Berkshire and Surrey Pathology Services

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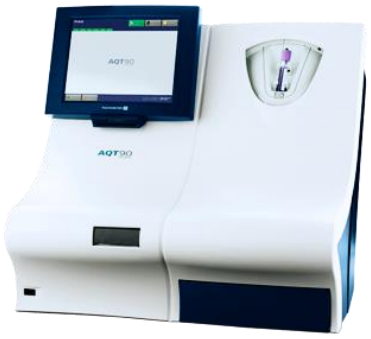
POCT-BSPS-SOP-600

RADIOMETER AQT90 FLEX ANALYSER



1. HEALTH AND SAFETY

COSHH Information	
GLP	Good Laboratory Practice H&S includes the use of personal protective equipment (PPE), use of SOPs, clear work place etc. Laboratory PPE includes; Laboratory coat, gloves and eye protection.
Colour Codes	Purple = High Risk } Red = Significant Risk } Blue = Moderate Risk } if GLP is followed Green = Low Risk }

Substance	COSHH Reference	COSHH Score	Hazard	Requirement for Use
Blood and Bodily Fluids	GEN-BSPS-COSHH-00200	Moderate	Biological	GLP, PPE, Appropriate Training / Vaccinations, appropriate signage.
AQT 90 Cleaning Kit	POCT-BSPS-COSHH-019	Low	Irritant / corrosive/ Biological	GLP, PPE
AQT 90 Reagent kits & Cal cartridges	POCT-BSPS-COSHH-020	Low	Biological	GLP, PPE
AQT90 Solution Pack 903-006	POCT-BSPS-COSHH-078	Low	Biological	GLP, PPE

AQT90 Technopath Multi-CHECK Combi (IQC material for D-Dimer, BhCG, CRP & PCT)	POCT-BSPS_COSHH-079	Low	Biological	GLP, PPE

Risk Assessment	RA Reference	Rating	Requirement for Use
POCT Staff Risk Assessment	POCT-BSPS-RA -001	Low / Moderate	PPE and GLP
POCT Risk Assessment Clinical Areas	POCT-BSPS-RA-2	Low / Moderate	Manual Handling Training
POCT Sample Pathway Risk Assessment	POCT-BSPS-RA-003	Refer to document	Refer to document

2. PERSONNEL AND TRAINING REQUIREMENTS

To be qualified to perform a POCT AQT90 test, individuals must meet the following requirements:

1. Training:
   - Complete an approved POCT Training programme for use of the AQT90 covering equipment use, sample quality and approved sample types, quality control and result interpretation where appropriate.

2. Completion of a POCT Competency:
   - Complete and have an in date POCT approved competency assessment, which may include initial assessment training or periodic refresher training to maintain authorisation.

It is the responsibility of the user not to deviate from procedures outlined during training. The result obtained at the Point of Care is the responsibility of the user. Clinical management of the patient based on a point of care result is the responsibility of the clinician.
Training, device maintenance, governance and troubleshooting are the responsibility of the POCT team.

3. PURPOSE OF THE EXAMINATION

The AQT90 FLEX may be used to estimate the concentrations of a variety of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

The D-dimer test is intended for use as an aid in the diagnosis of venous thromboembolism (deep vein thrombosis (DVT) and pulmonary embolism (PE)).

Under normal physiological conditions, the hemostatic system maintains the balance between the coagulation and fibrinolytic processes. Coagulation leads to the formation of thrombin, which converts fibrinogen to fibrin monomer molecules. These fibrin monomer molecules polymerize forming an insoluble fibrin network

stabilized by covalent cross-links introduced by the action of the enzyme factor XIIIa, causing the formation of a thrombus. Fibrinolysis of the cross-linked fibrin by plasmin results in a heterogeneous population of fragments released into the blood which are called D-dimer.

Under pathological conditions, a thrombus may avoid the normal fibrinolytic system to grow and propagate. As D-dimer is a specific marker of the breakdown of a fibrin clot and an indirect marker of fibrin formation, its measurement may reflect a disturbance in this hemostatic balance. D-dimer levels increase one hour after thrombus and have a half-life of 4-6 hours. The presence of D-dimer can be used as an early sensitive (although **NOT** specific) marker for thrombotic disorders including DVT, PE and disseminated intravascular coagulation (DIC). The D-dimer assay is used as an aid in ruling out the suspicion of DVT or PE when a result below the cut-off value is obtained and should be clinically validated.

The **C-Reactive Protein (CRP)** test is used in the detection and monitoring of inflammatory conditions. CRP levels rise within 6-8 hours after an acute stimulus and may double approximately every 8 hours.

CRP is an acute phase protein which is synthesized in the liver by hepatocytes. CRP has been shown to interact with the humoral and cellular effector system and has an important role in the elimination of foreign pathogens and potentially toxic substances produced as a result of tissue damage.

4. PRINCIPLE OF THE PROCEDURE USED FOR EXAMINATIONS

The AQT90 FLEX is a fully automatic continuous access analyser. All assays are based on a chemistry in which all the reagents are provided in a dry form within a test cup. Biotinylated antibodies (Ab) are immobilized on the streptavidin surface of the cup. A separating layer isolates the biotinylated capture Ab from the europium-labelled tracer Ab. Addition of sample together with the generic buffer solution dissolves the separating layer and starts the immunoreaction. Incubation is at 37 °C with shaking for 15 minutes, during which the immunocomplex forms. During the assay process, the parameter to be measured reacts with both the capture and tracer Ab. Excess free tracer Ab, the sample components and other material present in the cup are removed by a washing step which is followed by a drying step. This is followed by the measurement of the time-resolved fluorescence of the europium-labelled Ab from the surface of the cup. After the measurement, the measured signal is converted to a concentration value, using the instrument adjusted, lot-specific calibration curves, and a quantitative result is reported. The concentration of the parameter is proportional to the time-resolved fluorescence signal emitted from the europium-labelled Ab. The measured signal is converted to a concentration using the calibration curve, which is stored in the memory of the analyser.

5. PERFORMANCE SPECIFICATIONS (PRECISION, ACCURACY, MEASUREMENT UNCERTAINTY, DETECTION LIMITS, MEASURING INTERVAL, TRUENESS OF MEASUREMENT, ANALYTICAL SENSITIVITY, AND SPECIFICITY)

See:
POCT-BSPS-SOP-600 ED1 : AQT90 FLEX Instructions for Use.

Prior to the introduction of the AQT90 FLEX a verification against comparable laboratory methods and manufacturers performance claims was undertaken.
Refer to these listed documents for further details ;
POCT-BSPS-VV-007 AQT90 D-Dimer Verification & appendices 1-4
POCT-BSPS-VV-013 AQT90 D-Dimer Reverification against laboratory
POCT-BSPS-VV-014 POCT AQT90 CRP Reverification against Laboratory
Measurement of Uncertainty data is regularly reviewed. Please refer to POCT-BSPS-SOP-600-Appendix-003: AQT90 D-dimer Measurement Uncertainty Summary

6. SPECIMEN REQUIREMENTS, MEANS OF ID, PATIENT PREPARATION. (PRIMARY SAMPLE TYPE EG SERUM/SAMPLE CONTAINERS & ADDITIVES)

6.1 D-Dimer & CRP Sample requirements

Tests should only be performed under the order of a Healthcare professional directly involved in the patient's care. Patient consent for the test is inferred if the patient willingly submits to the sample being collected. All patients must be positively identified (where possible) prior to sample collection and the user must ensure that the sample/patient ad analyzer records correspond.

Whole blood venous samples for D-dimer analysis should be collected into into an evacuated lithium heparin blood tube on all BSPS sites except SASH where an EDTA sample is the preferred sample type.
Whole blood venous samples for CRP analysis should be collected into into an evacuated EDTA blood tube on all BSPS sites.

Mix the sample by gentle inversion at least 5 times as soon as it is drawn.
The minimum sample volume is 2mL.
Samples should be labelled with at least three points of patient identification.
Samples may be kept at an ambient temperature of 18-25ºC and should be analysed within 3 hours of collection
Do not use tubes that contain a gel.

7. REQUIRED EQUIPMENT AND REAGENTS

The following consumables are supplied by Radiometer and the stock and onboard consumables are managed by the POCT Team or trained key operators.

Check local protocol for storage arrangements.
903-006 AQT90 FLEX Solution pack - Store at 2-32 °C
942-915 AQT90 FLEX D-dimer Test kit – Store unopened pouches at 2-8ºC
942-936 AQT90 FLEX CRP Test kit – Store unopened pouches at 2-8ºC
942-962 AQT90 FLEX Blank Cartridge – Store unopened pouches at -25-35 ºC
905-843 Cleaning Solution Tube – Store at 2-8ºC
944-230 AQT90 Empty Tube Kit – no storage temperature limits noted.
944-198 Technopath Multi-CHECK Combi Level 1 store at -20ºC or colder

944-199 Technopath Multi-CHECK Combi Level 2 store at -20ºC or colder
For both Multi-CHECK Combi Level 1 & Level 2 the thawed product is stable for 2 hours maximum when kept unused at ambient temperature (maximum 30oC)

8. CALIBRATION PROCEDURE (Metrological Traceability - The primary purpose of metrological traceability is to ensure that laboratories produce meaningful test results that are both comparable and portable)

Can be performed by POCT Team & key operator trained clinical staff only

Reagents / consumables required;
944-220 AQT90 FLEX D-dimer CAL Cartridge - Store unopened at 2-8ºC.
944-267 AQT90 FLEX CRP CAL Cartridge - Store unopened at 2-8ºC.

A calibration cartridge and calibration data barcode is received with each reagent kit.
A calibration adjustment procedure must be performed every time a new lot test cartridge is put into use.
This can be completed by the POCT team or staff who have completed key operator training according to the instructions provided in the BSPS-POCT-SOP-600 ED 1 AQT 90 Flex Instructions for Use (section 6)

After every calibration adjustment, liquid quality control measurements must be performed.

Ensure that only the new lot of cartridges is onboard to ensure LQC is performed on the correct cartridge lot.

Any failure in a calibration, system or quality check will be highlighted in red on the front screen menu and the test will not be available until the error has been resolved.

Product calibrator traceability
The manufacturer advises:-
The calibration of the D-dimer assay is traceable to Radiometer in-house calibrators
Calibration of the CRP assay is traceable to ERM-D472/IFCC

The AQT90 D-dimer assay initially generates a result in D-dimer units (DDU) due to the choice of calibration material. The AQT90 software applies a conversion factor making it equivalent to Fibrinogen Equivalent Units (FEU) so that the recommended cut off is 500 µg/L / 500ng/mL.

9. INTERNAL QUALITY CONTROL AND EXTERNAL QUALITY ASSURANCE

9.1 Internal Quality Control

Can be performed by POCT Team & key operator trained clinical staff only

Reagents / consumables required;
944-198 Technopath Multi-CHECK Combi Level 1
944-199 Technopath Multi-CHECK Combi Level 2
Store at -20 ºC or colder until the printed expiry date.

Thaw and mix gently prior to use.
Each tube contains sufficient to run five tests and is stable for 2 hours (maximum) when kept unused at ambient temperature (maximum 30°C) or for 4 days if thawed and stored at 2 – 8°C unopened.

Liquid quality control Level 1& 2 measurements must be performed:-

- Once per week
- To verify performance of each new lot or shipment of reagent cartridges and solution packs
- After every calibration adjustment.
- If there is any question about the performance of the instrument.

9.1.1 To run Liquid Quality Controls (LQC)

9.1.1.1 Select "**introduce Sample**" from main screen

9.1.1.2 insert QC sample with the barcode facing inwards. The device will automatically detect which level of QC is present and bypass the patient ID entry screen. Press "**Start**".

9.1.1.3 Following running of LQC test results should be checked to ensure they fall within stated range & LQC Plots should be checked as well as checking that results fall within range numerically

9.1.1.4 If LQC falls out of range, AQT90 will automatically disable testing until LQC passes. Repeat using a fresh vial of LQC. If it fails again contact the Radiometer Service for advice.

9.1.2 To check LJ Plots of LQC

9.1.2.1 Tap **Menu** > **Data logs** > **QC logs** > **LQC Log**

9.1.2.2 Tap a measurement with the Test Type 'LQC'

9.1.2.3 Tap the Plot button

9.1.2.4 Check results are falling close to the mean and report concerns to the site coordinator/ Radiometer as appropriate.

9.1.3 Procedure to register new QC lots on the AQT90

9.1.3.1 Tap **Menu** > **Utilities** > **Setup** > **LQC setup** > **LQC**

9.1.3.2 Highlight an empty number in the position column.

9.1.3.3 Scan the upper and lower limit barcodes on the specifications insert.

9.1.3.4 Tap the **Accept** button

9.1.3.5 Tap the **Close** button.

9.2 External Quality Assessment

Can be performed by POCT Team & key operator trained clinical staff only

Devices are registered with an appropriate EQA scheme (WEQAS POCT D-dimer /POCT CRP circulated on alternative months) as documented in: POCT EQA Scheme Participation POCT-BSPS-MAN-6 Appendix 1. EQA samples are run by the POCT team.

9.2.1 Procedure for running EQA samples

Reagents / consumables required;
944-230 AQT90 Empty Tube Kit
EQA samples provided by WEQAS

9.2.1.1 Decant EQA serum into Radiometer empty tube.
9.2.1.2 Cap & label tube with EQA sample details.
9.2.1.3 Log onto AQT90, press **Introduce Sample** button
9.2.1.4 Press **Sample ID** button
9.2.1.5 Input sample details, press **accept**.
9.2.1.6 Follow on screen prompts to confirm sample and test type.
9.2.1.7 Insert tube into sample holder and press **start**.
9.2.1.8 Record results on WEQAS website before the distribution deadline.

Follow procedure for EQA sample handling and reporting and investigation of poor performance as detailed in the SOP POCT-BSPS-MAN-6 Receipt and Follow up of EQA Samples and Reports

10. PROCEDURE/METHOD

a. Decision to run a D-Dimer sample

Use a NICE- aligned pathway, including the use of Wells score for clinical assessment and to determine the need for D-dimer testing. NICE NG158 for DVT (deep vein thrombosis) or PE (pulmonary embolism) or local Trust pathways.

D-dimer should not be used in patients with high clinical probability of PE or in isolation for the rule-out of high probability DVT.

b. Running a patient sample for D-Dimer or CRP

For D-Dimer Testing

10.2.1 Scan POCT barcode to log onto AQT90 Flex & check traffic light is green or amber (Use nearest alternative analyser and report fault to POCT Team if red).
10.2.2 Touch 'Introduce sample' icon found top right of screen.
10.2.3 Select 'Patient I.D' icon found at the bottom of the screen.
10.2.4 Enter correct Hospital number and press return. **WAIT!** Device will query PAS for patient name. If supplied – double check name and proceed.
If patient is not found, the device will display the comment "No sample and patient data available" in which case check that the hospital number /MRN has been entered correctly, amend if necessary, then enter data for demographic fields.

Fields accompanied by a pointing finger symbol are mandatory & results will not be issued if these fields are left blank.
10.2.5 Enter Wells (clinical) score using drop down menu on devices

10.2.6 Press 'Accept' button.
10.2.7 Invert sample x 5 to mix then insert sample into holder.
10.2.8 Select Lithium Heparin tube type from display.
10.2.9 Select required test(s) and press 'Start'.

For CRP Testing

10.2.10 Scan POCT barcode to log onto AQT90 Flex & check traffic light is green or amber (Use nearest alternative analyser and report fault to POCT Team if red).
10.2.11 Touch 'Introduce sample' icon found top right of screen.
10.2.12 Select 'Patient I.D' icon found at the bottom of the screen.
10.2.13 Enter correct Hospital number and press return. **WAIT!** Device will query PAS for patient name. If supplied – double check name and proceed.
If patient is not found, the device will display the comment "No sample and patient data available" in which case check that the hospital number /MRN has been entered correctly, amend if necessary, then enter data for demographic fields.

Fields accompanied by a pointing finger symbol are mandatory & results will not be issued if these fields are left blank.

10.2.14 Press 'Accept' button.
10.2.15 Invert sample x 5 to mix then insert sample into holder.
10.2.16 Select EDTA tube type from display
10.2.17 Select required test(s) and press 'Start'
10.2.18 A barcode 'ticket' unique to the sample automatically prints on sites where this is enabled and can be used to retrieve the result once the test is complete.
10.2.19 The tube will rotate into the analyser and present back to its original position once sampling has occurred. It may then be removed by pressing 'Remove Tube'.
10.2.20 The next sample can be loaded once the 'READY' sign shows at the top left-hand corner of the screen.

10.3 Troubleshooting & Maintenance

10.3.1 Replacing Solution Packs & Test Cartridges

Can be performed by POCT Team & key operator trained clinical staff only

Reagents / consumables required;
903-006 AQT90 FLEX Solution pack - Store at 2-32 °C
942-915 AQT90 FLEX D-dimer Test kit – Store unopened pouches at 2-8ºC
942-936 AQT90 FLEX CRP Test kit – Store unopened pouches at 2-8ºC
942-962 AQT90 FLEX Blank Cartridge – Store unopened pouches at -25-35 ºC

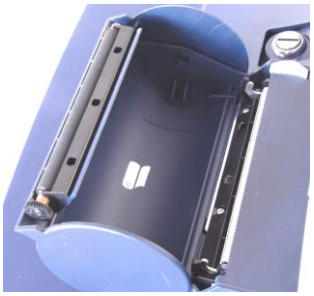
10.3.1.1 Replace consumables when prompted by the analyser or pre-emptively as required (check detailed inventory for onboard expiry dates).
10.3.1.2 Follow the on screen instructions.

10.3.1.3 Further detail is provided in in the AQT 90 Flex Instructions for Use (section 4)

10.2.1.4 Please note partially used solution packs may be transferred from one device to another to ensure full use of consumables but test cartridges should not be moved from one analyser to another.

10.3.2 Replacing Paper

Can be performed by all trained staff



10.3.2.1 Open the printer cover by pressing the latch on the right.

10.3.2.2 Remove the core from the used roll.

10.3.2.3 Open a new roll of paper and drop in as shown above.

10.3.2.4 Close the printer paper cover (should hear a 'snap')

10.3.2.5 If no results print following a paper change check paper has been inserted facing the right way as thermal paper only prints on one side

10.3.3 System Clean

Can be performed by POCT Team & key operator trained clinical staff only

Reagents / consumables required;

942-962 AQT90 FLEX Blank Cartridge – Store unopened pouches at -25-35 ºC

905-843 Cleaning Solution Tube – Store at 2-8ºC

10.3.3.1 The analyser is preset to request this at intervals specified in the setup the critical limit being 220 samples.

10.3.3.2 Before starting ensure there are is a minimum cup capacity of 2 on board and a blank cartridge containing one blank cup.

10.3.3.3 Press "Introduce Sample", load a cleaning tube, barcode inwards and press "Start".

10.3.3.4 Further information is provide in POCT-BSPS-SOP-600 ED 1.AQT 90 Flex Instructions for Use (section 4)

10.3.4 Cleaning / Decontamination

Can be performed by all trained staff

10.3.4.1 Any spillage should be cleaned according to ward protocol.

10.3.4.2 The outside of the analyser should be cleaned daily using a tissue dampened with water – do not use organic solvents or spray detergents as this could damage the surface of the instrument.

10.3.5 Basic Troubleshooting

Can be performed by all trained staff

10.3.5.1 The instrument will not power on, the screen is blank, no lights are on - Check the main power switch (rocker switch located right back of analyser) is ON. Turn OFF. Verify power to wall socket.

10.3.5.2 Frozen screen or results not printing - Power down via the 'menu'. Wait for 5-10 minutes before

switching on again. If this is not possible turn off via the main power switch as above.

10.3.5.3 If problem is not resolved by switching OFF/ON then inform the POCT Team.

10.3.6 System Check

- The AQT90 FLEX performs automatic system checks throughout a 24 hour period and will alert if a fault is detected during the check.
- Inform the POCT Team if a fault is reported.
- The POCT will perform a reboot and system check. If this fails POCT will seek advice from the Radiometer Service Team.

10.3.7 Returning a device to service

If an engineer visit is required, or the device has to be taken out of service due to suspected performance issues, GEN-BSPS-H&S-9-SDRF-02: BSPS Engineer Visit Pack must be completed.

The return to service certificate should be filled and the following back into service checks completed:

- For device breakdown requiring an engineer visit, All levels of QC must be run and pass before returning the device to service.
- If there were any reports of spurious results or there is any suspected impact on patient results a Clinical Scientist must be informed and they will advise on the necessary return to service evidence.
- If a software update has been performed, then POCT-BSPS-SOP-600-SDRF-1: AQT90 Flex Install Checklist (D-Dimer) must also be completed

11 INTERFERENCES, CROSS REACTIONS and POTENTIAL SOURCES OF VARIABILITY

D-dimer

- Refer to POCT-BSPS-DOC-002-APPENDIX-002**:** GUIDANCE FOR MANAGING PATIENTS USING POCT RESULTS_AQT90 D-dimer for a list of conditions apart from VTE (venous thromboembolism) which may result in a raised D-dimer, and advice on clinical result interpretation.

Note also;

- D-Dimers should not be repeated within 48 hours unless being used to monitor DIC.
- Anticoagulation therapy reduces D-dimer concentration. Repeat testing during / after recent therapy is not recommended for VTE assessment. If required for further assessment of risk, or investigation of other conditions, interpret with caution.
- Haemolysis, lipaemia and icterus were shown not to interfere with the assay.

- The following substance was found to have no medically meaningful interference below the interfering concentration. A concentration higher than the interfering concentration could cause an increase of more than 10% in a D-Dimer test result.

Substance	Interfering concentration (U/L)
Nystatin	230 229

- A list of potentially interfering substances has been tested by the manufacturer and shown to have no notable effect on the assay. Details are provided in the kit insert. These include, Abciximab, Acetaminophen, Acetlycysteine, Acetylsalicylic acid, Alkaline phosphatase, Allopurinol, Ambroxol, Ampicillin, Ascorbic acid, Atenolol, Bilirubin (unconjugated and conjugated), Caffeine, Captopril, Cefoxitin, Cinnarizine, Cocaine, Cyclosporine, Diclofenac, Digoxin, Dopamine, Erythromycin, Ethanol, Furosemide, Fibrinogen, Glucose, LMWH (heparin), Heparin sodium, Human albumin, Ibuprofen, IgG, Levodopa, Methyldopa, Metronidazole, Nicotine, Nifedipine, Nitrofurantoin, Nitroglycerin, Oxytetracycline, Phenylbutazone, Phenytoin, Propanolol, Quinidine, Rifampicin, Tetracycline, Theophylline, Trimethoprim, Verapamil, Warfarin.

C-Reactive Protein

- Haemolytic, lipaemic and icteric samples were shown not to interfere with the assay.
- A list of potentially interfering substances has been tested by the manufacturer and shown to have no notable effect on the assay. Details are provided in the kit insert. These include Abciximab, Acetaminophen, Acetlycysteine, Acetylsalicylic acid, Allopurinol, Ambroxol, Ampicillin, Ascorbic acid, Atenolol, Biotin, Caffeine, Captopril, Cefoxitin, Cinnarizine, Cocaine, Cyclosporine, Diclofenac, Digoxin, Dopamine, Erythromycin, Ethanol, Furosemide, LMWH (heparin), Heparin sodium, Ibuprofen, Levodopa, Methyldopa, Metronidazole, Nicotine, Nifedipine, Nitrofurantoin, Nitroglycerin, Nystatin, Oxytetracycline, Phenylbutazone, Phenytoin, Propanolol, Quinidine, Rifampicin, Tetracycline, Theophylline, Trimethoprim, Verapamil, Warfarin.
- Samples containing heterophilic antibodies may result in falsely elevated or depressed results.

12 RESULTS include principle of procedure for calculating results & measurement uncertainty.

12.1 Retrieving Results from AQT90 FLEX

Can be performed by all trained staff

12.1.1 Results should transmit automatically to electronic patient record systems & can be viewed there once test has completed.

If results stop transmitting please inform the POCT Team who will follow up with Radiometer / POCT IT/ Trust IT as appropriate.

12.2.1 To retrieve printed result with ticket barcode (where enabled)

12.2.1.1 Log onto AQT90 FLEX using POCT barcode

12.2.1.2 Scan the ticket barcode, patient results will appear on screen, check patient details are

Correct then press the print icon to print out.

12.3.1 To retrieve printed result without barcode ticket;

12.3.1.1 Scan POCT barcode to log onto AQT90 FLEX.

12.3.1.2 The last 5 patient MRNs will be displayed on the main screen.

12.3.1.3 Press the printer icon by required MRN to print results.

12.3.1.4 If required results are not displayed on screen, press the Data logs folder (top right of screen)

12.3.1.5 Scroll down until correct MRN highlighted, press results icon at bottom of screen to view results

12.3.1.6 press print icon to print out.

12.2 Arrow markings on Result Print Out:

Single arrow up or down,  : Result is outside the user-defined reference range (but not yet critical)

Double arrows up or down,  : Result is beyond the critical limit

Triple arrows up or down,  : Result is outside the test range

10.1.2

13 BIOLOGICAL REFERENCE INTERVALS AND CLINICAL DECISION LIMITS

Refer to POCT-BSPS-DOC-002-APPENDIX-002**:** GUIDANCE FOR MANAGING PATIENTS USING POCT RESULTS_AQT90 D-dimer for further information on clinical result interpretation.

D-dimer:

Less than 500ng/mL (<500ng/mL) is the clinical decision limit in patients aged 50 years or younger for ruling out VTE .

In patients aged over 50 years, clinical decision limit = age(years) x 10 ng/mL

e.g for a patient aged 63 years;

63 years x 10 = 630 ng/mL cut-off for (VTE) rule-out.

Using the age-related cut-off will decrease the likelihood of false positive interpretation and unnecessary further testing / scanning / interim anticoagulation.
Age-adjusted clinical decision limits are now reported in the EPRs (Epic/Cerner) however the AQT90 only reports a single decision limit of 500ng/mL and there is a notification to use age-related decision limits on the main screen.

CRP:

In healthy people, serum and plasma concentrations of CRP are normally below 5 mg/L.

14 LABORATORY INTERPRETATION

(responsibilities of personnel in authorising, reporting and monitoring reports)

The results generated using point of care equipment are the responsibility of the user. Management of the patient based upon results generated at the point of care is the responsibility of the clinician.

A D-dimer result below the age-adjusted clinical decision limit can rule-out VTE with >99% negative predictive value.

If a POCT result is in doubt, repeat the test

- **if the sample was taken within the last 3h, mix and rerun immediately.**
- **if the sample is too old (more than 3h), or the rerun result very different from the first result, take a new sample for POCT d-dimer**
- **If the 2nd result is very discrepant from the original, inform the POCT Team to investigate.**
- **inform the clinician in charge of the care of the affected patient - nurse or medic**

DO NOT take the analyser out of use unless there is a pattern of suspicious results, in which case contact your local POCT team.

Note that D-dimer may be raised in a number of conditions unrelated to a VTE (see **POCT-BSPS-DOC-002-APPENDIX-002**: GUIDANCE FOR MANAGING PATIENTS USING POCT RESULTS_AQT90).

POCT D-dimer results should not be compared to results from the laboratory D-dimer test. The are likely to be numerically discrepant, and the laboratory is more likely to give false positive results for VTE (see POCT-BSPS-DOC-002-APPENDIX-002**:** GUIDANCE FOR MANAGING PATIENTS USING POCT RESULTS_AQT90**).**

CRP

CRP results should only be interpreted in conjunction with clinical assessment and not in isolation. Raised concentrations are associated with infection, particularly but not exclusively bacterial, and inflammation.

CRP testing can help in making decisions on antimicrobial treatments as part of the whole clinical picture. Previous

NICE guidance (NG191, now superseded by NG250) advised that CRP <20mg/L rules out the need for antibiotics, and patients with CRP >100mg/L should be offered antibiotics. An intermediate CRP level could require a delayed antibiotic prescription, and monitoring or repeat testing in 48h.

Patients with cancer and inflammatory conditions will have a higher baseline CRP.

Frail and elderly patients, and those with impaired liver function may fail to mount a CRP response to infection. During treatment, high levels of CRP, or levels that do not significantly improve with treatment, are associated with treatment failure and require senior clinical review (NG250).

The Royal College of Pathologists recommends that CRP is not retested within 24h.

The AQT90 CRP test has been shown to compare very well to the laboratory, particularly below 200mg/L. Above 200mg/L, the AQT90 POCT CRP is slightly negatively biassed (approx. 5%) compared to the laboratory.

15 DISPOSAL OF SAMPLES AND REAGENTS.

Samples are disposed of appropriately as clinical waste normally in a sharps bin once analysis is complete and the result has been reviewed by the operator.
Reagent cartridge wedges and reagent packs should be disposed of appropriately as clinical waste according to local protocol.

16 REFERENCES

Internal

POCT-BSPS-COSHH-079: AQT90 Technopath Multi-CHECK Combi
POCT-BSPS-SOP-600-ED-3 AQT90 Flex Solution Pack Insert
POCT-BSPS-VV-013: AQT90 D-Dimer Reverification against laboratory
POCT-BSPS-VV-007: AQT90 D-Dimer Verification
POCT-BSPS-SOP-600-SDRF-1: AQT90 Flex Install Checklist (D-Dimer)
POCT-BSPS-CCN-043: AQT90 Replacement D-dimer Analyser Roll-Out – 2024
POCT-BSPS-DOC-002-APPENDIX-002: GUIDANCE FOR MANAGING PATIENTS USING POCT RESULTS_AQT90 D-dimer
POCT-BSPS-VV-014: POCT AQT90 CRP reverification against Laboratory
POCT-BSPS-FSN-001: Radiometer AQT90 Risk of Patient Mix Up FSN (MHRA ref. 2020/004/008/291/002)
POCT-BSPS-MAN-12-SDRF-2 POCT AQT90 Reagent Acceptance Spreadsheet
POCT-BSPS-SOP-600-Appendix-2 AQT90 Current Location

External

POCT-BSPS-SOP-600 ED 1:AQT 90 Flex Instructions for Use
POCT-BSPS-SOP-600 ED 2: AQT90 Flex D-dimer Test Kit Insert
POCT-BSPS-SOP-600 ED 4: AQT90 Flex CRP Test Kit Insert
POCT-BSPS-SOP-600 ED 5: Technopath Multi-CHECK Combi Insert

17 APPENDICES AND SDRFs

POCT-BSPS-SOP-600 Appendix 1 AQT90 Quick User Guide
POCT-BSPS-SOP-600 TRAIN 1: AQT 90 User Training Record
POCT-BSPS-SOP-600 TRAIN 2: AQT 90 FLEX Key Operator Training Record
POCT-BSPS-MAN-4-TRAIN-007: Radiometer AQT90 Competency for POCT Team
POCT-ASPH-MAIN-003: AQT90 A&E S/N: I393-838R0375N0003 Daily Maintenance Records 2019-2024
POCT-ASPH-MAIN-002: AQT90 AMU/AECU/SDEC S/N: I393-838R0375N0004 Daily Maintenance Records 2019-2024
POCT-RBH-MAIN-019: RBH AQT90 Flex Plus Maintenance logs 2023-2028
POCT-ASPH-SOP-1-SDRF-5: ASPH Radiometer Daily Maintenance Sheets
POCT-BSPS-SOP-600-Appendix-003: AQT90 D-dimer Measurement Uncertainty Summary
POCT-BSPS-SOP-600-Appendix-5: AQT90 Template Print Layout