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Royal Cornwall Hospitals NHS Trust

Urinalysis Point-of-Care Testing: Siemens Multistix 8SG and Siemens Clintek Reader Clinical Guideline

V1.0

January 2021

1. Aim/Purpose of this Guideline

1.1. To ensure that point-of-care urine dipstick testing is performed safely and consistently.

1.2. To minimise risk to patients from the errors that may occur from using these devices incorrectly.

1.3. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We cannot rely on opt out, it must be opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the *Information Use Framework Policy* or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1. Introduction

2.1.1. Urine dipstick testing is a useful tool for screening and monitoring a wide variety of pathological conditions.

2.1.2. Siemens Multistix 8SG test strips provide semi-quantitative results for pH, specific gravity, leucocytes, nitrite, protein, glucose, ketones and blood. This is the only approved urine test strip for use at the Royal Cornwall Hospital.

2.1.3. Test strips are obtained from Pharmacy in pots containing 100 test strips

2.1.4. Indications for testing are as follows:

- *pH* - Acid base disturbances such as DKA, fasting, respiratory acidosis, diuretics, vomiting, potassium deficiency, Urinary Tract Infection, Renal Tubular Disease, Renal Calculi, Renal Failure
- *Leucocytes* – Inflammatory diseases of the kidneys & urinary tract, Bacterial infections, cystitis, urethritis
- *Nitrite* - Bacterial Urinary Tract Infections

- *Protein* - Urinary Tract Infections, Renal disorders such as Post Renal Proteinuria, Extra Renal Proteinuria Hypertension, Pre-Eclampsia
- *Glucose* - Diabetes, Renal Glycosuria, Alimentary Glycosuria, Renal Damage, Cushings Disease, Acute Pancreatitis
- *Ketones* - Fasting, Vomiting, Diabetes, DKA, crash dieting, insufficient intake of carbohydrates
- *Blood* - Stone Formation, Glomerulonephritis, Renal TB, Pyelonephritis, Urinary Tract Infection, Muscular Injury

2.2. Pre-analytical Treatment

2.2.1. Reliable analytical results can only be obtained from a urine sample that has been collected and stored properly.

2.2.2. Collection vessels must be clean, sterile and completely free from detergents. Use a silver top or white top universal 25ml or 50ml container. Please note that red top pots are unsuitable for analysis as they contain boric acid as a preservative

2.2.3. The first (early morning) urine is the most useful for the majority of urinalysis, although random samples can be tested.

2.2.4. Examination of the urine with test strips should be carried out within 2 hours of collection, since longer standing can lead to incorrect results. If testing is delayed then store the sample in a sealed pot in a refrigerator.

2.3. Performing the Test – Visual Read (if you have a Clinitek meter skip to 2.6)

2.3.1. Collect the urine specimen in a clean, disposable, sterile container. Label the urine container with the patient details.

2.3.2. Sample must be at room temperature and mixed before testing.

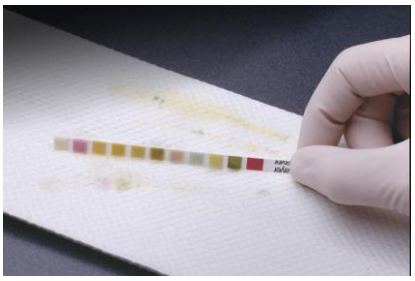
2.3.3. Remove strip and recap pot. Hold the long handle of the strip at the top.

2.3.4. Dip the test strip in the urine for no longer than 1 second ensuring that all pads are covered (The following images are taken from the manufacturer's instructions – Siemens)

2.3.5. Remove strip from sample running strip edge over the rim of the

container

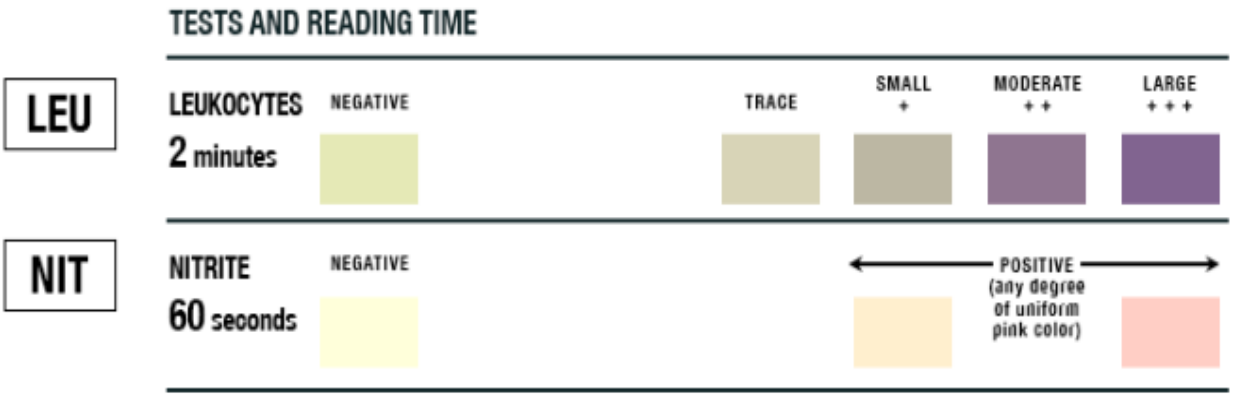
2.3.6. Briefly blot the long edge and back of the urine test strip into absorbent paper to remove excess urine.

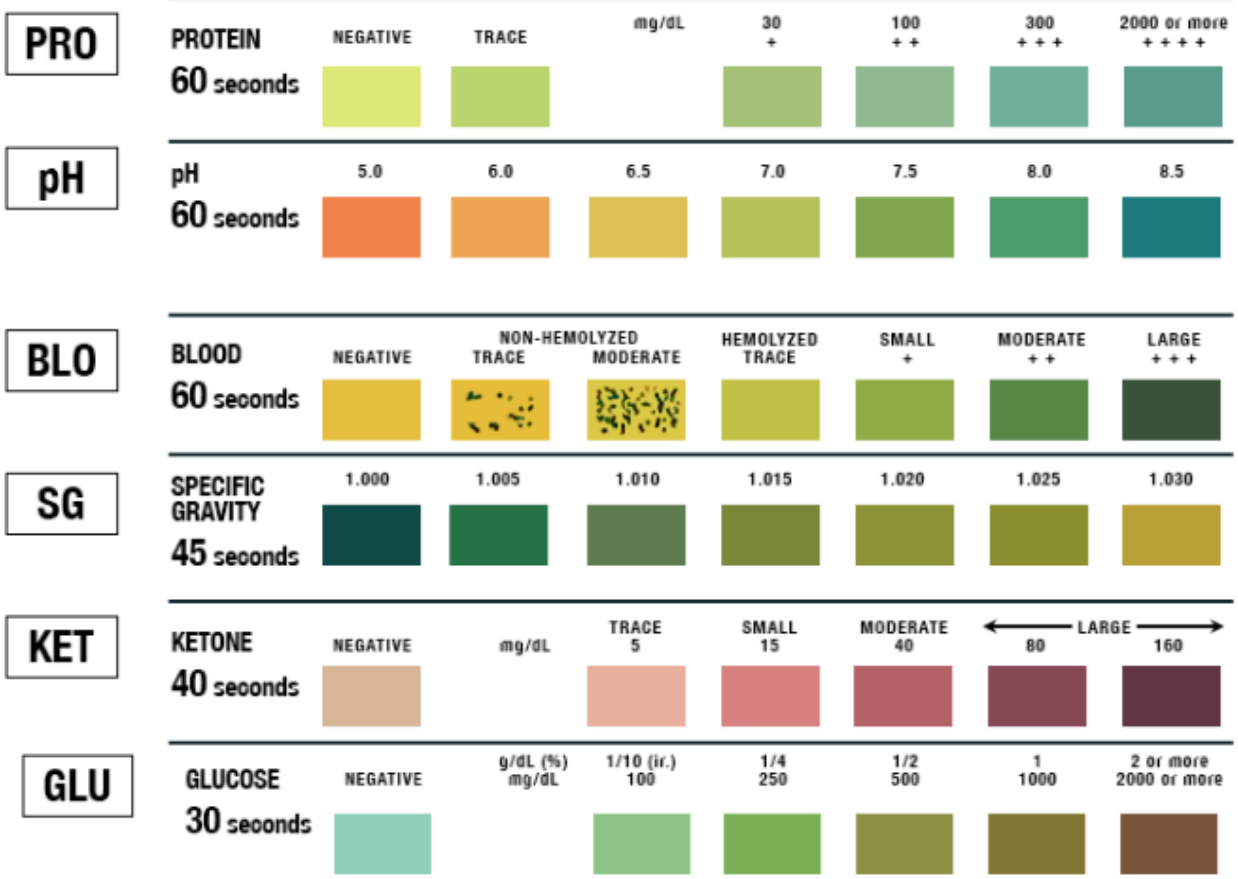


2.3.7. Start timer for **120 seconds**

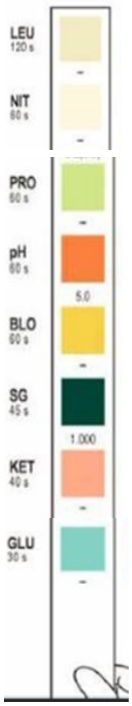
2.4. Reading the Results

2.4.1. At 30 – 120 seconds compare results to the colour chart on the side of the strip pot





2.4.2. Make sure that the test strip is properly aligned so that the test area is opposite the correct part of the colour chart.



Hold the test strip this way up ie LEU at the *top*, GLU at the *bottom*

2.4.3. Compare the results for blood carefully against the two scales:

- Blood Pad will be ‘spotty’ if the urine sample contains whole blood cells

- Blood Pad will be a uniform colour if the red cells have lysed (haemolysed)

2.4.4. If the colour appears to be between two colour blocks, report the lower result.

2.5. Automated Urinalysis

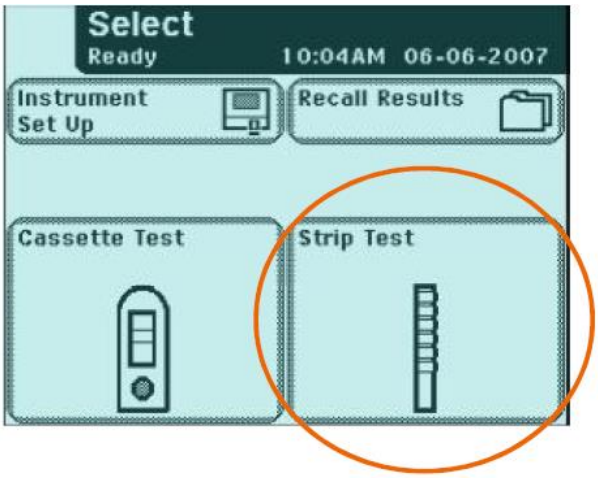
2.5.1. Some high-use areas have a Siemens Clinitek automated meter for measurement of MultiStix 8SG

2.5.2. Collect the urine specimen in a clean, disposable, sterile container. Label the urine container with the patient details.

2.5.3. Sample must be at room temperature and mixed before testing.

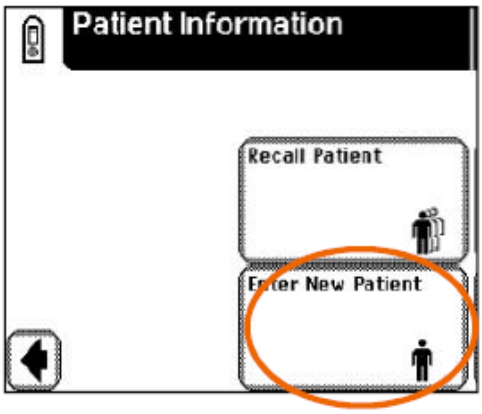
2.5.4. Switch on the Clinitek Status Reader - the On/Off switch is location on the front of the analyser. Each time the analyser is switched on; it will run a self-check to test its hardware and software functionality.

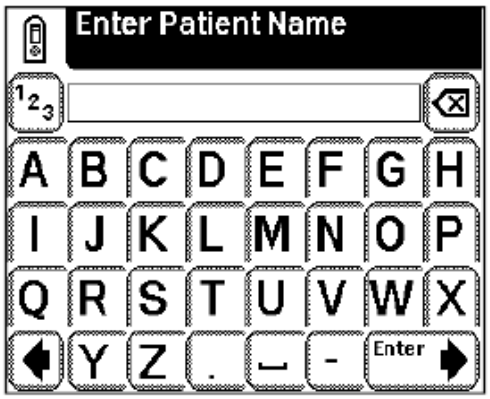
2.5.5. Select 'Strip Test' from the Ready Screen



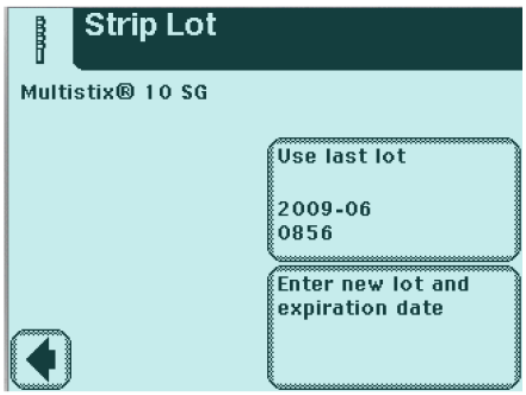
2.5.6. Using the barcode scanner, scan the barcode on your Trust ID badge to enter operator ID or enter your IT username (capitals) via the on screen keyboard

2.5.7. Enter the patient's Hospital Number or NHS Number via on screen keyboard or scanner

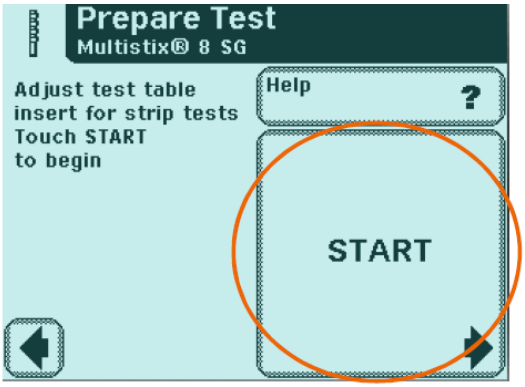




2.5.8. Using the barcode reader, scan the test lot barcode on side of the strip pot



2.5.9. Press START to begin the sampling process and the 8 second countdown

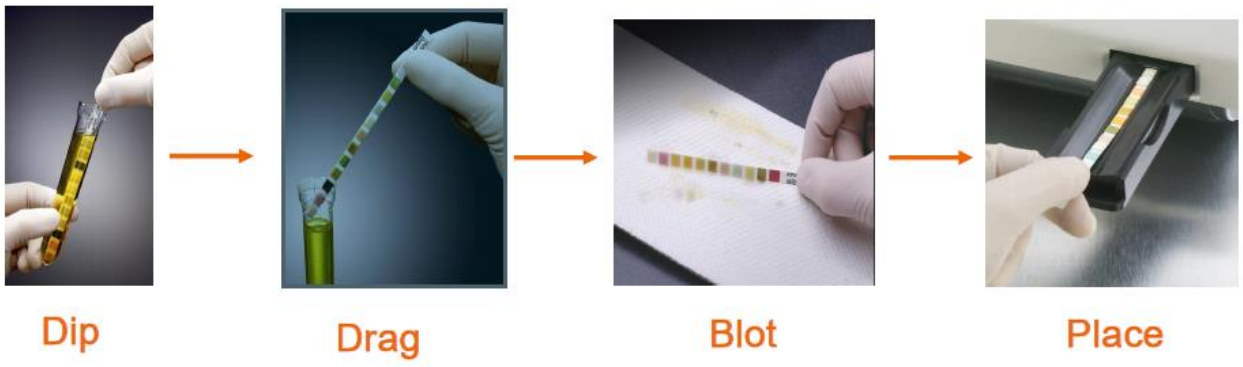


2.5.10. Hold the long handle of the strip at the top then dip the test strip in the urine for no longer than 1 second ensuring that all pads are covered

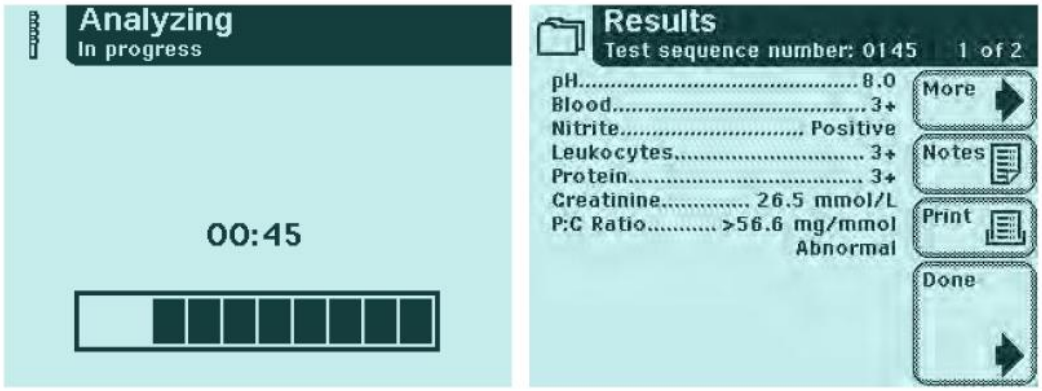
2.5.11. Remove strip from sample running strip edge over the rim of the container

2.5.12. Briefly blot the long edge and back of the urine test strip into absorbent paper to remove excess urine

2.5.13. Place the test strip, with the reagent pads facing upward, on the tray.

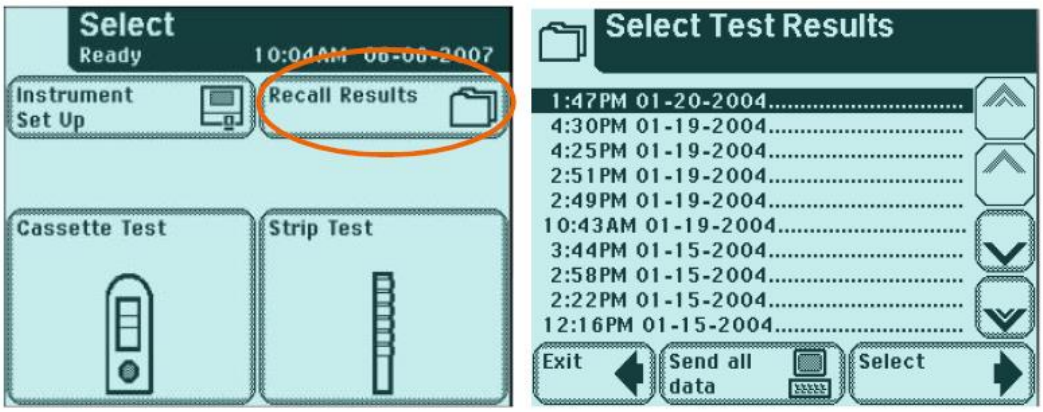


2.5.14. The test strip tray will automatically be introduced into the Clinitek Status meter, where the strip will be identified and read



2.5.15. After the analysis is completed the results will be printed out

2.5.16. You can recall and re-print results if required



2.6. Maintenance

2.6.1. Daily Cleaning of the removable test table insert

The test insert is the reversible plastic strip holder that sits inside the calibration bar – this is shown as '2' in the diagram below.

Clean by wiping with a lint free tissue dampened with distilled water, or run under the tap to prevent urine build-up. Dry inset using a clean dry tissue.

Please do not use solvents (such as sanicloth wipes)

2.6.2. **Daily Checking of the test table**

Remove and check the test table by pulling it slowly out of the front of the analyser, and check that the white strip is clean, dry and not discoloured.

2.6.3. **Periodic Cleaning of the test table**

If the test table is dirty or discoloured, clean gently with a damp (water) lint free cloth taking care not to scratch the white calibration bar. If the calibration bar appears damaged, please contact Clinical Chemistry to obtain a spare.

2.7. Replacing the Printer Paper

2.7.1. Open the printer cover and paper roll compartment

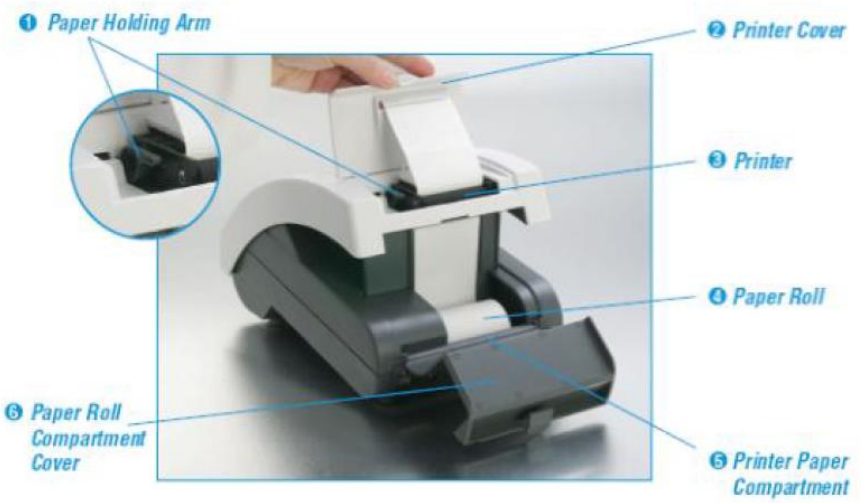
2.7.2. Lift the paper holding arm into the open, upright position.

2.7.3. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath.

2.7.4. Feed the paper up along wall and through the printer, then feed the edge of the paper through the printer cover.

2.7.5. Push the paper holding arm down into the closed position.

2.7.6. Close the printer and paper roll covers by clicking them into position



2.8. Troubleshooting

2.8.1. List of Errors

Error Code	Description	Action
E01 or E23	Low Battery Power	Replace batteries
E10 or E48	Loss of test results	1. Switch instrument off using on/off button 2. Switch instrument on again 3. Repeat test
E11	Failure of test table	1. Gently remove test table and check cal strip 2. Replace test table 3. If error persists, switch instrument off and on again 4. If error persists, contact Clinical Chemistry
E24	No printer paper	Replace printer paper - instructions in section 2.8
E25, E64 or E65	Failure of auto calibration	Clean calibration strip
E27	Set up failure	1. Switch instrument off using on/off button 2. Switch instrument on again
E28	Printer Error	Lift printer cover and push the paper holding arm back in position
E50	Incorrect strip type	Repeat using a Multistix 8SG or Clinitest hCG
E52	Invalid Barcode	Repeat using a Multistix 8SG or Clinitest hCG
E53	Strip test selected but casette used	Repeat test using the cassette test routine
E54	Cassette test selected but strip detected	Repeat test using the strip test routine
E56	Incorrect size test table	Repeat test using correct table
E57	Missing strip or cassette	Repeat test ensuring strip or cassette is correctly placed
E58	Misplaced strip	Repeat test ensuring strip is correctly placed
E59	Inverted strip positioned on test table	Repeat test ensuring strip is correctly placed
E60	Tilted Strip	Repeat test ensuring strip or is correctly placed
E61	Dry Strip	Repeat test with a fresh strip ensuring it has been correctly dipped
E63	Failure to find end strip	Repeat test ensuring strip is correctly placed
E67 or E68	Insufficient sample	Sample flow issue has been detected in the cassette Repeat test ensuring correct volume of sample is dispensed
	Paper out icon	Replace printer paper - instructions in section 2.8

2.8.2. **Irregular or Slow Movement of Test Table**

If movement of the test table is irregular or slow, this may be caused by either low battery power, in which case replace the 6 x AA batteries.

Alternatively this could be caused by a heavy build-up of dried urine on the test table. Clean the test table as described in *section 2.7.3 Periodic Cleaning of test table.*

2.9. Interferences

Parameter	Influencing Factor	Interference
pH	Diet: meat ↓ vegetarian ↑	
Leukocytes	Vaginal secretion	Strong colour of urine ↑ High glucose and protein↓ Certain antibiotics ↑ or ↓
Nitrite	Bacterial count	Strong color of urine ↑ Ascorbic acid ↓ Phenazopyridine ↑
Protein	Physical activity	Ejaculate ↑ Preservatives ↑
Glucose	Pregnancy, fever, old age	Bacteria ↓
Ketones	Starvation	Phenylketones ↑ Phthaleins ↑
Blood	Menstruation, strong physical activity	Oxidizing cleaning agents ↑

2.10. Urinalysis Do's and Don't's

DO	DO NOT
✓ Use clean and sterile containers	X Transfer test strips from vial to vial
✓ Use fresh as possible urine	X Prolong the dipping
✓ Use the urine within 2 hours of collection	X Touch the test pads
✓ Only use in-date test strips	X Freeze urine
✓ Replace cap of test strips immediately	X Expose urine or test strips to sunlight
✓ Store test strips in a cool dry place	X Test unlabelled samples
✓ Ensure containers are detergent free	X Use second hand containers
✓ Prepare the patient properly	X Bend the test strip

2.11. Contact Details for Troubleshooting and Training:

Please contact Clinical Chemistry for any queries relating to urine dipstick testing please contact: rcht.poct@nhs.net, or call ext 01872 25 2556 / 2581 / 2837

3. Monitoring compliance and effectiveness

Element to be monitored	Quality
Lead	Dr Anthea Patterson
Tool	WEQAS – external quality assurance scheme
Frequency	One sample / month
Reporting arrangements	Performance feedback to Ward/Unit Manager
Acting on recommendations and Lead(s)	• RCHT Point of Care Testing Committee • RCHT Point of Care Testing Steering Group
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned with one month. A lead member of the team will be identified to take each change forward where appropriate, eg refresher training. Lessons will be shared with the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Urinalysis Point-of-Care Testing: Siemens Multistix 8SG and Siemens Clintek Reader Clinical Guideline V1.0			
This document replaces (exact title of previous version):	New Document			
Date Issued/Approved:	12th November 2020			
Date Valid From:	January 2021			
Date Valid To:	January 2024			
Directorate / Department responsible (author/owner):	Helen Hobba, Senior Biomedical Scientist			
Contact details:	01872 25 2556			
Brief summary of contents	Instructional Guide for the safe use of Siemens Multistix 8SG and the Clinitek Reader			
Suggested Keywords:	Dipstick Siemens Clinitek Multistix 8SG Urinalysis			
Target Audience	RCHT	CFT	KCCG	
	✓			
Executive Director responsible for Policy:	Medical Director			
Approval route for consultation and ratification:	Pathology Specialty Meeting			
General Manager confirming approval processes	Bruce Daniel - Pathology Service Manager			
Name of Governance Lead confirming approval by specialty and care group management meetings	Kevin Wright			
Links to key external standards	None required			
Related Documents:	None required			
Training Need Identified?	No			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical / Pathology			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job*
12th November 2020	V1.0	Initial issue **Pictures in guideline reproduced from manufacture manual as allowed for non-profit organisation*	Helen Hobba, Senior Biomedical Scientist

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

<table>
<tr><th colspan="6">Section 1: Equality Impact Assessment Form</th></tr>
<tr><td colspan="6">Name of the strategy / policy /proposal / service function to be assessed
Urinalysis Point-of-Care Testing: Siemens Multistix 8SG and Siemens Clintek Reader Clinical Guideline V1.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Pathology</td><td colspan="3">Is this a new or existing Policy?
New</td></tr>
<tr><td colspan="3">Name of individual/group completing EIA
Helen Hobba, Senior Biomedical Scientist</td><td colspan="3">Contact details:
01872 25 2556</td></tr>
<tr><td>1. Policy Aim
Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">This policy has been designed to ensure that urinalysis performed, at the point-of-care, within the Royal Cornwall NHS Hospitals Trust is managed in accordance with national guidelines and accreditation standards.</td></tr>
<tr><td>2. Policy Objectives</td><td colspan="5">The purpose of this policy is to ensure that consistent procedures are in place for dipstick urinalysis throughout the RCHT, to reduce to a minimum the risk to patients and staff from errors that may occur from the use of these devices.</td></tr>
<tr><td>3. Policy Intended Outcomes</td><td colspan="5">A safe service</td></tr>
<tr><td>4. How will you measure the outcome?</td><td colspan="5">Quality Assurance monitoring</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">All patients attending RCHT</td></tr>
<tr><td rowspan="3">6a). Who did you consult with?

b). Please list any groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups:

Pathology Specialty Meeting</td></tr>
<tr><td>c). What was the outcome of the consultation?</td><td colspan="5">Agreed</td></tr>
</table>

7. The Impact
Please complete the following table. If you are unsure/don't know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy **could** have a positive/negative impact on:

Protected Characteristic	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		X		
Sex (male, female non-binary, asexual etc.)		X		
Gender reassignment		X		
Race/ethnic communities /groups		X		
Disability (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)		X		
Religion/ other beliefs		X		
Marriage and civil partnership		X		
Pregnancy and maternity		X		
Sexual orientation (bisexual, gay, heterosexual, lesbian)		X		

If all characteristics are ticked 'no', and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:	Helen Hobba, Senior Biomedical Scientist

If you have ticked 'yes' to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net