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**Summary of Significant Changes at this Revision**

To alter the centrifuge speed to 3400 for 10 minutes as the SciSpin centrifuge is in use with a smaller rota. The catalogue numbers for the controls and devices have changed  
 Include connection to POCcelerator for patient, iQC, and daily check results to move to and be stored in.

<p><b>Purpose and Scope</b></p> <p>The Quidel Triage® MeterPro is a Point of Care instrument used for the estimation of Placental Growth Factor.</p> <p>The purpose of this document is to direct staff in the following practices and procedures:</p> <ul style="list-style-type: none"> <li>• Undertaking a Placental Growth Factor test using the Quidel Triage® MeterPro test cassettes.</li> <li>• Undertaking Quality Control Checks</li> <li>• Cleaning and maintaining the meter</li> </ul> <p>It is vital that the procedure is carried out exactly as directed and any concerns be brought to the attention of the Point of Care Testing department.</p>	<p><b>Items Required</b></p> <ul style="list-style-type: none"> <li>○ <b>Quidel Triage® MeterPro</b></li> <li>○ <b>Supervisor Access Code Chip</b> included with each Quidel Triage® MeterPro which contains a code to activate the supervisor functions labelled SPR</li> <li>○ <b>Reagent code chip</b> included in each box of test devices labelled with W</li> <li>○ <b>QC Sample code chip</b> included in each box of controls labelled with C</li> <li>○ <b>Software upgrade code chip</b> (sent separately when Quidel Triage® MeterPro upgrades are available)</li> <li>○ <b>Test devices</b></li> <li>○ <b>Liquid iQC level 1 and 2</b></li> <li>○ <b>Centrifuge</b></li> <li>○ <b>EDTA</b> sample tubes</li> <li>○ <b>User Manual</b> stored on the intranet and on Qpulse.</li> </ul>
<p><b>Definitions and Abbreviations</b></p> <p>PLGF – Placental Growth Factor                  iQC – internal quality control                  EQA – External quality assurance                  POCT – Point of care testing                  DAU – Day Assessment Unit                  WEQAS – Welsh external quality assurance scheme</p>	<p><b>Qualifications</b></p> <p>Competencies Required Current Version of:  <b>QMS/FM/POCT/COMP/5</b></p>

**Safety Precautions for This Procedure:** Disposable gloves and aprons to be worn.

**Risk Assessment**  
**Current Version of:** RA/POCT/9, can be found on the intra net POCT page

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## 1 CLINICAL RELEVANCE/PURPOSE OF THE EXAMINATION

The Quidel Triage® MeterPro is a Point of Care fluorescence immunoassay used for the quantitative determination of Placental Growth Factor (PLGF), in EDTA anticoagulated plasma specimens.

The test is used in conjunction with other clinical information as an aid in the diagnosis of preterm pre-eclampsia and as an aid in the prognosis of delivery in women presenting signs and symptoms of pre-eclampsia prior to 35 weeks of gestation.

Testing using the Quidel Triage® MeterPro is undertaken by competent staff in Day assessment Unit (DAU) in PAW. The test procedure involves the addition of several drops of an EDTA anticoagulated plasma specimen to a sample port on the Test Device. After addition of the specimen, the specimen reacts with the fluorescent antibody conjugates and flows through the Test Device by capillary action. Complexes of the fluorescent antibody conjugate are captured on a discrete zone specific to the analyte.

The Test Device is inserted into the Quidel Triage Meter. The Meter is programmed to perform the analysis after the specimen has reacted with the reagents within the Test Device. The analysis is based on the amount of fluorescence detected. The results are displayed on the Meter screen in 15 minutes from the addition of specimen. All results are stored in the Meter memory to display or print when needed. Results are also stored in POCcelerator the POCT middleware system, these can be accessed by the POCT team.

The limitations can be found in the User manual/test device insert and in section 4.4.

To ensure accurate results and consequently appropriate intervention, sample testing using the Quidel Triage® MeterPro and quality control procedures must be undertaken as directed in this protocol.

**Note:** The Quidel Triage® MeterPro must only be used by staff that have been trained in its use and have been issued a personal operator ID, which will have to be entered into the instrument each time a test is performed to ensure full traceability.

**2 REFERENCES AND DEFINITIONS:**

**REFERENCES**

- User manual – EXT/POCT/7
- Test Device kit insert – EXT/POCT/8
- iQC kit insert – EXT/POCT/10
- Competency sheet – POCT/COMP/5
- Risk assessment – RA/POCT/9
- Trust POCT Policy – Ref:772
- Validation documentation – VAL/POCT/18
- Maintenance & iQC log sheet – FM/POCT/62
- Procedural summary/flow chart – FM/POCT/63
- Clinical Guidelines/pathway – Intra net, policy index, M107
- ISO: 15189 & ISO: 22870

**DEFINITIONS**

- PLGF – Placental Growth Factor
- iQC – internal quality control
- EQA – External quality assurance
- POCT – Point of care testing
- DAU – Day Assessment Unit
- PCC – POCcelerator middleware

**3 ACTIONS AND METHODS:**

**3.1 3.1 Principle and Method of the Procedure Used for the Examination**

The Quidel Triage PLGF Test is a single use fluorescence immunoassay device designed to determine the concentration of PLGF in EDTA anticoagulated plasma specimens.

**3.2 Specimen Requirements and Means of Identification**

Use standard veni-puncture techniques. A plasma specimen anticoagulated using EDTA is required for testing with this product. Alternative blood-specimen types draw methods or anti-coagulants have not been evaluated. Follow the sample collection recommendation of the sample tube manufacturer.

Test patient specimens immediately or within 4 hours of collection, if testing cannot be completed within 4 hours, the plasma should be stored frozen. No more than a single freeze/thaw cycle is recommended.

Specimens should be handled using universal precautions and disposed of in the biological waste bin (yellow burn bin).

Haemolysed samples should not be used.

Frozen samples (e.g. Liquid QC Controls) should be allowed to reach room temperature before testing. Mix well before testing.

Transfer pipette-filled with EDTA anticoagulated Plasma is used to apply plasma to the test device.

All samples will be labelled with a minimum of three patient identifications, out of:

- hospital number or NHS number
- First name
- Surname
- Date of birth

This is to positively identify the patient’s sample. Time and date, person taking the sample, and address should also be written onto the tube.

**3.3 Sample Preparation**

Samples should be centrifuged at 3400rpm for 10 minutes to allow for separation of plasma from cells.

**3.4 Environmental and Safety Controls**

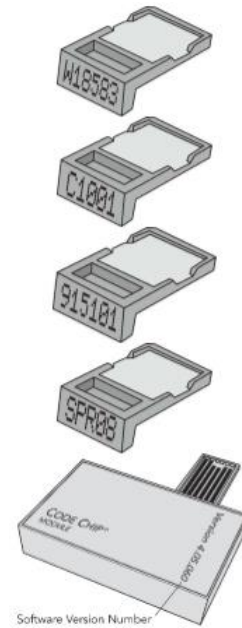
Refer to risk assessment QMS/RA/POCT/9

**3.5 Required Reagents, Quality Controls, Calibrators and Equipment Preparation iQC and Test Device**

Triage® PLGF Test Device	Catalogue Number: HFL9162
Triage® PLGF Control 1	catalogue Number: HFL9163
Triage® PLGF Control 2	catalogue Number: HFL9164
Quidel Triage® MeterPro	catalogue Number: 55071

- Store the Test Devices at 2°C to 8°C in the DAU fridge. When stored at 2°C to 8°C, devices are stable until the manufacturer’s expiration date, which is printed on the box and on the individual test pouches.
- Once removed from the 2°C to 8°C storage, the pouch is stable for 7 days at room temperature. Therefore, once removed from the 2°C to 8°C storage, the User is required to label the kits, with an expiry date 7 days from the date of removal for the fridge.
- Discard unused pouches in 7 days.
- The user is required to leave the pouches at room temperature for 20 mins before use.
- Once equilibrated to room temperature, do not return the test kits to refrigeration. Do not remove the Test Device from the pouch until ready to use. The Reagent Test CODE CHIP™ module – included in each box of test devices, contains calibration, expiration date and other data about the device lot. The user must insert this chip when a new box of strips are opened.
- Store the new boxes at the back of the fridge to ensure adequate product rotation.
- Do not use the kit beyond the expiry date.

- Reagent CODE CHIP module – included in each box of test devices. Lot number begins with a W.
- QC Sample CODE CHIP module – included in each box of controls. Lot number begins with a C.
- QC Device CODE CHIP module – included in the black QC Device box (comes with meter) and is labelled with the serial number of the QC Device.
- Supervisor Access CODE CHIP module – included with meter. Lot Number begins with SPR
- Software Upgrade CODE CHIP module – sent separately when the meter software upgrades are available.



### 3.6 Meter Set Up

#### Supervisor Access

A supervisor CODE CHIP module is shipped with each meter. Installing the CODE CHIP module gives the supervisor access to SET PARAMETERS and DELTETE RESULTS function.

#### List of Programmable Parameters

Heading	Parameters
ID SETTINGS	Number of Characters in User ID, Number of Characters in Patient ID, Number of Characters in Auxiliary ID, Enable or Disable Auxiliary ID, Number of Characters in Misc Test ID
DISPLAY SETTINGS	Language, Printer Mode, Auto Power-Off, Display Contrast, Printer Contrast
COMMUNICATIONS	Baud Rate, Enable or Disable LIS, Enable or Disable Auto Upload, Enable or Disable Patient Result Approval
CLOCK	Time, Date, and Display Format
USER ID	Add New User ID, Update User ID, Delete User ID or User ID List
RANGES	Test Cutoffs
TEST SETTINGS	Block Analytes
QC PARAMETERS	Minimum Frequency for QC Tests, Number of Controls, Number of Standard Deviations (Quantitative Tests)
BYPASS	Disable User ID requirement

Refer to the user manual for step by step instructions on how to programme each parameter (User manual – EXT/POCT/7 pages 23 – 36).




### 3.7 Internal Quality Control Requirements

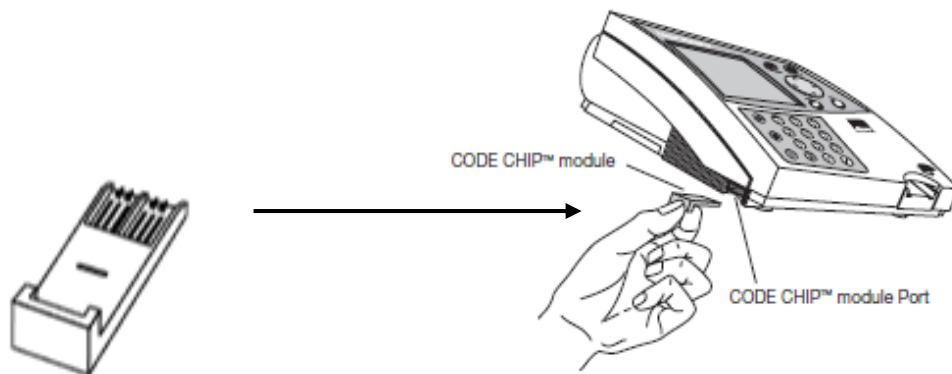
A QC Device is provided with each meter to allow the user to further check the integrity of the meter. The simulator contains six fluorescent zones of varying intensity that are measured by the meter. There are pre-programmed acceptable ranges for the six zones. In addition, the zones allow the meter to check for horizontal and vertical alignment of the zone measurement to verify laser alignment and device transport. The QC Device also confirms laser stability. A Bar Code is printed on the bottom of every test device to identify the reagent lot number and to prevent the use of expired reagents



- **First use of a new QC Device** -The CODE CHIP™ module must first be installed.
- **Daily** – QC device is run daily and is an optical check.
- **Monthly** - liquid controls at two levels, Level 1 and 2 (one positive control and one negative control) are tested once a month by the POCT team.

#### 3.7.1 First Use of a New QC Device




The QC Device CODE CHIP module MUST be installed:

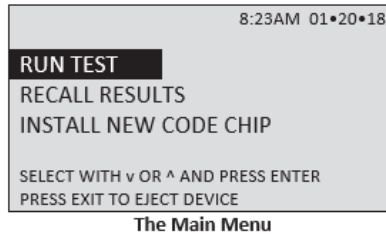
1. From the **Main Menu** select **Install Code Chip** using the   keys.
2. Press the  key.
3. Slide the CODE CHIP module into the CODE CHIP module Port in the Quidel Triage® MeterPro, as shown in the picture.








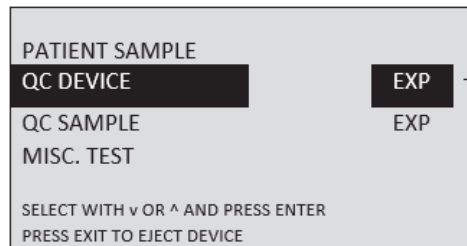
4. Press the  key.
5. The meter will display a confirmation message that the information was installed into the memory of the Quidel Triage® MeterPro.
6. Press the  key to acknowledge the message.
7. Remove the CODE CHIP module from the CODE CHIP module port.
8. Place the CODE CHIP module back into its original container for storage.

**3.7.2 QC Device (Daily)**





1. To run the QC Device test, press the  key to turn the Quidel Triage® MeterPro on.
2. Select Run Test using the   keys from the available options (below):



3. Press the  key.
4. Type or scan in your identification number (User ID), to correct, press the delete  key to clear the entire ID. Then type in the correct ID.
5. Press the  key.
6. Select **QC Device** using the   keys from options (below):



"EXP" indicates that the QC Device re-test frequency has expired.

7. Press the  key.
8. **Gently** insert the QC Device into the Quidel Triage® MeterPro until you feel the QC device catch on the pin and hear an audible 'click.'
9. Press the  key.
10. The Quidel Triage® MeterPro pulls in the QC Device and scans it. The test device may partially move in and out of the meter several times.
11. When the test is complete, the meter will beep, eject the device, display the results on the meter's screen and automatically print results.
12. If results do not print press the printer symbol key to make a printed copy of the results.
13. Remove the **QC Device** from the Meter and place in the QC Device Box.
14. Record the QC Device results on the Maintenance & iQC log (FM/POCT/62).
15. Press exit , if no samples to run press the  to switch off the meter.

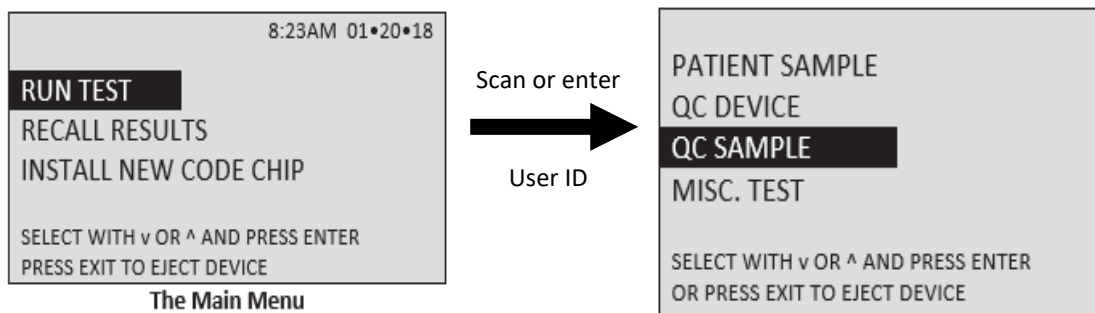







### 3.7.3 Liquid Quality Control sample (Monthly)

The liquid QC level 1 and 2 are run by laboratory POCT staff once every thirty days and as appropriate with each new lot of reagents opened.

Frozen liquid QC is stored at -20°C in the biochemistry laboratory and must be allowed to thaw and mix thoroughly.

1. If opening a new box of QC install the QC Sample code chip module first by selecting “install new code chip” on main menu and following instructions.
2. To run the QC sample, from the main menu the user should choose QC sample (as below):



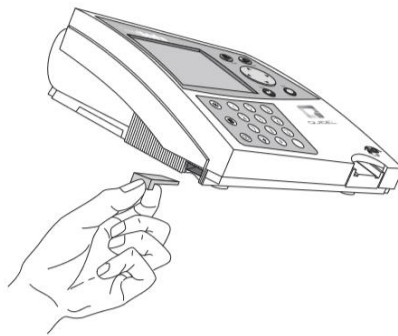
3. Press the  key.
4. Enter the QC lot number (LN) without the preceding letter.
5. Press the  key.
6. Empty the QC vial onto the cassette test pad and insert into the Quidel Triage® MeterPro until you feel the QC Device catch on the pin and hear an audible ‘click.’
7. Press the  key.
8. The Quidel Triage® MeterPro pulls in the test cassette and scans it. The measurement starts.
9. When the test is complete, the meter will beep, eject the device and display the results on the meter’s screen.
10. Remove the device from the meter and discard in burn or sharps bin.
11. Press exit , if no samples to run press the green  button to switch off the meter.
12. Results are recorded on the Quidel Triage Meter Quality Maintenance & iQC Log (FM/POCT/62).
13. Results are also sent to POCcelerator middleware IT system where they are stored and can be accessed by the POCT team.

### 3.8 Calibration Requirements

The calibration information is loaded onto the meter via the Reagent code chip module (provided with each box of test devices) and should be installed upon opening a box of new lot number of test devices.

Perform one time for each new lot of Test Devices:

1. From the main screen, select Install New Code Chip. Press Enter.
2. Place the Reagent CODE CHIP module into the lower left front corner of the Meter and follow the prompts on the screen.



3. Remove the Reagent CODE CHIP module from the Meter when data transfer is complete.
4. Place the Reagent CODE CHIP module back into its original container for storage.

The Self-Test Mode is initiated each time the meter is turned ON. In the self-test mode, the meter scans an internal calibration chip. Each calibration chip scan is used to validate and adjust, if necessary, the meter calibration. In the self-test mode, the available memory for patient results is checked. When the capacity is below a pre-set limit, the remaining capacity is related via a screen message.

Standardization The Quidel Triage PLGF Test has been standardised using purified protein preparations of PLGF based on the mass (concentration) of analyte present in EDTA anticoagulated plasma (see Test kit insert, EXT/POCT/8 page 6)

### 3.9 Cleaning and Maintenance

#### 3.9.1 Routine Maintenance

Occasional cleaning of the exterior with detergent wipes is advised:

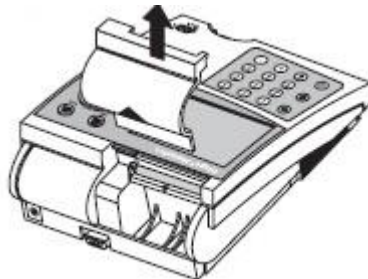
1. Wipe external surfaces of the meter with a detergent wipe.
2. Wipe the meter dry using dry tissue. Do not allow liquid to seep into the printer
3. Do not immerse the meter in water or other liquids.

In order to ensure there is no residue, blood, or other fluids on the devices, the device track door requires regular cleaning:

1. Using an alcohol wipe carefully lift the door and clean both front and back of the door using the wipe held with a pair of tweezers.

#### 3.9.2 Procedure to Load Printer Paper

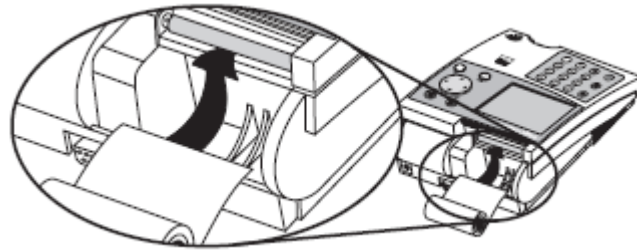
1. Remove the printer cover by pulling up on the cover as indicated by the arrow on the back of the cover.



2. Tear or cut a clean, straight edge to feed into the printer. Do not cut paper at an angle, as the printer must sense the edge of the paper along the feed path.



3. Position the paper such that the paper will feed from under the roll (as opposed to over the top of the roll, see picture)



4. Insert the paper edge under the paper roller (platen) until it firmly seats or resistance is felt.
5. Press the key twice, paper will feed through the printer and extend out the meter.
6. Place the roll of paper into the paper compartment.
7. Replace the printer cover and continue operation.

#### 4 Instructions for the Performance of the Examination













In order to run a patient sample, the meter requires that:


- A valid User ID has been entered.
- A QC Device has passed within the specified time period (24 hours).
- A QC Sample for the test device lot has passed within the specified time period (monthly).

If any of these conditions do not exist, the meter will not continue and will prompt the user to perform the required steps.

##### 4.1 Testing Patient Samples

*Note: The Test device should be inserted within 30 mins from the time the sample was added*

1. Collect a full EDTA blood sample
2. Mix the specimen by inversion several times.
3. Centrifuge the sample for 10 minutes at 3400rpm
4. Open the pouch and label Test Device with patient's ID number
5. Squeeze the larger bulb on the transfer pipette completely and insert into the plasma of the specimen.
6. Release the bulb slowly; the transfer pipette barrel should be full of plasma with some flowing into the smaller bulb.
7. Place the tip of the pipette into the sample port of the TEST device and squeeze the bulb completely. The entire sample in the pipette barrel must flow into the sample port leaving behind the plasma in the bulb.
8. Remove the transfer pipette tip from the sample port and then release the larger bulb.
9. Discard the transfer pipette.
10. Press the  key to power the Quidel Triage® MeterPro on.
11. Select **Run Test** using the   keys.
12. Press the  key.
13. Type or scan in your identification (User ID). To correct, press the  key to clear the entire ID, or select the incorrect character by using the   keys. Then type in the correct ID.
14. Press the  key.
15. Select Patient Sample using the   keys.
16. Press the  key.
17. Type or scan in the patient's identification (Patient ID).
18. Confirm the number is entered correctly by selecting **confirm patient ID**. Press **Enter** .

19. Insert the Test Device into the meter and press **Enter** . The results will be displayed and printed out when the analysis is complete.
20. Discard Test device into a burn or sharps bin after release from meter.

#### 4.2 Procedure for Calculating and Recording of Results

The printed report should be transcribed into the patient’s record and the test results given to the appropriate medical personnel. Abnormal/critical results should be followed up as per clinical pathway (Intra net, policy index, M107).

Results are also sent to and stored in PCC middleware only accessible by the POCT team.

Samples should be discarded into clinical waste burn bins after analysis is complete.

#### 4.3 Potential Sources of Variation and Measurement Uncertainty of Measured Values

Potential sources of variation impact on uncertainty within a method. The variables that impact on the examination procedure have been considered in the document qpulse ref (VAL/POCT/18) Validation documents.

Refer to validation documents for Measurement Uncertainty calculation.

#### 4.4 Performance characteristics and interferences

- The Quidel Triage® MeterPro must be used within the operating temperature range required by the specific test device product being used. Refer to the test device package insert for details.
- Operate the Quidel Triage® MeterPro on a level, dry surface away from direct sunlight.
- The QC Device is light-sensitive and should be stored in its black opaque case when not in use.
- Do NOT write or place a label anywhere on the QC device, as it may interfere with the device functionality.
- Do not move the Quidel Triage® MeterPro while a test is in progress.
- Ensure all sample fluids have absorbed into the test device prior to running the test to prevent internal contamination of the meter.
- Use only the AC/DC power adapter provided with the Quidel Triage® MeterPro. An identifying tag has been placed on the cord for quick identification.
- Do not drop the Quidel Triage® MeterPro.
- Do not place objects on the Quidel Triage® MeterPro.
- Do not immerse the Quidel Triage® MeterPro in water or any liquids.
- None of the following substances influenced the accuracy of the measurement of the PLGF concentration.

Interfering substance	Test Concentration	Solvent	% Recovery	Interference, Yes/No
Atenolol	37.6 µM (10 µg/mL)	PBS	95.56%	No
Bilirubin (conjugated)	50 µg/mL	PBS	93.55%	No
Cholesterol	2.5 mg/mL	Neat	110.07%	No
Haemoglobin	200 µg/mL	PBS	96.87%	No
Magnesium Sulphate	640 µg/mL	PBS	93.78%	No

- The following proteins were tested for analytical specificity:

Substance	Maximum Concentration Tested (pg/mL)	Cross-reactivity (%)
VEGF 165	10,000	<0.1
VEGF/ PLGF -heterodimer	10,000	9.3
Recombinant human PLGF -2	5,000	9.6

- Samples containing up to 20mg/mL haemoglobin, 250mg/dL cholesterol or 5 mg/dL bilirubin (conjugated) were evaluated for potential cross-reactivity. These substances did not impact the PLGF results.
- No hook effect was observed at all concentrations up to 15,000 pg/mL for all PLGF device lots tested.

#### 4.5 Validation and Verification Report

Please see the validation and verification report Q-pulse reference: VAL/POCT/18 available from the POCT team. This document also includes the UoM.

For details on sensitivity, specificity, linearity, accuracy and precision of the assay please refer to:

- Manufacturer’s Test kit insert (EXT/POCT/8, page 9 – 10)
- Manufacturer’s Instrument instructions (EXT/POCT/7)

#### 4.6 External Quality Assessment Schemes

The Triage meter is registered with the WEQAS pre-eclampsia scheme, this is a serum based scheme which we receive 3 samples per month. Samples should be brought to room temperature and analysed as a patient, this is currently performed by laboratory staff (see SOP/POCT/66).

## 5 Reference Limits, Reportable intervals, Reporting and Interpretation

### 5.1 Reference Ranges

PIGF result (pg/ml)	Interpretation
<12	Severe Placental Dysfunction
≥12 < 100	Placental Dysfunction
≥100	Placental Dysfunction Unlikely

### 5.2 Reportable Intervals

PLGF 12 pg/mL – 3000 pg/ml

### 5.3 Results outside Reportable Intervals

Values below 12 pg/ml are reported as <12 pg/ml.

Values above the measure able range are reported as >3000 pg/ml

### 5.4 Reporting and Interpretation

The printed report should be transcribed into the patient’s record and the test results given to the appropriate medical staff. Abnormal/critical results should be followed up as per local policies and procedures (clinical pathway, Intra net, policy index, M107).

Results are transmitted to POCcelerator (POCT middleware) where they are stored and can be accessed by the POCT team.

### 5.5 Personnel Involved in Interpretation, Authorising, Reporting and Monitoring of Reports

Only midwives and maternity doctors should be authorised to use the analyser and only once training and competency has been completed. Results produced are the responsibility of the user to act on. The user should interpret result following the clinical pathway set out in the document - Clinical pathway, Intra net, policy index, M107.

LOCATION OF COPIES:	<ol style="list-style-type: none"> <li>1. Electronically through Q-Pulse.</li> <li>2. Paper copy in SOP folder on Day Assessment Unit</li> <li>3. Electronically on the intra net</li> </ol>
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