

# Key Trainer Handbook

## POCT Siemens Clinitek Status+ Urinalysis and Clinitest hCG



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# Introduction

This handbook has been compiled by the Point of Care Testing Department for LTHT to help you, the healthcare professional, achieve consistently reliable and accurate results.

The different sections of the booklet cover aspects of working with the Clinitek Status+ to perform urinalysis and Clinitest hCG testing including routine use and quality control. On completing this training all users should be able to analyse samples obtaining an accurate result whilst minimising risk to themselves and patients. The purpose of this booklet is to provide you with the information you need to achieve accurate results and therefore provide the best quality care for your patients.

## Ensuring Quality

Leeds Teaching Hospitals Trust Pathology service is required to meet the nationally agreed standards set by UKAS, the national accreditation body recognised by the UK Government. A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. Pathology is currently using ISO standards to assess their performance. Following the Clinical Area Standard Operating Procedure (SOP) and using the training material provided is essential to us meeting these standards.

The use of analysers by untrained staff can lead to misleading results and adversely affecting the treatment of patients.

## Definitions

**Internal Quality Control (IQC)** - The role of IQC is to monitor the day-to-day precision and accuracy of a given assay by comparing it to known values. Best practice dictates both a high and low are run, ensuring accuracy at both ends of the result range.

**External Quality Assurance (EQA)** - The role of EQA is to provide a broader comparison. Enrolling in an EQA scheme allows one analyser's results to be compared to many others, both of similar and different methods. It is also performed by a member of staff and so can be used to monitor user proficiency.

***Remember – a decision based on an incorrect or unreliable result could lead to serious consequences for the patient in your care.***

## Key Trainer Role

The role of the Key Trainer is to cascade training from the POCT department to all members of Ward staff that are required to use the Siemens Clinitek Status+ analyser. They are also responsible for keeping a copy of training documentation for all trained members of staff.

Their main duties consist of the following:-

- Ensure members of staff who wish to undergo training read the Knowledge and Assessment Form 1 and complete the Competency Questions Form 2.
- Witness the trainee run a standard test and then complete the Competency Assessment Form 3.
- Maintain ward records. This involves retaining a copy of Competency Assessment Form 3 as part of the Key Trainer records on the ward. These can be used as proof of training and also as a reminder for 2 yearly retraining.
- Complete and return the Training Register to the POCT department so that passwords can be updated and access granted. This also allows the POCT team to update MELVIS.
- Key Trainers will be expected to attend training session updates with a member of the POCT team every 2 years and relay any changes in practice.

## Training Documents

**Form 1: Knowledge and Skills.** To be read by the member of staff being assessed to ensure knowledge and understanding of the standards required. This form should be retained by the Trainee for future reference.

**Form 2: Competency Questions.** Contains questions which are based on the information in Form 1. This form should be assessed by the key trainer and retained by the member of staff as a reminder for reassessment.

**Form 3: Competency Assessment.** To be filled in by the Key Trainer and member of staff when the assessment has been undertaken to ensure standards are being met. This form is held as a paper copy by the Key Trainer. It may form part of the Personal Development Record (PDR).

**Training Register.** Please complete fully, providing all contact details requested to allow POCT staff to update user access. Please return to the POCT department by email as soon as training has been completed. [Leedsth-tr.pointofcare@nhs.net](mailto:Leedsth-tr.pointofcare@nhs.net)

The key trainer handbook is available on the Pathology website - <http://www.pathology.leadsth.nhs.uk>

## Objective

This competency covers the urinalysis and Clinitest hCG analysis of patients using the Siemens Clinitek Status+ analyser in a Point of Care (POC) setting. 5654

**This document is for use within the Leeds Teaching Hospitals NHS Trust ONLY. It should not be printed, but accessed electronically so that only the most up to date instructions are available.**

**PLEASE NOTE: The sharing of passwords is against Trust policy, both the Data protection policy and the use of computers policy. Every member of staff is required to undertake mandatory Information Governance (IG) training and should be aware of this. Sharing passwords breaks principle 7 of the Data Protection Act (1998), which could be interpreted as unauthorised processing. This is unlawful under section 55 of the Act. It is also an offence under the Computer Misuse Act (1990).**

## Assessment

This assessment is relevant to anyone required to carry out urine analysis strip testing on the Clinitek Status+ analyser. Additional training documentation is also included for anyone required to carry out Clinitest hCG analysis cassette testing on the CLINITEK Status+ analyser.

The training documentation includes details on appropriate sample collection, how to perform a patient test and quality control (QC), how to carry out basic maintenance and troubleshooting, all relevant health and safety issues, who to contact for machine failure and the importance of password protection and patient ID.

**All staff undergoing hCG training must have previously completed POCT Siemens Clinitek Status+ Urinalysis Machine (Multistix 8SG/10SG) Strip Testing Competency Assessment.**

**Not all wards have access to Clinitest hCG testing. If you are unsure whether your ward is authorised to perform the test please contact POCT the department. If your ward does not currently have access to Clinitest hCG testing but has a clinical requirement for access to the test, please contact POCT.**

### Contact Details

Please feel free to contact the POCT department regarding any issues.

**Phone:** LGI:22338 or SJUH:64791

**Email:** [leedsth-tr.pointofcare@nhs.net](mailto:leedsth-tr.pointofcare@nhs.net)

### Further Information

**Part number of Printer Paper: 8727986**

email: [dx-diag-sales-uk.team@siemens-healthineers.com](mailto:dx-diag-sales-uk.team@siemens-healthineers.com)

Clinical area SOP (BSF2POC085 + BSF2POC114)

**Form 1– Knowledge & Assessment Worksheet - Siemens Clinitek Status+ Urinalysis Machine**

Competency	Knowledge and Understanding
<b>Contact Details</b>	To report a fault, please contact POCT: Working hours 08:30 to 17:00 Mon-Sun LGI: 22338 SJUH: 64791 or e-mail: leedsth-tr.pointofcare@nhs.net
<b>Medico-Legal</b>	<ul style="list-style-type: none"> <li>• Passwords (Trust ID badge barcodes) <b>MUST NEVER</b> be shared to prevent device misuse and to protect both patients and staff. Passwords are unique to every user.</li> <li>• It is against Information Governance and Trust IT Policies to share passwords. It is a disciplinary offence.</li> <li>• Training will last for two years. All users must have an update before password expiry to ensure continuous access to the machines.</li> <li>• The sample must be labelled with at least 3 forms of patient ID.</li> <li>• <b>Acceptable forms of patient ID are:</b></li> <li>• The NHS, PAS or A&amp;E number</li> <li>• If the above are not available, the patient's FULL name</li> <li>• For an unknown patient, use unknown, gender and condition e.g. unknownmalecrash</li> </ul>
<b>Analyser overview (Hardware)</b>	<ul style="list-style-type: none"> <li>• Test table with white calibration bar, test table insert</li> <li>• Barcode scanner, printer, TP link box, touch screen and on/off button</li> <li>• QC - Level 1 - negative (Green Label) and Level 2 - Positive (Red Label) - stable at <b>2-8°C</b> until expiry date printed on vial, <b>keep refrigerated where possible</b></li> <li>• Strips - Siemens Multistix- stable at <b>15-30°C</b> until expiry date printed on pot</li> </ul>
<b>Analyser Overview (Screen)</b>	<ul style="list-style-type: none"> <li>• Title bar</li> <li>• Home screen</li> <li>• Instrument set up</li> <li>• Recall results</li> <li>• Cassette test/QC due</li> <li>• Strip test/QC due</li> </ul>
<b>Calibration</b>	No action required - automatically done by the machine before each sample analysis.
<b>Quality Control</b>	<ul style="list-style-type: none"> <li>• <b>QC to be analysed by the user on a weekly basis</b> - cannot be used for patient test until the QC has been analysed</li> <li>• QC to be stored at <b>2-8°C</b>, return the fridge when not in use</li> <li>• Two levels to analyse, analyser will prompt which level to analyse</li> <li>• Additional QC testing should be performed for a new strip lot</li> </ul> <p><b>Preparing/running QC solution</b></p> <ol style="list-style-type: none"> <li>1. Select <b>QC Test Due</b> then <b>QC Strip test</b></li> <li>2. Scan Trust ID badge as <b>Operator ID</b> then press <b>ENTER</b>.</li> <li>3. Scan <b>Control lot number and enter the expiry date</b> manually when prompted</li> <li>4. Scan <b>Strip lot number</b> when prompted</li> <li>5. Press <b>Start</b> (8 seconds countdown begins), <b>dip</b> the test strip into the sample, <b>drag</b> the back of the strip against the edge of the vial to remove excess liquid, <b>blot</b> the strip by quickly touching the side of the strip against an absorbent towel. Place the strip into the sample tray. <b>Ensure that the strip has not bent at any point in the sampling procedure.</b></li> <li>6. Repeat the same process for positive QC (Level 2)</li> </ol> <p><b>IF A QC TEST FAILS</b></p> <p>Check that the correct QC level was analysed          Check expiry dates of QC and strips          Ensure the QC sample used is not contaminated          Clean the test table with alcohol wipes and rinse the white calibration bar under water and clean with a lint-free paper towel. Repeat the QC          Contact POCT if QC tests still fail</p>
<b>Pre-Analytical/ Sample Preparation</b>	<ul style="list-style-type: none"> <li>• Keep strips and sample at room temperature and not on radiator or windowsill.</li> <li>• Do not use expired strips. Do not attempt to read the results on the strip visually.</li> <li>• Do not touch the test areas of the strip. Do not bend the strip prior to analysis as the strip can get stuck in the analyser.</li> <li>• <b>DO NOT</b> re-dip urine strips.</li> <li>• Sample must be analysed within 2 hours of collection and collected into a plain universal container. If unable to test within 2 hours, refrigerate and allow sample to reach room temperature before analysis</li> <li>• Pulp products may affect the results. Boric acid can affect the pH and may interfere with the test. Residual detergent from a washed container can affect the constituents of urine.</li> <li>• Always mix the sample prior to analysis.</li> <li>• Visually bloody, severely turbid, viscous, mucoid and highly coloured samples may interfere with the sample flow and the test and may produce a false positive result.</li> </ul>

<b>Patient Sample Analysis</b>	<ol style="list-style-type: none"> <li>1. Ensure the machine is switched on and performs a self-test</li> <li>2. The patient sample should be clearly labelled, fresh and well mixed</li> <li>3. Select Test Strip and scan Trust ID badge when <b>Operator ID</b> is prompted then press <b>ENTER</b>.</li> <li>4. Press <b>“Enter New Patient”</b>.</li> <li>5. Scan/manually enter <b>PAS/NHS/A&amp;E</b> number or full name - and press <b>ENTER</b>.</li> <li>6. Scan <b>Strip lot number</b> when prompted</li> <li>7. Press <b>START</b> (8 seconds countdown begins), <b>dip</b> the test strip into the urine, <b>drag</b> the back of the strip against the edge of the universal to remove excess liquid, <b>blot</b> the strip by quickly touching the side of the strip against an absorbent towel. Place the strip into the sample tray. <b>Ensure that the strip has not bent at any point in the sampling procedure.</b></li> <li>8. The table is automatically pulled into the analyser for reading and the results are available in one minute.</li> <li>9. When the results appear and the test strip table is ejected from the analyser, remove the used reagent test strip and discard into a yellow waste bag for incineration.</li> <li>10. Clean the test table insert after analysis to avoid cross contamination of subsequent samples</li> </ol>
<b>Results</b>	<ul style="list-style-type: none"> <li>• If results do not fit with patient’s clinical picture, send a sample to the lab for confirmation.</li> <li>• <b>URINE PRESERVATIVES MAY AFFECT RESULTS.</b> Preservatives will <u>not</u> prevent deterioration of ketones, urobilinogen or bilirubin.</li> <li>• Bacterial growth from contaminating organisms may affect glucose, pH and blood results.</li> </ul>
<b>Results recall</b>	<ul style="list-style-type: none"> <li>• Analyser can store 950 patient test results</li> <li>• Select <b>Recall Results</b></li> <li>• Select <b>Patient Tests or QC Tests</b>. You can recall results by name, ID, date or search all results</li> <li>• Use the up and down arrow keys to scroll and <b>Select</b> the results you want to recall, press <b>Print</b> to reprint results</li> <li>• Press <b>Done</b> to log out and return to main screen</li> </ul>
<b>Health and Safety</b>	<ul style="list-style-type: none"> <li>• Samples must be capped as soon as possible to avoid spillages</li> <li>• Conform to Trust Infection Control policies at all times</li> <li>• Gloves should be worn when handling urine samples</li> <li>• Universal containers must be disposed of in the infectious waste bin</li> <li>• Spillages must be dealt with in line with Departmental H&amp;S policies</li> </ul>
<b>Troubleshooting/Maintenance</b>	<ul style="list-style-type: none"> <li>• Test table - this must be positioned properly in order for the analyser to function. Push it half way into the analyser after cleaning and switch the machine off and on again to allow the machine to readjust the table. <b>DO NOT push the table fully inside of the analyser as this will cause the table to become jammed.</b></li> <li>• Printer paper - must be changed when the red stripe appears on result printouts. Ensure that the paper is in the correct way by scratching it before inserting into the feeder. Ensure lever is pushed down.</li> <li>• <b>ALWAYS</b> wipe the test table between each strip test</li> <li>• Daily - remove the test table and insert and rinse under water, dry with a lint-free paper towel</li> <li>• Weekly - disinfect the test table insert by wiping with 70% isopropyl alcohol wipes, allow to air-dry and then rinse thoroughly. Dry with a lint-free paper towel before reinserting the test table.</li> <li>• <b>DO NOT</b> scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests.</li> <li>• <b>DO NOT</b> use solvents.</li> <li>• When reporting clinical incidents on DATIX, tick the tick box for incidents involving Trust equipment and select <b>‘in-vitro Medical Devices’</b> from the drop down list.</li> </ul>
<b>Key Trainers (FOR POCT USE ONLY)</b>	<ol style="list-style-type: none"> <li>1. Form 1 should be used by Key Trainer to train other staff</li> <li>2. Copy of a controlled version of the Key Trainer Handbook will be made available to Key Trainer</li> <li>3. Training register should be used to inform POCT of any new training sessions.</li> <li>4. POCT contact details</li> </ol>
Name of member of staff (Please Print)	Name of assessor (Please Print)
Member of staff signature:	Assessor Signature:
Date of Training:	Date Recertification Due:

**Form 2 Competency Answers - Siemens Clinitek Status+ Urinalysis Machine**

1. If the sample cannot be analysed immediately, how long is the sample stable for?  
 .....
2. Describe the process of carrying out a strip test after you press the 'Start' button.  
 .....  
 .....
3. Why is the timing of reading strips vital in urinalysis  
 .....  
 .....
4. What are the correct storage conditions for the test strips  
 .....  
 .....
5. What mandatory patient ID is required?  
 .....
6. How would you know if the test strips have gone off?  
 .....
7. Why do you perform Internal Quality Control? How often do you perform IQC tests?  
 .....
8. What should you do if IQC fails?  
 .....  
 .....
9. How do you clean the test table, test table insert and calibration bar, and how often should you do it?  
 .....  
 .....
10. Who is allowed to use my password  
 .....
11. My password will stay active for  
 .....

Name:	Department:
Email:	Date:



## Form 2 Competency Questions - Answers for Key Trainers

1. If the sample cannot be analysed immediately, how long is the sample stable for? **2 hours**
2. Describe the process of carrying out a strip test after you press the 'Start' button. **Dip, drag and blot**
3. Why is the timing of reading strips vital in urinalysis?  
**Reaction is not end point and colour changes after 2 minutes are not of diagnostic values**
4. What are the correct storage conditions for the test strips?  
**Away from radiator or windowsill at room temperature, Always keep desiccant in strip pot, and used by the expiry date**
5. What mandatory patient ID is required?  
**Full name, DOB, NHS/PAS/A&E number**
6. How would you know if the test strips have gone off?  
**The colour change of the white pad on end of strip is an indication if strips have gone off**
7. Why do you perform Internal Quality Control?  
**The IQC checks that the analysers is producing accurate results**
8. How often do you perform IQC tests?  
**Positive and Negative QC - once a week**
9. What should you know if IQC fails?  
**Check that QC solutions and strips are in date and are not contaminated/deteriorated, Ensure that the correct QC was run and clean the calibration bar and rerun QC. If QC still fails, contact POCT**
10. How do you clean the test table, test table insert and calibration bar, and how often should you do it?  
**Wipe test table insert after every test, Disinfect the test table by wiping with 70% isoproryl alcohol wipes allow to air-dry and then rinse. Clean calibration bar by running it under water and wipe with soft cloth or cotton bud - do not scratch the calibration bar.**
11. Who is allowed to use my password? **Only me**
12. My password will stay active for? **Two years and then I need to attend a refresher training**



**FORM 3- Competency Assessment**

**Observational Assessment: Performing a urinalysis strip test on the Siemens Clinitek Status+ Analyser**

**TO BE RETURNED TO POINT OF CARE**

Core competency	Please record whether or not the member of staff completed the task.
<b>1 Has the member of staff read the knowledge and understanding worksheet (Form 1)?</b>	
<b>2 Has the member of staff completed the questions?</b>	
<b>3 Did the member of staff correctly use the relevant ID?</b> <ul style="list-style-type: none"> <li>Did the member of staff scan the correct patient bar code as ID?</li> <li>Did the member of staff check the patient ID on screen matched that of the patient who the sample came from?</li> <li><b><i>Did the member of staff enter their own bar code password?</i></b></li> </ul>	
<b>4 Sampling-can be done with either patient or QC sample</b> <ul style="list-style-type: none"> <li>Did the member of staff mix the sample prior to analysis?</li> <li>Did the member of staff perform the correct method for test strip analysis (dip, drag and blot)?</li> <li>Did the member of staff check the test strip prior analysis to see if the white pad has changed colour?</li> </ul>	
<b>5 Urinalysis maintenance</b> <ul style="list-style-type: none"> <li>Does the member of staff know how remove the test table from the analyser and clean the calibration bar when required?</li> <li>Does the member of staff know how to contact Point of Care in the event of machine breakdown?</li> </ul>	
<b>6 Did the member of staff demonstrate effective health and safety measures?</b> <ul style="list-style-type: none"> <li>Were gloves worn?</li> <li>Were the used universal container and test strip disposed of in a clinical waste or infectious waste bin?</li> <li>Was the machine left clean for the next user?</li> </ul>	
<b>7 Result Reporting</b> <ul style="list-style-type: none"> <li>Were the results reported according to ward/departmental procedures ensuring the correct patient ID?</li> <li>Were the results acted on accordingly?</li> </ul>	
<b>8 Key Trainers (FOR POCT USE ONLY)</b> <ul style="list-style-type: none"> <li>Able to recall and convey relevant information</li> <li>Understands training requirements and how to complete the training documentation</li> </ul>	

**Staff Member**

I the undersigned declare that I have read Form 1 and completed the multiple choice questions and the practical assessment

**Assessor**

I the undersigned declare that the staff member has completed the competency tests to a satisfactory standard.

Name of member of staff (Please Print):	<b>FOR POCT USE ONLY</b>				
Operator Number:	Name of assessor (Please Print)				
Department:	Date of assessment:				
Site access required for:	Signature:				
Staff member's E-mail:	Key Trainer?	Update KT List	MELVIS KT course	Update KT email group	Email KT Docs
Signature:					

**Form 1– Knowledge & Assessment Worksheet - Clinitest hCG cassette analysis on Siemens  
Clinitek Status+ Urinalysis Machine**

Competency	Knowledge and Understanding
<b>Contact Details</b>	To report a fault, please contact POCT: Working hours 08:30 to 17:00 Mon-Sun LGI: 22338 SJUH: 64791 or e-mail: leedsth-tr.pointofcare@nhs.net
<b>Medico-Legal</b>	<ul style="list-style-type: none"> <li>• Staff members must have completed the Clinitek Status+ strip testing competency assessment</li> <li>• Passwords (Trust ID badge barcodes) <b>MUST NEVER</b> be shared to prevent device misuse and to protect both patients and staff. Passwords are unique to every user.</li> <li>• It is against Information Governance and Trust IT Policies to share passwords. It is a disciplinary offence.</li> <li>• Training will last for two years. All users must have an update before password expiry to ensure continuous access to the machines.</li> <li>• The sample must be labelled with at least 3 forms of patient ID.</li> <li>• <b>Acceptable forms of patient ID are:</b></li> <li>• The NHS, PAS or A&amp;E number</li> <li>• If the above are not available, the patient's FULL name</li> </ul> <p>For an unknown patient, use unknown, gender and condition e.g. unknownmalecrash</p>
<b>Analyser overview (Hardware)</b>	<ul style="list-style-type: none"> <li>• Test table with white calibration bar, test table insert</li> <li>• Barcode scanner, printer, TP link box, touch screen and on/off button</li> <li>• QC - Level 1 - negative (Green Label) and Level 2 - Positive (Red Label) - stable at <b>2-8°C</b> until expiry date printed on vial, <b>keep refrigerated after use</b></li> <li>• Cassettes - Siemens Clinitest hCG cassette + single use pipette- stable at <b>2-30°C</b> until expiry date printed on packaging</li> </ul>
<b>Analyser Overview (Screen)</b>	<ul style="list-style-type: none"> <li>• Title bar</li> <li>• Home screen</li> <li>• Instrument set up</li> <li>• Recall results</li> <li>• Cassette test/QC due</li> <li>• Strip test/QC due</li> </ul>
<b>Calibration</b>	No action required - automatically done by the machine before each sample analysis.
<b>Quality control</b>	<ul style="list-style-type: none"> <li>• <b>QC to be analysed by the user on a weekly basis</b> - cannot be used for patient test until the QC has been analysed. Importance of QC - to check analyser is performing accurately for both high and low results and to check user's technique.</li> <li>• QC to be stored at <b>2-8°C</b>, return the fridge when not in use</li> <li>• Two levels to analyse, always analyse negative (Level 1) QC first</li> <li>• Additional QC testing should be performed for a new cassette lot and after corrective maintenance</li> </ul> <p><b>Preparing/running QC solution</b></p> <ol style="list-style-type: none"> <li>1. Select <b>QC Test Due</b> then <b>QC Cassette test</b></li> <li>2. Scan Trust ID badge as <b>Operator ID</b> then press <b>ENTER</b>.</li> <li>3. Scan <b>Control lot number and enter the expiry date</b> manually when prompted</li> <li>4. Scan <b>cassette lot number</b> when prompted, place cassette onto the test table</li> <li>5. Hold the pipette at 45° and squeeze the upper bulb to draw sample up and completely fill pipette stem, ensuring no air bubbles are present. Any excess liquid will move into reservoir bulb. <b>DO NOT</b> attempt to squeeze or empty the liquid in the reservoir bulb.</li> <li>6. Press <b>Start</b> (8 seconds countdown begins), empty the sample into the cassette sample well by squeezing the upper bulb in one squeeze, ensuring the tip of the pipette does not touch the bottom of the well</li> <li>7. Repeat the same process for positive QC (Level 2)</li> </ol> <p><b>SHOULD A QC TEST FAIL</b></p> <p>Check that the correct QC level was analysed            Check expiry dates of QC and cassettes            Ensure the QC sample used is not contaminated            Clean the test table with alcohol wipes and rinse the white calibration bar under water and clean with a lint-free paper towel. Repeat the QC            Contact POCT if QC tests still fail</p>
<b>Pre-Analytical/ Sample Preparation</b>	<ul style="list-style-type: none"> <li>• <b>Do not attempt to read the results on the cassette visually</b></li> <li>• hCG cassette testing is solely used for detecting pregnancy</li> <li>• Do not use expired cassettes</li> <li>• Cassettes can be stored at room temperature or refrigerated</li> <li>• Sample must be collected into a plain universal container and analysed immediately or refrigerated for up to 72 hours</li> <li>• If refrigerated, bring the test cassette and sample to room temperature prior to analysis</li> <li>• Pulp products may affect the results. Boric acid may interfere with the test. Residual detergent from a</li> </ul>

	<p>washed container can affect the constituents of urine</p> <ul style="list-style-type: none"> <li>Always mix sample prior analysis</li> <li>Visually bloody, severely turbid, viscous, mucoid and highly coloured samples may interfere with the sample flow and the test and may produce a false positive result.</li> </ul>		
<b>Patient Sample Analysis</b>	<ol style="list-style-type: none"> <li>The patient sample should be clearly labelled, fresh and well mixed</li> <li>Select Cassette Test and scan Trust ID badge as <b>Operator ID</b> is prompted then press <b>ENTER</b>.</li> <li>Press <b>“Enter New Patient”</b>.</li> <li>Scan/manually enter <b>PAS/NHS/A&amp;E</b> number or full name - and press <b>ENTER</b>.</li> <li>Scan <b>Cassette lot number</b> when prompted, place cassette onto the test table</li> <li>Hold the pipette at 45° to draw sample into the pipette stem ensuring there is no air bubble present</li> <li>Press <b>Start</b> (8 seconds countdown begins), empty the sample into the cassette sample well</li> <li>Make sure the tip of the pipette does not touch the bottom of the well</li> <li>The hCG test can take up to 5 minutes and the results will be displayed and printed out.</li> <li>Press <b>Done</b> to log out and return to main screen</li> <li>Remove and discard the cassette</li> <li>Do not re-use the same cassette if you have failed to empty the sample into the well within 8 seconds Repeat the whole process if required</li> </ol>		
<b>Results</b>	<ul style="list-style-type: none"> <li>If results do not fit with patient’s clinical picture, send a blood sample to the lab for confirmation</li> <li>Borderline results are classed as indeterminate and should not be considered as a false positive results, repeat in 48-72 hours or send a blood sample to the lab for confirmation</li> <li>Spontaneous abortions may cause false results as hCG may remain in the bladder for hours before voided</li> <li>Pre-embryo implantation may cause false negative results</li> <li>hCG levels remains detectable several weeks after pregnancy, miscarriage or hCG injections (IVF treatments)</li> <li>Contaminated containers may cause false results</li> <li>Over or under filled sample may also produce false results</li> <li>Cassettes that are either too warm or too cold may produce false results</li> </ul>		
<b>Results recall</b>	<ul style="list-style-type: none"> <li>Analyser can store 950 patient test results</li> <li>Select <b>Recall Results</b></li> <li>Select <b>Patient Tests or QC Tests</b>. You can recall results by name, ID, date or search all results</li> <li>Use the up and down arrow keys to scroll and <b>Select</b> the results you want to recall, press <b>Print</b> to reprint results</li> <li>Press <b>Done</b> to log out and return to main screen</li> </ul>		
<b>Health and Safety</b>	<ul style="list-style-type: none"> <li>Samples must be capped as soon as possible to avoid spillages</li> <li>Conform to Trust Infection Control policies at all times</li> <li>Gloves should be worn when handling urine samples</li> <li>Universal containers must be disposed of in the infectious waste bin</li> <li>Spillages must be dealt with in line with Departmental H&amp;S policies</li> </ul>		
<b>Troubleshooting/Maintenance</b>	<ul style="list-style-type: none"> <li>Test table - this must be positioned properly in order for the analyser to function. Push it half way into the analyser after cleaning and switch the machine off and on again to allow the machine to readjust the table. <b>DO NOT push the table fully inside of the analyser as this will cause the table to become jammed.</b></li> <li>Printer paper - must be changed when the red stripe appears on result printouts. Ensure that the paper is in the correct way by scratching it before inserting into the feeder. Ensure lever is pushed down.</li> <li><b>ALWAYS</b> wipe the test table between each strip test</li> <li>Daily - remove the test table and insert and rinse under water, dry with a lint-free paper towel</li> <li>Weekly - disinfect the test table insert by wiping with 70% isopropyl alcohol wipes, allow to air-dry and then rinse thoroughly. Dry with a lint-free paper towel before reinserting the test table.</li> <li><b>DO NOT</b> scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests.</li> <li><b>DO NOT</b> use solvents.</li> <li>When reporting clinical incidents on DATIX, tick the tick box for incidents involving Trust equipment and select <b>‘in-vitro Medical Devices’</b> from the drop down list.</li> </ul>		
<b>Key Trainers (FOR POCT USE ONLY)</b>	<ol style="list-style-type: none"> <li>Form 1 should be used by Key Trainer to train other staff</li> <li>Copy of a controlled version of the Key Trainer Handbook will be made available to Key Trainer</li> <li>Training register should be used to inform POCT of any new training sessions.</li> <li>POCT contact details</li> </ol>		
Name of member of staff (Please Print)		Name of assessor (Please Print)	
Member of staff signature:		Assessor Signature:	
Date of Training:		Date Recertification Due:	

**Form 2 Competency Questions - - Clinitest hCG cassette analysis on Siemens Clinitek Status+ Urinalysis Machine**

1. If the sample cannot be analysed immediately, how long is the sample stable for?

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 .....

2. Describe the process of carrying out a cassette test?

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 .....

3. Why is it important that there is no air bubble present in the pipette stem?

.....  
 .....

4. What are the correct storage conditions for the cassettes?

.....  
 .....

5. Under what conditions false results may be produced?

.....  
 .....

6. What mandatory patient ID is required?

.....  
 .....

7. How often do you perform QC tests?

.....  
 .....

8. What should you do if the QC fails?

.....  
 .....

Name:	Operator ID Number:
Ward:	Extension:
Email:	Date:

**Form 2 Competency Answers - Clinitest hCG cassette analysis on Siemens Clinitek Status+ Urinalysis Machine**

1. If the sample cannot be analysed immediately, how long is the sample stable for?

**72 hours if refrigerated**

2. Describe the process of carrying out a cassette test?

**Hold the pipette at 45° to draw sample into the pipette stem ensuring there is no air bubble present. Press start then empty the pipette into the sample well**

3. Why is it important that there is no air bubble present in the pipette stem?

**Under or overfilled sample may produce false results**

4. What are the correct storage conditions for the cassettes?

**At room temperature or refrigerated. Bring to room temperature before use.**

5. Under what conditions false results may be produced?

**Pulp products, boric acid containers, contaminated containers, viscous, mucoid, highly coloured, bloody sample, over or under filled sample well, spontaneous abortion, pre-embryo implantation, test performed several weeks after pregnancy, miscarriage and IVF treatments, cassettes that are too warm or too cold**

6. What mandatory patient ID is required?

**Full name, NHS/PAS/A&E number**

7. How often do you perform QC tests?

**Weekly QC - Positive and Negative**

8. What should you do if QC fails?

**Check that QC solutions and cassettes are in date and are not contaminated/deteriorated. Ensure that the correct QC was run and clean the calibration bar and rerun QC. If QC still fails, contact POCT**

**FORM 3- Competency Assessment**

**Observational Assessment; Performing Clinitest hCG cassette analysis on the Siemens Clinitek Status+ Analyser**

**TO BE RETURNED TO POINT OF CARE**

Core competency	Please record whether or not the member of staff completed the task.
<b>1 Has the member of staff read the knowledge and understanding worksheet (Form 1)?</b>	
<b>2 Has the member of staff completed the questions?</b>	
<b>3 Did the member of staff correctly use the relevant ID</b> <ul style="list-style-type: none"> <li>Did the member of staff scan the correct patient bar code as ID?</li> <li>Did the member of staff check the patients ID on screen matched that of the patient who the sample came from?</li> <li><b><u>Did the member of staff enter their own bar code password?</u></b></li> </ul>	
<b>4 Sampling-can be done with either patient or QC sample</b> <ul style="list-style-type: none"> <li>Did the member of staff mix the sample prior analysis?</li> <li>Did the member of staff perform the correct method for cassette analysis (pipette the sample, press start, empty sample into well)?</li> <li>Did the member of staff check the cassette prior analysis to see if it is at room temperature and is in date?</li> </ul>	
<b>5 Urinalysis maintenance</b> <ul style="list-style-type: none"> <li>Does the member of staff know how remove the test table from the analyser and clean the calibration bar when required?</li> <li>Does the member of staff know how to contact Point of Care in the event of machine breakdown?</li> </ul>	
<b>6 Did the member of staff demonstrate effective health and safety measures?</b> <ul style="list-style-type: none"> <li>Were gloves worn?</li> <li>Were the used universal container and test strip disposed of in a clinical waste or infectious waste bin?</li> <li>Was the machine left clean for the next user?</li> </ul>	
<b>7 Result Reporting</b> <ul style="list-style-type: none"> <li>Were the results reported according to ward/departmental procedures ensuring the correct patient ID?</li> <li>Were the results acted on accordingly?</li> </ul>	
<b>8 Key Trainers (FOR POCT USE ONLY)</b> <ul style="list-style-type: none"> <li>Able to recall and convey relevant information</li> <li>Understands training requirements and how to complete the training documentation</li> </ul>	

**Staff Member**

I the undersigned declare that I have read Form 1 and completed the multiple choice questions and the practical assessment

**Assessor**

I the undersigned declare that the staff member has completed the competency tests to a satisfactory standard.

Name of member of staff (Please Print):	<b>FOR POCT USE ONLY</b>				
Operator Number:	Name of assessor (Please Print)				
Department:	Date of assessment:				
Site access required for:	Signature:				
Staff member's E-mail:	Key Trainer?	Update KT List	MELVIS KT course	Update KT email group	Email KT Docs
Signature:					

