+1
	Nitrofurantoin	≥20mg/dL	+1
	Riboflavin	≥25mg/dL	-1
	Urobilinogen	≥20mg/dL	-1
	pH	≥9	+1
Leukocytes	Albumin	≥1000mg/dL	-1
	Bilirubin	≥4mg/dL	+1
	Captopril	≥150mg/dL	-1
	Chlorine Bleach	≥0.5%	+1
	Formaldehyde	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	-1
	Nitrofurantoin	≥30mg/dL	+1
	Oxalic Acid	≥45mg/dL	-1
	Glucose	≥1500mg/dL	-1
	Phenazopyridine	≥50mg/dL	+1
	Riboflavin	≥37mg/dL	+1
	Selenium	≥300mg/dL	+1
	Tetracycline	≥40mg/dL	-1
	Urobilinogen	≥15mg/dL	+1
Blood	Albumin	≥1000mg/dL	-1
	Ascorbic Acid	≥30mg/dL	-1
	Bilirubin	≥6mg/dL +	+1
	Captopril	≥150mg/dL	-1
	Chlorine Bleach	≥0.5%	+1
	Formaldehyde	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	-1
	Nitrofurantoin	≥30mg/dL	+1
	Riboflavin	≥50mg/d	+1
	Urobilinogen	≥20mg/dL	-1

c. Precision (Repeatability and Reproducibility)

Precision testing was done in accordance with CLSI EP5-A3. The repeatability/ reproducibility was determined at three clinical sites, using commercially available control solutions. Studies were performed by medical technicians, using 2 levels of commercially available urine-based control solutions. For within-run precision studies, 10 test strips from 3 different lots at 3 sites were tested (30 tests at each site = 90 replicates per level). For within-day precision studies, 1 test strip a day from 3 different lots was tested at 3 sites for 10 days (30 tests at each site = 90 replicates per level).

Conclusion: The results show 100% agreement.

Level 1 control

		Within-run (n=90)		Within-day (n=90)	
Item	**Test Results**	**Exact agreement (%)**	**Agreement within +/-one block(%)**	**Exact agreement (%)**	**Agreement within +/-one block(%)**
Urobilinogen	Normal	100	100	100	100
Glucose	Negative	100	100	100	100
Bilirubin	Negative	100	100	100	100
Ketones	Negative	100	100	100	100
SG	1.02	100	100	100	100
Blood	Negative	100	100	100	100
pH	6	100	100	100	100
Protein	Negative	100	100	100	100
Nitrite	Negative	100	100	100	100
Leukocytes	Negative	100	100	100	100

Level 2 control

		Within-run (n=90)		Within-day (n=90)	
Item	**Test Results**	**Exact agreement (%)**	**Agreement within +/-one block(%)**	**Exact agreement (%)**	**Agreement within +/-one block(%)**
Urobilinogen	4 mg/dL	100	100	100	100
Glucose	1000 mg/dL	100	100	100	100
Bilirubin	4 mg/dL	100	100	100	100
Ketones	40 mg/dL	100	100	100	100
SG	1.02	98.9	100	100	100
Blood	200 RBC/uL	100	100	100	100
pH	7	100	100	98.9	100
Protein	100 mg/dL	100	100	100	100
Nitrite	Positive	100	100	100	100
Leukocytes	70 WBC/uL	100	100	100	100

d. Linearity

Specimens were created by spiking known concentration of each standard material or by serial dilution of a high concentration urine specimen with negative urine. Testing was performed by 3 medical technicians using 3 lots of test strips. Each concentration level was tested in 10 replicates with each lot of test strips. The results are summarised below:

Analyte	Urine specimen concentration	Colour block output	% Exact match
Nitrite	Negative	Neg.	100 % (90/90)
	0.05 mg/dL	Trace	100 % (90/90)
	10 mg/dL	Pos.	100 % (90/90)
Urobilinogen	Negative/ Norm	0.1	100% (90/90)
	1 mg/dL	1 mg/dL	100 % (90/90)
	2 mg/dL	2 mg/dL	98.8 % (89/90)
	4 mg/dL	4 mg/dL	98.8 % (89/90)
	8 mg/dL	8 mg/dL	100 % (90/90)

Analyte	Potential Interfering Substance	Concentration at which Interference was observed	Change in colour block output
Ketones	Negative	Neg.	100 % (90/90)
	5 mg/dL	±(5 mg/dL)	100 % (90/90)
	15 mg/dL	+(15 mg/dL)	96.6 % (87/90)
	40 mg/dL	++(40 mg/dL)	98.8 % (89/90)
	80 mg/dL	+++(80 mg/dL)	97.7 % (88/90)
	160 mg/dL	++++(160 mg/dL)	100 % (90/90)
Bilirubin	Negative	Neg.	100 % (90/90)
	1 mg/dL	+	98.8 % (89/90)
	2 mg/dL	++	98.8 % (89/90)
	4 mg/dL	+++	100 % (90/90)
pH	5	5	100 % (90/90)
	6	6	98.8 % (89/90)
	6.5	6.5	98.8 % (89/90)
	7	7	98.8 % (89/90)
	7.5	7.5	97.7 % (88/90)
	8	8	100 % (90/90)
	8.5	8.5	100 % (90/90)
SG	1.000	1.000	100 % (90/90)
	1.005	1.005	98.8 % (89/90)
	1.010	1.010	97.7 % (88/90)
	1.015	1.015	96.6 % (87/90)
	1.020	1.020	98.8 % (89/90)
	1.025	1.025	96.6 % (87/90)
	1.030	1.030	100 % (90/90)
Blood	Negative	Neg.	100 % (90/90)
	10 RBC/µL	Trace	100 % (90/90)
	25 RBC/µL	+(25 RBC/µL)	100 % (90/90)
	80 RBC/µL	++(80 RBC/µL)	98.8 % (89/90)
	200 RBC/µL	+++(200 RBC/µL)	97.7 % (88/90)
Protein	Negative	Neg.	100 % (90/90)
	15 mg/dL	Trace	98.8 % (89/90)
	30 mg/dL	(+) 30 mg/dL	97.7 % (88/90)
	100 mg/dL	(++) 100 mg/dL	97.7 % (88/90)
	300 mg/dL	(+++) 300 mg/dL	97.7 % (88/90)
	1000 mg/dL	(++++) 1000 mg/dL	100 % (90/90)
Leukocytes	Negative	Neg.	100 % (90/90)
	15 WBC/µL	15 WBC/µL	100 % (90/90)
	70 WBC/µL	70 WBC/µL	97.7 % (88/90)
	125 WBC/µL	125 WBC/µL	97.7 % (88/90)
	500 WBC/µL	500 WBC/µL	98.8 % (89/90)
Glucose	Negative	Neg.	100 % (90/90)
	100 mg/dL	± (100 mg/dL)	100 % (90/90)
	250 mg/dL	+(250 mg/dL)	98.8 % (89/90)
	500 mg/dL	++(500 mg/dL)	96.6 % (87/90
	1000 mg/dL	+++(1000 mg/dL)	98.8 % (89/90)
	2000 mg/dL	++++(2000 mg/dL)	100 % (90/90)

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10.2. Clinical Performance

10.2.1 Diagnostic Sensitivity

Glucose	75-125mg/dl (Glucose)
Blood	10-15 RBC/µl (haemoglobin)
Bilirubin	0.8-1.0mg/dl (Bilirubin)
Ketone	5-10mg/dl (Acetoacetic acid)
Protein	15-30mg/dl (albumin)
Nitrite	0.05-0.1mg/dl (Nitrite ion)
Leukocytes	20-25 WBC/µl (Intact and lysed WBCs)

11. Disposal

Dispose of unused or expired UTS-10 Cap™ and UTS Tube 5ml™, human specimens and consumable waste according to local or national regulations.

NOTE: Handle all specimens as if they contain infectious agents.

See Section 7 for Warnings and Precautions before using the UTS-10 Cap™.

12. References

Clinical and Laboratory Standards Institute (formerly NCCLS) GP16-A2, *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition,* Vol.21 No.19

Burtis, C. A., Ashwood, E. R., & Bruns, D. E. (2012). *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. Elsevier Health Sciences.

13. Troubleshooting and Support

Please contact your local/ regional distributor for assistance.

NOTE: Any serious incident that has occurred in relation to this device should be reported by the user to the manufacturer (quality@clinical.design) and the Competent Authority of the country/ Member State in which the user and/or the patient is established.

14. Manufacturer

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15. Copyright Notice and Policy Statement

Policy Statement

The information in this manual was correct at the time of printing. However, Clinical Design Technologies Ltd continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Copyright Notice

16. Symbols

SYMBOL	DEFINITION
	Manufacturer and Address Details.
	Please consult IFU
CE	CE Mark for European Conformity
UK CA	UKCA Mark for Great Britain
IVD	*in vitro* Diagnostic Medical Device
LOT	Batch Code/Lot Number
REF	Catalogue Reference/ Product Code
	Use-by Date/ Expiry Date (CCYY-MM-DD)
	Near Patient Testing
UDI	Unique Device Identifier
Σ	Sufficient for / Tests per kit
	Single use/ Do not Reuse
	Do not use if package is damaged
	Keep away from sunlight
	Storage: Upper and Lower Temperature Limits
EC REP	EU Authorised Representative
	EU Importer

EC REP

MedEnvoy Global BV
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2595 AM The Hague
The Netherlands

UDI **506069102UTS10C50MG**

REF **UTSCA01**

uts™ Urine Testing System

CE UK CA IVD