

Active	BioSign Urine Pregnancy Test SOP		Version: 1.40
Author: S.Phillips	Doc Manager: K.Ashton	Authorised by: K.Ashton Signature :	Ver Date: 08/11/12

The Royal Liverpool and 
Broadgreen University Hospitals
 NHS Trust

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Related Documents	
Hazard Data Sheets	Biosign hCG Urine Pregnancy Test_COSHH_121278 Urine pregnancy IQC solutions_COSHH_121407
Risk Assessments	Biosign urine pregnancy testing RA
Others	

Significant changes from previous version:

Addition of information for laboratory staff.

Purpose

To describe the use of the Biosign[®] hCG Pregnancy Test cassettes for urine pregnancy testing on the Lifesign Dexpress[™] Reader.

The Biosign[®] hCG Pregnancy test is only intended for use with the Lifesign Dexpress[™] Reader. These pregnancy test kits should not be read visually.

Clinical indications

Human Chorionic Gonadotrophin (hCG) is a glycoprotein hormone consisting of two subunits. The α -subunit has a similar amino acid sequence to that of luteinising hormone (LH), follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH). The β -subunit has some similarity to LH but hCG has 30 more amino acid residues.

The placenta produces hCG shortly after fertilisation, stimulating the enlargement of the corpus luteum and thus allowing pregnancy to continue. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth, make it a good marker for the early detection of pregnancy. In normal pregnancy hCG may be detected in the urine 7-10 days after conception.

Principles of method

The Biosign[®] hCG Urine Pregnancy Test employs a solid phase, chromatographic immunoassay for the rapid detection of hCG in urine. When urine is applied to the test cassette if hCG is present in the sample it will react with the conjugate dye, which binds to the antibody on the membrane to generate a coloured line. The

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Page 1 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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reaction involves both mouse monoclonal and goat anti-hCG antibodies. The Dxpess™ reader interprets the test result automatically by comparing the intensity of the coloured line to the preset cut off value.

Specimen requirements

The test requires a small volume of urine, collected into any clean glass or plastic container. Refrigerate specimens at 2–8 °C for up to 48 hours, if the testing is not performed immediately. If refrigerated the specimen should be brought to room temperature before performing the test. **All specimens should be labelled with adequate patient identification: Full name, date of birth and a unique patient identifier (hospital RQ6 number).**

Collection Procedure

No special preparations are necessary. Use of the first morning urine is recommended, as it generally contains the highest concentration of β hCG, although this is not essential.

Instrumentation

Lifesign Dxpess™ Reader



Reagents

BioSign® hCG Urine Pregnancy Test cassettes

- Clinical Biochemistry is responsible for ordering reagents. **Stocks of BioSign® hCG Pregnancy Test Kits are stored in Clinical Biochemistry - Tel 4235.**

- This kit is distributed by:

Chirus Limited Park House 15-23 Greenhill Crescent Watford Business Park Watford Hertfordshire WD18 8PH	All enquires to Roche Diagnostics: Roche Diagnostics UK Ltd Charles Avenue Burgess Hill West Sussex RH 15 9RY
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- **Storage and stability**

The test kit can be stored refrigerated or at room temperature, 2 – 30 °C for the duration of the shelf life. If the test kits are refrigerated bring the foil wrapped cassettes to room temperature before opening, to avoid moisture condensation on the test membrane. Do not use the test kit beyond the expiration date. Use the test cassette immediately once the sealed foiled pouch is opened

Calibration

The Dxpess™ Reader must be calibrated before reading the BioSign hCG Pregnancy Test cassettes. **A Self Check must be performed at least daily**, this checks the instruments hardware and software. **A Calibration QC must be performed weekly**, this checks and calibrates the instruments optical system using the reference values for a barcoded Calibrator cassette.

Do not photocopy this document

Page 2 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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Self Check

The Dxpess™ Reader performs a Self Check automatically every time it is turned on. This takes about 15 seconds and PASS or FAIL is displayed when testing is finished.

If the instrument is left on or in power save mode, a Self Check should be manually requested daily.

To manually request a Self Check:-

- From the main menu select [2] RUN QC
- Then select [1] SELF CHECK

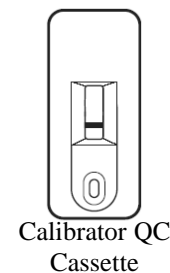
When a blinking “S” appears in the top right corner of the screen, the reader is performing a Self Check.

Calibration QC

Calibration QC requires the barcoded Calibrator QC cassette.
The barcode contains the quality control parameters for the Calibrator.

**Always store the Calibrator in the clean pouch provided.
Make sure it is free of scratches and dust.**

Do not lose or damage the Calibrator QC cassette – there will be a cost to issue a replacement.



The calibrator QC cassette is stored in a designated area at each location.

Calibration QC is successful when the actual value obtained using the Calibrator matches the reference value within a predefined tolerance range. If the actual value obtained using the Calibrator does not match the reference value within the predefined tolerance range, the reader will perform a full recalibration automatically.

The full recalibration process may require several cycles of reading the Calibrator. Recalibration is successful when the actual value obtained using the Calibrator is essentially equal to the reference value.

The instrument will prompt when Calibrator QC is due (every week)

To perform a Calibration QC:-

- Make sure the Calibrator is not expired and the surface is clean.
- From the main menu select [2] RUN QC
- Then select [2] CALIBRATION QC
- Scan Operator ID
- Scan the Calibrator QC ID from the barcode on the Calibrator QC cassette.
- Insert the Calibrator into the Dxpess™ Reader and press ENTER.
- If successful, the reader displays the “Calibration QC – Pass” result screen, which can be printed.
- Press ENTER to continue.
- After Calibration QC completes successfully, the instrument prompts to perform a Blank calibration. Select CANCEL.
- If the reader is unable to calibrate successfully, the screen will display "CALIBRATION FAILED". DO NOT use the instrument for patient samples and contact Clinical Biochemistry immediately. See Contact Details for a list of Biochemistry support staff.

Do not photocopy this document

Page 3 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

Active	BioSign Urine Pregnancy Test SOP		Version: 1.40
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When a blinking "C" appears in the top right corner of the screen, the reader is performing a Calibration QC.

Quality control

Each BioSign® Test cassette has a built-in Positive Procedural Control indicating that the procedure has been performed properly: the sample volume is adequate; the sample and reagents have migrated; and the internal test control reagents and the conjugated-colour indicator are working properly. In addition, the background in the result window will become clear and provide a distinct result, which may be considered an internal Negative Procedural Control.

If the instrument detects a failure of either of these two procedural controls, an error is reported and the test must be repeated.

Internal Quality Control

Positive and Negative control solutions **must** be analysed at least weekly. The control solutions are distributed on a weekly basis by Clinical Biochemistry to all areas performing urine pregnancy tests.

To perform a quality control test:

- From the main menu select [2] RUN QC
- Then select [3] EXTERNAL QC
- Scan the Lot no. of the test cassette. Select OK to confirm and continue.
- Scan Operator ID
- Scan the sample ID using the barcode sheets provided with the samples.
- Continue as for a patient sample
- Stick the result print outs into the control log book and complete the details requested.

If the results do not give the expected positive or negative result, DO NOT use the analyser for patient samples and contact Clinical Biochemistry immediately

See Contact Details for a list of Biochemistry support staff.

MAS® UrichemTRAK 1 and 2 internal control solutions are used. Controls are supplied liquid stable. In use controls are stored as approximately 0.4 mL aliquots at 4°C in the endocrine cold room, CCR9, prior to distribution. Stock controls are stored in corelab coldroom CCR1.

MAS® UrichemTRAK 1 and 2, Cat. No. UR11001 and UR22002, respectively, are obtained from:
Microgenics GmbH
P.O.Box 64,
St. Albans,
Hertfordshire,
AL2 1RA.

External Quality Assurance (EQA)

ALL areas performing urine pregnancy tests **MUST** participate in the Welsh External Quality Assurance Scheme (WEQAS) scheme.

Three samples are distributed by Clinical Biochemistry at approximately 2 monthly intervals. Analyse the samples on receipt and return the results to Clinical Biochemistry using the results sheet and SAE enclosed with the samples. A summary report is sent to external users when the results have been collated.

- From the main menu select [2] RUN QC

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Page 4 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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- Then select [3] EXTERNAL QC
- Scan the Lot no. of the test cassette. Select OK to confirm and continue.
- Scan Operator ID
- Scan the sample ID using the barcode sheets provided with the samples.
- Continue as for a patient sample

Method

***Only staff who have received training from Clinical Biochemistry can use the Dpress™ Reader to perform BioSign® hCG urine pregnancy tests*.**

Dpress™ Reader Operating Instructions

Instrument Set Up

Place the analyser on a level work surface where the temperature and humidity are fairly constant. The best temperature for using the instrument is between 22°C and 26°C (72°F and 79°F). Do not place the analyser outside or near windows, ovens, hot plates, or radiators. Plug the appropriate end of the power cord into the power inlet socket located on the rear of the Dpress™ Reader. Plug the other end of the power cord into a electrical wall socket. Connect the barcode scanner to the barcode port at the back of the instrument.

Loading the Printer Paper

1. Open the printer cover by pressing the eject button.
2. Place the new paper roll into the printer paper compartment with coated (glossy) surface facing the LCD screen i.e. with the paper unrolling from underneath and toward the compartment wall.
3. Pull about 5 cm of paper from the roll, then close the cover ensuring the end of the paper comes out of the printer roll compartment.

Turning on/off the Dpress™ Reader

- To turn on: Locate the Power Switch on the lower right-hand side of the reader. Use the Power Switch to turn on the instrument.
- To turn off: To properly turn off the reader and ensure data integrity, select [6] SHUTDOWN from the main menu screen. This procedure ensures that all data is safely stored in the DXpress™ Reader memory. *The SHUTDOWN menu choice is not available while a test is pending in the Scheduler. Wait until all scheduled tests are completed before attempting to SHUTDOWN.*

Operation

- Symbol legend
 - Text inside a double box indicates a screen/menu name.
 - BOLDDED SMALL CAPITAL LETTERS indicate a choice displayed on the screen.
 - An image indicates a keypad button.
- How to “SELECT” menu choices
There are two ways to select choices displayed on screen:
 - Use the arrow keys on the keypad highlight the choice, then press ENTER.
 - Directly select choices that have bracketed numbers (i.e., [1], [2]) by pressing that number on the keypad.
- Entering data
 - To SCAN a barcode, place the head of the Barcode Scanner against the barcode, then press the button located under the handle. The Barcode Scanner will beep when it scans successfully.

Do not photocopy this document

Page 5 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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- To *ENTER* data using the keypad, use the alphanumeric keys, then press ENTER. Toggle between alpha (ABC) and numeric (123) characters by pressing the $1 \leftrightarrow A$ button . In alpha mode, press a key repeatedly until you see the desired character in lower case or CAPITAL.

- Inserting a test device

1. Pull out the Tray. Stop at the click-stop.
2. Place the test device in the Tray as indicated on the reader housing. *Make sure the window is facing up and the sample well is pointing toward the Tray handle*
3. Close the Tray fully.
4. The instrument will alarm if the test cassette is inserted the wrong way round.

Keep the Tray closed when not in use, to prevent excessive dust and debris from entering the reader.

- Printing

- The instrument is set to automatically print test results.

Performing a BioSign Urine Pregnancy Test

Standard safety procedures should be followed for handling patients' urine samples. All patient samples, used test cassettes and control cassettes should be disposed of as hazardous waste.

***Laboratory Staff also see additional information below*.**

1. Make sure the machine is switched on and performs a Self Check.
2. Make sure that calibration QC has been performed within the last week.
3. Check that internal quality control solutions have been tested within the last week and that the results were acceptable.
4. The patient's urine specimen should be fresh, well mixed and uncentrifuged.
5. From the main menu select [1] RUN PATIENT.
6. Scan the Lot no. of the test cassette. Select OK to confirm and continue.
7. Select Urine.
8. Scan Operator ID
9. Scan or Enter the Patient ID.
10. Remove a BioSign[®] test cassette from its sealed pouch and write the patient ID on the bottom. Use the test cassette immediately after opening.
11. Fill the sample pipette with urine, ensuring there are **NO air bubbles**.
12. **Holding the sample pipette vertically**, apply **three full drops** directly to the sample well on the test cassette, be careful NOT to splash sample onto the test area. **The test result is only reliable if the correct amount of sample is applied.** DO NOT over or underdose the cassette. If insufficient sample is applied a result of invalid will be obtained.
13. **IMMEDIATELY** place the test cassette into the Dxpess[™] Reader and close the tray.
14. When the tray is closed the instrument automatically begins to count down the preset incubation time.
15. After incubation the instrument automatically reads the test cassette and the result appears on the screen. All results are automatically printed. Results are available after 3-5 minutes.
16. Remove the test cassette from the instrument and discard in clinical waste.
17. The instrument will alarm if the tray is opened whilst a test is in progress. If the tray is closed within 10 seconds the test will continue. If the tray is not closed within 10 seconds the incubation timing will be lost and the test will not be read, therefore repeat the test.

Additional Information for Laboratory Staff ONLY

For the Patient ID use the laboratory specimen number.

Ensure all results are entered and released on Telepath.

Do not photocopy this document

Page 6 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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Limitations

This test is not intended to detect conditions other than pregnancy. It does not diagnose ectopic pregnancy or molar pregnancy. Serial serum β hCG values are required for this.

All qualitative pregnancy tests will produce a small number of false negatives.

- Because of the lag between conception and the appearance of hCG in urine, Negative test results in patients suspected to be pregnant should be re-tested with a sample obtained 48 to 72 hours later or by performing a quantitative serum β hCG.
- False negative results may be obtained with old samples due to degradation of hCG.
- Samples with low specific gravity may not contain representative levels of hCG, therefore negative results should be repeated with an early morning sample.
- Patients on antibody therapies may obtain invalid results due to interfering antibodies in the medications.

All qualitative pregnancy tests will produce a small number of false positives (<1%).

Reasons for a Borderline/Positive result in women who are NOT pregnant:-

- Low levels of hCG in women of childbearing age are sometimes observed due to a recent pregnancy that has spontaneously aborted (about 22% of pregnancies abort spontaneously, without being detected).
- hCG levels may remain detectable for up to several weeks following normal delivery, caesarean section, miscarriage, therapeutic abortion or hCG injections (IVF)
- Passively acquired hCG from a blood transfusion
- An ectopic pregnancy
- Trophoblastic diseases e.g. an ovarian tumor or hydatidiform mole
- The use of some fertility drugs
- The presence of interfering substances, such as endogenous proteins, drugs, micro organisms, erythrocytes and/ or leucocytes.
- The presence of heterophile antibodies or non specific protein binding may cause false-positive results in sensitive immunoassays. If a qualitative interpretation is inconsistent with the clinical evidence, results should be confirmed by an alternative hCG detection method.
- In rare occasions persistent low levels of hCG present in men and non-pregnant women (3 – 100 mIU/mL) may result in positive results.

Urine specimens with inconsistent results MUST be retained for further investigation and ideally a serum sample must be sent to the lab for hCG

Troubleshooting

In case of analyser malfunction, samples can be sent to the laboratory for analysis.

Assay characteristics

Analytical sensitivity

The BioSign[®] hCG Urine Pregnancy Test detects urinary hCG concentrations of at least 25 mIU/mL (calibrated to the World Health Organisation 4th International Standard).

Analytical specificity

Cross-reactivity studies with 300 mIU/mL LH, 1000 mIU/mL FSH and 1000 μ IU/mL TSH all yielded negative results.

Do not photocopy this document

Page 8 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc

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Maintenance

- Keep the outside of the Dxpess™ Reader clean and free of dust.
- To clean the outer case, LCD screen or test tray, wipe with a soft damp cloth dipped in a neutral detergent. Sanicloth multi surface wipes can be used for routine cleaning. .
- To disinfect the test tray, soak it for minimum of two minutes and a maximum of 10 minutes in one of the disinfectant solutions listed below. Thoroughly rinse with water and dry with a soft cloth.
- The outer case and LCD screen may be disinfected by wiping with a damp cloth dipped in one of the disinfectant solutions listed below.

NEVER USE highly volatile material such as benzenes, acetone or paint thinner to clean the reader or any of its components

Disinfectant solutions

Clinical Biochemistry should use virusolve for disinfecting.

Ward areas should use Actichlor Plus for disinfecting the instruments. The instruments should be disinfected with a damp cloth wetted with a solution of Actichlor Plus.

Make up 1,000ppm available chlorine by adding 1x 1.7g tablet to 1 litre of cold water in the Actichlor plus dilution container. Allow 10 minutes to dissolve. The fresh solution should be discarded after 24 hours. The solution must not be accessible to patients or the general public and must be stored behind a locked door if not in a locked cupboard (in order to comply with COSHH regulations).

Out Patient Departments should first clean the instruments with a damp cloth wetted with a solution of Hospec. The instruments should then be disinfected using a damp cloth wetted with a freshly prepared Haz Tab solution.

Make up 1,000 ppm Haz Tab solution by adding 1 x 2.5 litres of cool water in the dilution container provided by Pharmacy. The fresh solution must be discarded after 24 hours.

Additional Information

Refer to the BioSign® hCG urine pregnancy test kit insert.

Clinical Interpretation

For pregnant women, β hCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period. hCG levels peak about 8-10 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. Values approaching the cut off of the test (25 mIU/L) may be achieved very early following conception but due to the wide variation in β hCG secretion in each pregnancy the rapidity with which a positive result appears, and the density of the band, are neither an indication of the total β hCG present, nor the gestational age. hCG levels rapidly decrease and usually return to normal within days after delivery.

Health and Safety

All COSHH and risk assessment documents for urine pregnancy testing are available from POCT if required (see contacts).

Contacts

Trust Point of Care Manager :	Kath Ashton	Tel: ext 5587
POCT	Office	Tel; ext 4249
Department of Biochemistry:	Office	Tel: ext 4230

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Page 9 of 9

Last printed: 4 March 2013 (thine)

DMS Ref: 2499.doc