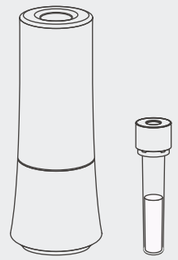
CLINICALDESIGN

URINE TESTING SYSTEM™

TECHNICAL INFORMATION

10 years

10 years research with Healthcare Professionals

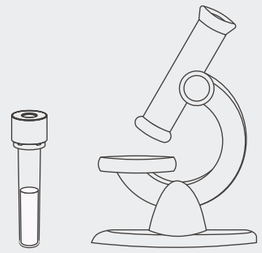


Worlds first closed urine testing system

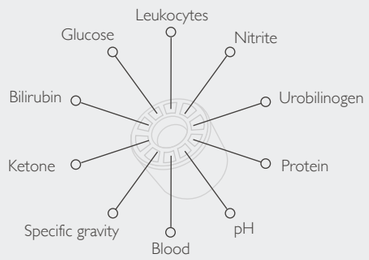
reddot award 2019
winner

GOLD AWARD 2020

Award-winning intuitive design



Tested at the Royal Devon and Exeter Pathology Laboratory



100% compliance for all ten parameters

CE IVD

Medical Device Directive 98/79/EC

Approved safe, compliant medical device

FOR A PERSONAL ONLINE DEMONSTRATION PLEASE GET IN TOUCH

Design Introduction

For the last 10 years we have worked side by side with Healthcare Professionals in our research. Together we have challenged every aspect of testing urine at point-of-care.

Our aim has always been to equip healthcare professionals with a solution that improves efficacy, provides digital results and a unique user experience.

Our solution is Urine Testing System™, the only closed system, designed for simplicity, engineered to be affordable. We look forward to sharing our story and Award-Winning technology with you.

Clinical Design has a bespoke facility in Cornwall, England and has been supported by the European Regional Development Fund and the South West AHSN Digital Accelerator Programme.

Technical specification and principles underpinning performance of UTS Digital Analyser™

UTS Digital Analyser™ uses the established principle of reflectance photometry. An LED light source illuminates the sample reagent pad and reflected light is captured by integrated camera technology and converted to a digitised image. This image is then compared to a colour image reference library stored within the device software. This reliable technology is already widely used in a range of existing clinical equipment applications.

Royal Devon & Exeter (RD&E) NHS Foundation Trust Pathology Laboratory has supported Clinical Design to generate a reliable internal colour reference library in the UTS Digital Analyser™ which provides the basis for comparison against digitised images of colour changes in reagent pads within the UTS-10 Cap™.

Performance in use

Urine Testing System™ has met predefined characteristics in accordance with industry and clinical standard tolerances. Extensive testing carried out at the RD&E has provided 100% compliance for all 10 parameters within these tolerances.

Regulatory requirements and safety in use

Urine Testing System™ has been designed and manufactured to meet the requirements of current Medical Device Directive 98/79/EC applicable to in vitro Diagnostic Devices. The device is a Class A in vitro diagnostic device and carries a CE Mark and an EC Declaration of Conformity has been recorded. Electrical Safety and EMI testing has been independently carried out and all risk assessments confirm the device is safe to use for both patients and healthcare professionals.[ii]

AWARD-WINNING SIMPLICITY

Urine Testing System™ is easy to use and has won the Prestigious Red Dot Award and iF Design Gold Award for its intuitive design and innovation.

reddot award 2019
winner

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Description of chemicals and related parameters

The table below shows parameters tested with the corresponding chemical composition of each reagent pad.[iii]

	PARAMETER	CHEMICAL INGREDIENTS AND PROCEDURAL PRINCIPLES
1	Urobilinogen	The test is based on the Ehrlich's reaction. Ingredients: 4-Methoxybenzenediazonium 2.9mg
2	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.
3	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.
4	Ketones	Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide. Ingredients: Sodium nitroprusside 23mg.
5	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.
6	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.
7	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.
8	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.
9	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.
10	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.

Reagents 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.

Glucose 75-125mg/dl (Glucose)

Bilirubin 0.8-1.0mg/dl (Bilirubin)

Ketone 5-10mg/dl

Blood 10-15 RBC/µl (haemoglobin)

Protein 15-30mg/dl (albumin)

Nitrite 0.05-0.1mg/dl (Nitrite ion)

Leukocytes 20-25 WBC/µl

(Intact and lysed WBCs)

The above list of reagent pad analyte detectable ranges 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.[iii]

[i] Clinical Design EU Declaration of Conformity document available on request. Guidance on the In Vitro Diagnostic Medical Devices Directive 98/79/EC, August 2013
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/404335/In_vitro_diagnostic_medical_devices_-_guidance_on_legislation.pdf

[ii] Essential Principles (EP) Checklist. Risk Analysis and Control Summary listed in the documentation supporting the issuance of the product "Certificate of Conformance" available on request.

[iii] Information supplied by chemical reagent manufacturer.

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