

## Clinitek Status Pregnancy Testing Training plan for Ward Staff

No. of copies :	12
Location of copies :	Accident & Emergency
	Ward 14
	Gynaecology OPD
	Dermatology
	Ward 32
	PIU
	DSEU
	GUM
	Rheumatology
	X-ray
	Ward 30 (SAU)
	POPD

Please keep this booklet with the Clinitek Status.  
**How to obtain further supplies**

Clinitek Test cartridges  
Control Solution  
Paper  
Patient Record Books

Contact Pharmacy  
Contact Chemical Pathology  
Contact Chemical Pathology  
Contact Chemical Pathology

### Useful Contacts & Telephone Numbers

Clinical Biochemistry 2733 or 2673  
Lindsey Wilson 2733 or 2673  
(Senior Biomedical Scientist, POCT Coordinator)

Your Link Nurse is: \_\_\_\_\_

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## Introduction

*Designed to help you*

This booklet has been compiled by the Clinical Biochemistry laboratory at BHNFT 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 kits including routine use and quality control. On completing this training all users of the kits should be able to analyse samples obtaining an accurate result whilst minimising risk to themselves and patients.

Further information can be seen in the SOP available within Clinical Biochemistry or in the Siemens Operator Manual. However, if you have any queries please don't hesitate to contact your Link Nurse or the Clinical Biochemistry laboratory.

**The purpose of this booklet is to provide you with the information you need to achieve accurate results. Thus providing the best quality care for your patients**

## Staff Responsibilities

Clinical Laboratory Accreditation Ltd (CPA) requires all Clinical Biochemistry/Chemical Pathology Laboratories to guarantee that all Point of Care Testing (POCT) within the Trust is performed to the same standard as required in the laboratory and, in doing so, ensures the safety of patients and staff.

The use of analysers by untrained staff, without adequate management supervision of the equipment and without the use of quality control procedures, can lead to misleading results, adversely affecting the treatment of patients<sup>1</sup>.

- **A management or therapeutic decision based on an unreliable result could be fatal.**
- **Getting it right first time is important**

### Recommendations

- All staff who perform sample analysis must be properly trained to use the equipment\*.
- Untrained or insufficiently trained staff should not use the equipment.
- Quality control checks should form part of the maintenance routine, with the Clinical Biochemistry laboratory directly involved.
- Quality control procedures should aim particularly at maintaining the competence of all equipment users and ensuring the reliability of the results obtained.

The above recommendations are contained within the Department of Health Hazard Notice pertaining to blood glucose measurement but apply equally to any Point of Care Testing.

\*It is extremely important that staff are properly trained in the use of the Clinitek Status testing kits. If in doubt please contact your Link Nurse or Chemical Pathology before using the kits. Do not pass kits onto other areas refer them to Chemical Pathology.

***Remember – an incorrect result could lead to serious consequences for the patient in your care.***

<sup>1</sup> Source: Blood glucose measurements: Reliability of results produced in extra-laboratory areas. Department of Health [HN [hazard] (87) 13]

## Protocol for the use of the Clinitek Status

This protocol relates to the responsibility of all staff designated to use the Clinitek Status.

1. Follow the manufacturer's guidelines and hospital policy on POCT.
2. Only staff who have received appropriate training and have a completed Competency form (see Appendix 3 of this booklet), may use the kits.
3. Each member of staff takes responsibility for the quality of the results obtained by him/herself using the following procedures:
  - Kits should be stored at room temperature out of direct sunlight.
  - The reaction unit should not be removed from the pouch until you are ready to perform the test.
  - Use a fresh dropper for each test.
  - User name and patient ID must be entered for all tests
  - Full patient details must be entered into the patient record book (including date and time of analysis). The top copy should then be sent to Clinical Biochemistry. The back copy may be kept either in the patient notes or in the book; these must be kept for the lifetime of the POCT method. A link nurse for each ward / department should be designated to ensure that procedures are followed.
4. The department must be enrolled in an external quality control scheme.
5. Unexpected or equivocal results **MUST** be confirmed by sending a brown top gel tube to Clinical Biochemistry for a serum BHCG.

## Data Collection

Accurate patient identification is essential to minimise clinical risk and to maintain pathology electronic patient records.

### Patient Record Sheets

To ensure the above, the following procedure MUST be followed:

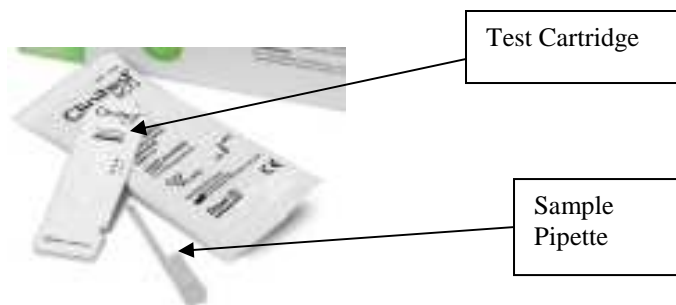
- Enter the patient's unit number, full name, date of birth and address.
- Enter your ward/department.
- Enter the consultant.
- Enter the date and time of sampling.
- Tick appropriate result box.
- Return the completed top copy (green) of the form to Clinical Biochemistry. Back copies should be kept by the ward/department for the lifetime of the instrument.

PATIENT DETAILS INCLUDING UNIT NO.	WARD/DEPT	CONSULTANT	TEST PERFORMED BY						
PATIENT, Duminy 123456	A/E	DM	A. ANGLE						
1/10/84	1/10/12	12:05	RESULT (TICK AS APPROPRIATE)						
1 BARNWELL STREET BARNWELL			<table border="1"> <tr> <td>POSITIVE</td> <td></td> </tr> <tr> <td>NEGATIVE</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>EQUIVOCAL</td> <td></td> </tr> </table>	POSITIVE		NEGATIVE	<input checked="" type="checkbox"/>	EQUIVOCAL	
POSITIVE									
NEGATIVE	<input checked="" type="checkbox"/>								
EQUIVOCAL									

## The Clinitek Status Analyser



## Clinitek Pregnancy Test Cartridge



## Quality Control

### Automated

Each test includes two Quality Control lines (a Reference line and a Control line).

If the instrument does not detect these within 2 minutes, an error is reported

Key reasons for this include:

- Short samples
- Incorrect storage of cassettes

(See Troubleshooting)

### Manual

On a weekly basis run a Positive and Negative control as you would a patient test using QC1 or QC2 (as appropriate) as the sample patient and sample identifiers..

When not in use the controls should be stored at 4°C.

## External Quality Control Scheme

Every POCT site using the Clinitek pregnancy testing cartridges must be enrolled in an external quality assurance scheme.

Barnsley Hospital NFT uses the WEQAS pregnancy testing scheme.

- The Chemical Pathology Department will send out the external QC samples six times a year.
- There are no 'expected' values for the external QC samples.
- The sample is treated as a patient's sample. Use QC and sample number as unit number and surname
- The results must be recorded on the sheet provided (see Appendix 1).
- This sheet must be returned to Chemical Pathology who will forward the results to WEQAS.



## Maintenance

### Daily

Check that the calibration strip on the instrument is clean and dry **EVERY** day. Failure to do this could result in false positive results.

- Switch Clinitek status analyser on.
- After initialisation pull test table holder forward to remove completely from analyser.
- Check the calibration strip is clean, if not, wipe with a soft cloth ensuring that you do not scratch it.
- Push test table holder into analyser until calibration strip is not visible.
- Power Clinitek status off.

### Weekly

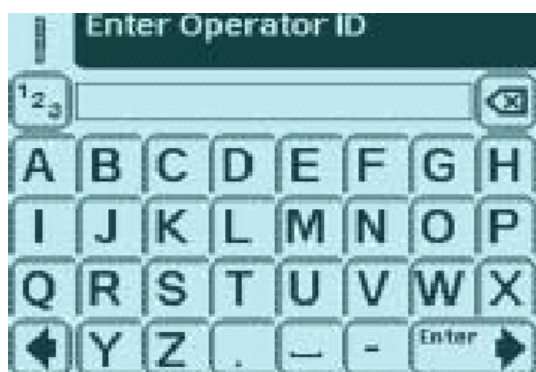
Remove the test table from the Clinitek Status and clean using a mild detergent to remove any build up. Dry thoroughly before replacing.

### Changing the Paper

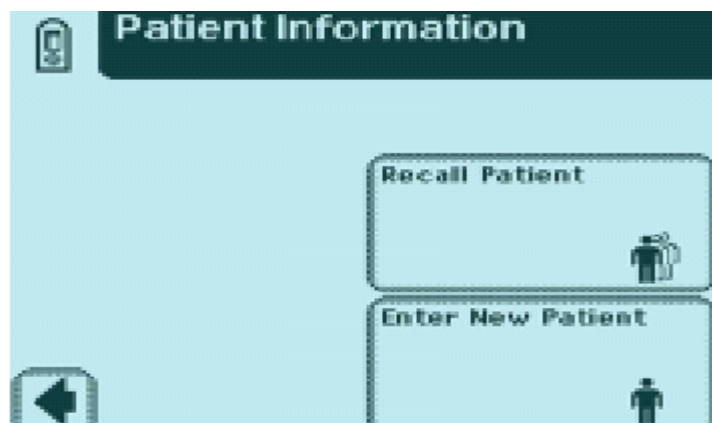
1. Open printer cover by pulling up on the tab.
2. Open the paper roll compartment by pressing down on its tab and pulling out.
3. Lift the paper holding arm to the upright position.
4. Remove the remains of any old paper.
5. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and toward the compartment wall.
6. Fold the leading edge of the paper into a point and feed up through the printer and through the printer cover.
7. Push the paper holding arm into the closed position.
8. Close the printer and paper roll covers by clicking into position.

## Assaying a Patient sample

1. Power up the Clinitek Status analyser by pressing the on/off button on the front of the instrument, the analyser will perform a system diagnostic test.
2. Select Cassette Test by touching the screen in the Cassette Test box.
3. Make sure the Test Table is set for a cassette test, if not turn over.
4. Remove the cartridge from the foil pouch only when ready to use, check the expiry date on the foil pouch. Do not use if the kit has expired. Do not use test devices which have become wet or have been left out of the foil pouch for more than 24 hours.
5. Touch Enter New Operator ID.
6. Use the keyboard to enter your surname and initial. Touch Enter when you have finished.



7. Touch Enter New Patient

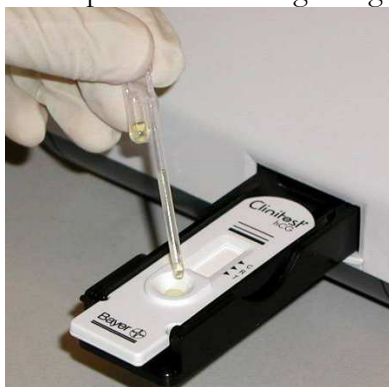


8. Using the touch screen enter the patients surname.
9. Using the touch screen select the number keyboard and enter the patient's unit number.

10. Draw up sufficient urine sample into the pipette, any excess sample will go into the overflow chamber. Use one pipette measurement ONLY (this is equal to 200 $\mu$ L)



11. Touch Start and put the sample into the sample well. Press and release the pipette to ensure that the full sample volume is applied, make sure there are no air bubbles 'under' the sample to prevent it moving along the strip. (DO NOT EMPTY THE OVERFLOW CHAMBER).



The instrument will now automatically time and record the result

12. Power off the Clinitek Status analyser by pressing the on/off button on the front of the instrument.

**REMEMBER TO FILL IN THE PATIENT RECORD BOOK!**

## Health and Safety

There is minimal risk in using the Clinitek Status (see appendix 2) as long as gloves and protective clothing are worn.

Departmental policy should be followed when dealing with a urine spillage.

- Dispose of all disposable droppers into a suitable yellow biohazard container.
- Dispose of Clinitek tests into a suitable yellow biohazard container.

## Troubleshooting

### False Positive (on patient or QC)

- Check calibration strip is clean and dry, clean if necessary.
- Check test cartridges are in date.
- Check sample for blood or high protein content using a urinalysis strip
- Run QC, if negative QC reads equivocal or positive contact laboratories

### Insufficient sample

- Repeat test making sure correct volume applied and that no air bubbles are preventing capillary action of test paper.
- Check calibration strip is clean and dry.
- Check test cartridges are in date.
- Check sample for high protein content using urinalysis strip
- Check sample for debris or high viscosity which may affect capillary action.
- If still getting insufficient sample error send urine to labs for analysis and run QC on your own analyser.
- If lab gets a result and/or your analyser still indicating insufficient sample contact laboratory for further advice.

# Appendix 1

## WEQAS Pregnancy Testing Scheme

Please assay these Quality control samples as normal patient samples and return to Chemical Pathology by the date stated below.

If you have any questions please phone extension 2733.

**WEQAS Distribution:**

**Date Sent:**

**Return by:**

**Ward /Department Name:**

**Performed by:**

<b>Sample number</b>	<b>Result</b>	<b>Test Performed By (Please Print)</b>
<b>1</b>		
<b>2</b>		
<b>3</b>		

## Appendix 2

### Details of process

This is an automated analyser for use with patient urine for measurement of HCG for pregnancy

### Chemicals to be used and hazards

None

### Other hazards

Patient material: Infectious material

Q.C. sera: Human sera - Infectious material

Mechanical: Moving test table.

Electrical: Electric shock.

### Control measures required

Proper Training and supervision

Installation and maintenance of equipment as defined by Health Authority policy

All spillages must be dealt with as by ward policy

Fire precautions must be observed as ward policy

### Disposal methods

All biological materials and contaminated waste materials must be discarded into appropriate bins for incineration < HS-PA-003; Section 10 >.

Sharps to be disposed of into 'SHARPSAFE' bins

Small amounts of chemical solutions, associated with minimal risk, may be disposed of down the sink and flushed away with copious amounts of water.

### Assessment of staff exposure

Consequence score (1-5) x Likelihood score (1-5).

Assessment of staff exposure : Consequence score (1-5) x Likelihood score (1-5).

Consequence 3 x Likelihood 1 = 3 (Low Risk)

Significant risk of infection from patient material/sharps, however adherence to the control measures above should be adequate in controlling the risk.

## Appendix 3

**Competency Statement:** To be able perform a pregnancy test accurately and safely.

**Category** Clinitek Status +

Name: ..... Job Title: .....  
 Department: ..... Ext. Number: .....  
 Trained By: ..... Date: .....

Method of Assessment: Self-assessment of competency in the use of medical device in relation to defined key elements and countersigned by appropriate member of staff (Key Trainer, Manager, Educator, Mentor etc).

Self assessment-key statements/elements	Competent Y/N	Date
1. Routine Use <ul style="list-style-type: none"> <li>• Demonstrate performing a patient’s test using the Clinitek Status. Include entering user and patient identification details and recording the result.</li> <li>• Describe how you change between cartridge and strip use.</li> <li>• Describe when you would perform QC</li> <li>• Describe how you would clean the test table.</li> <li>• Outline when you would request a serum BHCG from the laboratory</li> </ul>		

**Disclaimer:** (i). Having answered YES to the above key statements and taken into account my personal assessment of my competence in the use of the medical device, I declare that I am competent to use the device safely as per the Trusts’ guidelines.  
 Signature: ..... Print Name: ..... Date: .....

(ii). I require further training in the use of this equipment in order to reach a competent level of practice and will discuss these needs with my Mentor/Ward Manager/ Trainer/Equipment Controller.  
 Signature: ..... Print Name: ..... Date: .....

**I certify that** ..... **is competent in the use of**  
 .....

**Signed:** ..... **Position:** ..... **Date:** .....

## Appendix 4

### Point of care Password Request form

To ensure all staff who performs Point of Care sample analysis are properly trained the equipment is password protected. Staff will be issued with a password only after they have undergone recognised training and obtained a certificate of competence. It is therefore important that passwords should not be passed onto other members of staff. If you suspect someone is using your password without supervision, or you wish to change your password contact Chemical Pathology on 2673/2733. The password will expire after 12 months, users will need to demonstrate competency for the password to be renewed.

Please complete and send with a COPY of a signed Competence Form(s) to Chemical Pathology.

*I have read and understand the above statement*

Signature \_\_\_\_\_ Date \_\_\_\_\_

Please Print

Name: \_\_\_\_\_

Ward/Department: \_\_\_\_\_

Contact Telephone Number \_\_\_\_\_

#### Password required for:

GEM 4000 Blood Gas  Inform Blood Glucose   
Clinitek Status Urinalysis  Pregnancy (Designated Wards Only)

If you already have a **barcode** password for one of the above analysers please indicate below and we will use this number.

GEM 4000 Blood Gas  Inform Blood Glucose   
Clinitek Status Urinalysis  Pregnancy (Designated Wards Only)

#### For Lab Use

Competency Form(s) Enclosed (Please tick)

Attach Password Barcode

Password Issued (Date) \_\_\_\_\_ By (Please Print) \_\_\_\_\_