Foetal Anomaly Screening Laboratory

Dept Clinical Chemistry, Birmingham Women’s Hospital, Mindelsohn Way B15 2TG

Handbook for Users

For screening enquiries e-mail to bwc.clinchem@nhs.net
Phone number 0121 472 1377 ext. 5537

Check the Birmingham Women’s and Children’s Hospitals web site:
https://bwc.nhs.uk/laboratories
1 Introduction to Foetal Anomaly Screening Laboratory

Services Provided
Service Scope
Service Standards/Quality Assurance
Service Commitment

2 Useful Contacts

3 Information Governance

Data Protection
Complaints

4 Patient Information

5 Service Location & Availability

Location of the Department
Service Hours
Sending a Specimen
Request forms

6 Specimen Collection, completion of the request form and management of urgent and additional requests

Consent
Specimen Collection (including the preparation of the patient)
Instructions for the completion of the request form
Specimen labelling and minimum data set
Urgent Specimens

7 Transportation of samples to the laboratory

Criteria for acceptance and rejection of samples
Provision of further information

8 Examinations offered by the laboratory

Combined test
Second Trimester screening
First trimester screening by NT alone
Vanishing Twin Pregnancies

9 Reports, turnaround times and availability of clinical advice

10 Frequently asked questions

Can screening be performed in triplet pregnancies?
The gestational age on the report is different to that calculated locally – should the report be amended?
What action should be taken if the courier does not arrive?
What arrangements are made over Bank Holidays?
Where is my result/have you received a specimen?
We have noticed an increased/decreased number of increased chance results – is there a problem?
Can we offer a repeat screening test?
1 Introduction to Foetal Anomaly Screening Laboratory

Services Provided

The Foetal Anomaly Screening laboratory provides first and second trimester screening for Units within the West Midlands, North West London and East of England as well as other individual Units both within and outside the United Kingdom.

Service Scope

The Foetal Anomaly Screening laboratory provides a calculation of the chance of a foetus having trisomy 21, trisomy 18 or trisomy 13 (also known as Down’s, Edward’s and Patau’s syndromes). The laboratory operates under the auspices of the Foetal Anomaly Screening Programme (FASP) which is under the oversight of the National Screening Committee (NSC).

Service Standards/Quality Assurance

The Foetal Anomaly Screening Laboratory is currently in the process of applying for UKAS assessment in accordance with Medical Laboratories – requirements for quality and competence (ISO 15189:2012).

The quality of our service is maintained by recognised effective internal quality control measures and by participation in the following National External Quality Assurance (EQA) Schemes:

- UKNEQAS Maternal Serum Screening First Trimester
- UKNEQAS Maternal Serum Screening Second Trimester
- Downs Syndrome Screening Quality Assurance Support Service (DQASS)

Staff members within the department are fully qualified, specialised and experienced, providing a quality service. A high quality service is maintained by frequently looking at feedback from user meetings, audits and satisfaction surveys.

Service Commitment

The department is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users. Our aim is to provide a service of the highest quality and promote the trust mission and values and corporate, directorate and departmental objectives to ensure that the families we serve are at the heart of all we do.

The purpose of this handbook is to provide information on the Foetal Anomaly screening laboratory service including test repertoire, specimen requirements and details on accessing our service.
2 Useful Contacts

Laboratory e-mail

bwc.clinchem@nhs.net

Please address all service enquiries to this e-mail address. This means that they are dealt with by a senior member of staff as soon as possible. Communications handled in this way are auditable and advice given can be recorded for future reference.

Phone calls to the laboratory are disruptive and are the root cause of errors.

Head of Department & Director of Foetal Anomaly Screening Service

Dr Sarah Heap
0121 333 9922 (BCH)
0121 472 1377 ext. 5537 (BWH)

Laboratory Lead

Mr Ian Mills
0121 472 1377 ext. 5537

Laboratory Manager

Mr Bill Macdonald
0121 472 1377 ext. 5536

To ensure results are given to appropriate medical professionals they will only be given via e-mail to NHS mail addresses. Results will not be communicated by telephone or fax.
3 Information Governance

Data Protection

Information is a vital asset both in terms of the clinical management of individual patients and the efficient management of services and resources. It plays a key part in clinical governance, service planning and performance management. Your personal data is data which by itself or with other data available to us can be used to identify you. We are Birmingham Women’s and Children’s NHS Foundation Trust, the data controller. Our Trust is registered with the Information Commissioner’s Office (ICO) to process personal and special categories of information under the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (subject to parliamentary approval) and our registration number is Z6078102.

The department complies with the Trust policies relating to the handling, use and protection of personal information (add document here)

- We only ask for information that we need to allow interpretation of results
- We protect the information and ensure only those staff who need to see the information can access it
- We share the information only when we need to for patient case, for example sending the information to another laboratory for testing

The data will be stored in accordance with the retention and storage of pathological records and specimens (5th edition) Guidance from The Royal College of Pathologists and the Institute of Biomedical Science, April 2015. We do not store any information for any longer than is absolutely necessary.

For more information, please click on the following link to read the Trusts Privacy Policy. This data protection and privacy policy sets out how we will use your personal data when you access our website. You can contact our Data Protection Officer at Birmingham Children’s Hospital, Steelhouse Lane, Birmingham B4 6NH if you have any questions.

https://bwc.nhs.uk/privacy-policy

Complaints

Pathology Services operates a complaints system in line with the Trusts Complaints Policy ‘Making Experiences Count Policy’.

Complaints, comments or feedback regarding the services provided by pathology can be made verbally or in writing (letter or email). Please contact the Pathology Services Manager or the Quality Manager.

If you feel that your concerns have not been put right you can make a formal complaint:

https://bwc.nhs.uk/complaints
4 Patient Information

Information about the screening tests available on the NHS can be found at –

Information booklet provided by the Foetal Anomaly Screening Programme


This links to downloadable versions of the booklet in multiple languages and an accessible version.

Foetal Anomaly Screening Programme website

https://www.gov.uk/topic/population-screening-programmes/fetal-anomaly

Antenatal Results and choices website

https://www.arc-uk.org/
5 Service Location & Availability

Location of the Department

The laboratory is located within the pathology department on the first floor of Birmingham Women’s hospital. The pathology department has secure access and can only be accessed via staff swipe badges. Specimen reception is based opposite the patient lift on the first floor.

Laboratory postal address

Dept Clinical Chemistry
Birmingham Women’s Hospital
Mindelsohn Way
Edgbaston
B15 2TG

Service Hours

Normal Working Hours
09:00 – 17:15 Mon-Fri except Bank Holidays

Out of Hours Service
There is no out of hours service for Foetal Anomaly Screening.

Sending a Specimen

The department provides a courier service for most of its routine users. Where available we strongly recommend that this is used. Failure to do so may result in specimens being lost or results delayed.

For users where a courier service is not available, send specimens packaged according to local regulations to the above address by first class post. Do NOT post specimens on a Friday or the day before a Bank Holiday.

Request forms

To ask for a further supply of request forms please e-mail to bwc.clinchem@nhs.net

If a courier service is used then the forms will be passed to the courier who will deliver them to the location where he collects specimens. If there are specific address details then please indicate in the e-mail and we will address the parcel appropriately.

This request will be dealt with as soon as possible but please bear in mind the following –

- Courier for the West Midlands brings specimens to the lab between 2-3pm and collects supplies for delivery the following working day.
- Courier for the other regions collects supplies between 10 and 11am.

Requests for supplies received after these times will miss the courier and will be delayed by a further 24 hours. Please try to give sufficient notice so that you do not run out of forms.
6 Specimen Collection, completion of the request form and management of urgent and additional requests

Consent

The laboratory assumes that informed consent for testing to be carried out has been given at the time of the request form has been completed.

The screening tests consented to (where a choice is available) are indicated on the request form by tick boxes. Failure to indicate which tests have been consented will result in delay in reporting the result.

It is the responsibility of the requestor to obtain consent for specimen collection and the tests requested. It is implicit in the receipt of the request form that consent has been obtained. We never request more sample than we need to but where there is material left over after laboratory testing, it may be used for other purposes such as quality assurance or audit, under the provisions of the Human Tissue Act 2004. Specific research is regulated separately by the ethics committee. Consent for the use of tissue requires that patients must be given the option to refuse permission for spare material to be used. When this occurs, each request to the laboratory must be clearly marked so that specimens are not used for other purposes.

Specimen Collection (including the preparation of the patient)

1. First trimester (combined screening) blood specimens must be collected between 10 and 14+1 weeks GA.

2. The nuchal translucency of the foetus must be measured when the crown rump length is between 45 and 84 millimetres.

3. Second trimester (quad test) blood specimens must be collected between 14+2 and 20+0 weeks GA.

4. If the scan is performed on the same day that blood is collected for the quad test then the head circumference must be between 101 and 172mm (inclusive).

5. The GA for the quad test may be calculated using either a head circumference or a crown rump length. These measurements do not need to be performed on the same day as the blood specimen is collected but must be within the limits below -

- The smallest crown rump length that can be accepted as a valid measurement is 5mm and the largest is 84.0mm.
- The smallest head circumference measurement that can be accepted as a valid measurement is 80mm.

Specimens will be rejected if they fall outside these criteria. See Notes on form Completion for details of how to calculate gestational age. The laboratory uses the equations outlined in this paper to calculate gestational age and results will not be amended unless the scan information used in the calculation is not correct.

If patients are taking biotin supplements then these should be stopped at least 24 hours before specimen collection.

Specimens should be collected into a gel separator tube with NO preservative.
Preservatives such as EDTA, lithium heparin and fluoride oxalate interfere with the assays and are NOT suitable.
Instructions for the completion of the request form

The laboratories have well established acceptance criteria which need to be present for samples to be accepted and processed. All essential items need to be present on the form to ensure that patients are uniquely identified so that results are not allocated to the wrong patient.

It is the responsibility of the requestor to complete the request form fully, clearly and correctly. Incomplete information WILL result in delay in reporting results. Incorrect information WILL result in an incorrect report being produced.

To comply with laboratory procedures, specimens will be rejected unless the following essential information is completed:

<table>
<thead>
<tr>
<th>Essential Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname</td>
</tr>
<tr>
<td>Forename</td>
</tr>
<tr>
<td>Date of Birth</td>
</tr>
</tbody>
</table>

In addition the following fields are absolutely necessary for a final result to be reported. If this is not provided then the result WILL be delayed. The specimen will not however be rejected.

<table>
<thead>
<tr>
<th>Desirable Information – If not included, result will be delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of scan</td>
</tr>
<tr>
<td>Scan measurement including nuchal translucency for combined screening</td>
</tr>
<tr>
<td>Date of blood sample</td>
</tr>
<tr>
<td>Maternal weight</td>
</tr>
<tr>
<td>Maternal ethnicity</td>
</tr>
<tr>
<td>Maternal smoking status</td>
</tr>
<tr>
<td>Scan measurements for twin if appropriate</td>
</tr>
</tbody>
</table>

Where applicable, information on the following must be completed to give a correct result

<table>
<thead>
<tr>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous maternal history of chromosomal disorder</td>
</tr>
<tr>
<td>Maternal Diabetes</td>
</tr>
<tr>
<td>Information if assisted conception (donor date of birth; date of egg harvest if frozen collection)</td>
</tr>
<tr>
<td>Chorionicity of twin pregnancy</td>
</tr>
</tbody>
</table>

Gestational age calculation  Gestational age is calculated using scan measurements based on BMUS guidance. Information on how to use these measurements are found in the reference Chudleigh et al *Ultrasound* 2011; 19: 154–157. A practical solution to combining dating and screening for Down’s Syndrome.

Maternal Ethnicity  The family origin of the mother should be given. Please note that this is not the same as the nationality of the mother. A list of codes is on the reverse of the request form.

Assisted conception  If a donor pregnancy then the age of the donor is essential for a correct result. If the eggs have been stored frozen then the date at which they were removed and stored is required. **We do NOT need the date when the embryos were transferred back into the mother.**
Specimen labelling and minimum data set

The specimen must be labelled with the following information which MUST match the request form:

1. Surname
2. And two from
   - Forename
   - Date of Birth
   - NHS number

Urgent Specimens

Where a NT has been measured as greater than 3.5mm please inform the laboratory by e-mail (bwc.clinchem@nhs.net); and mark the request form clearly. This enables reception staff to identify and prioritise the sample.

Urgent requests for other reasons will not be accepted.

Criteria for acceptance and rejection of samples

Specimens will only be rejected if they are not labelled correctly, collected into the wrong specimen tube or are collected at the wrong gestation. A letter will follow outlining the reason for rejection and weekly reminders sent for a repeat specimen to be collected.

If information is missing from a request, the requestor will receive an e-mail asking for this information. This will be followed by a weekly reminder until the information is provided. The specimen will be processed and results held pending provision of the full information. If information is not sufficient to determine gestational age then all analytes will be measured and the requestor billed for both first and second trimester requests.

Add-on Tests / Verbal requests

The laboratory does not accommodate add-on tests or verbal requests.

Provision of further information

All information used to calculate a final result must be e-mailed to bwc.clinchem@nhs.net. The requests must contain the name and date of birth of the patient and should also contain our lab reference number to enable us to positively identify the correct request.

Recalculations will not be performed over the telephone as we must have evidence of where the information we have used to calculate the result has come from.
7 Transportation of samples to the laboratory

All specimens must be handled with care and treated by all personnel as a potential infection risk. However, additional precautions are required for samples that are deemed to be high risk.

NOTE – A screened population will contain women who have unidentified disease. No samples should be treated as low risk.

Low Risk Diagnostic Specimens (UN3373):

The majority of specimens collected and transported to the pathology departments do not present a significant risk of infection to staff handling them. Such specimens will normally be packaged in a primary container (e.g. blood tube, swab tube, specimen pot), and an outer secondary container (a sealed pathology transport bag or sealed plastic bag). All specimens must be accompanied by an accurately, fully completed request form.

High Risk Infectious Specimens (UN2114):

Some patients may be suffering from, or be suspected of having a disease which may present higher risk to staff. Legislation requires specimens from such patients to be identifiable.

- The specimen containers and pathology transport bags used for these specimens will be identical to those used for routine specimens. The identification of risk associated with these specimens will be by the use of “DANGER OF INFECTION” labels.

- It is the legal responsibility of the person who requests the laboratory examination of the specimen to ensure that both the request form and the container are correctly labelled to indicate a danger of infection. “DANGER OF INFECTION” labels must only be used for specimens which are suspected of or are known to contain pathogens.

Internal Transport

Specimens for foetal anomaly screening should be brought directly to the Clinical Chemistry Laboratory.

Air Tube

Specimens should not be sent via air tube.

Instructions for sending samples from an external source

Specimens collected outside the hospital should be delivered using the correct packaging that complies with national guidelines and sent via the courier provided or by first class post. The department should be notified in advance of any urgent or special requests.
### Examinations offered by the laboratory

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum sample volume</th>
<th>Special Precautions</th>
<th>Factors that will significantly affect interpretation of results</th>
<th>Cut off used to determine significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Combined test</strong></td>
<td>1mL of whole blood (0.5mL of serum)</td>
<td>Specimen must be collected at the correct gestation (10+0 - 14+1 weeks inclusive). NT measurement must be made when the CRL is between 45 and 84mm.</td>
<td>All fields on the request form must be complete and correct otherwise the result will be delayed or incorrect. Other factors include but are not confined to - Delay in specimen transport. Specimens not collected in correct container Specimen storage conditions Incorrect scan measurements (CRL, HC, NT) Biotin ingestion in 24 hours before sample collection Variation in scan measurement between individual sonographers The presence of a chromosomal disorder not being screened for. The presence of non fetal neoplastic tissue Presence of demised twin Women who go on to develop preeclampsia or IUGR later in pregnancy</td>
<td>A result of 1 in 150 or greater is deemed at being increased chance.</td>
</tr>
<tr>
<td><strong>Second Trimester screening</strong></td>
<td>1mL of whole blood (0.5mL of serum)</td>
<td>Specimen must be collected at the correct gestation (14+2 – 20+0 weeks inclusive)</td>
<td>A result of 1 in 150 or greater is deemed at being increased chance.</td>
<td></td>
</tr>
<tr>
<td>First trimester screening by NT alone</td>
<td>NA – calculation performed based on scan measurements</td>
<td>NT measurement must be made when the CRL is between 45 and 84mm.</td>
<td>A result of 1 in 150 or greater is deemed at being increased chance.</td>
<td></td>
</tr>
</tbody>
</table>
NOTES

All these tests are available in singleton and twin pregnancies.

Vanishing Twin Pregnancies

In pregnancies where a twin has been lost (vanishing twin pregnancies) the following apply –

- **First trimester – NT measured – foetus 1; no foetal pole present – foetus 2.** Send blood and request form as though a singleton pregnancy
- **First trimester – NT measured – foetus 1; demised foetal pole present – foetus 2.** Send request card for result to be assessed using nuchal translucency alone
- **First trimester – NT cannot be measured in surviving twin.** Send blood and request form after 14+2 for the quad test
- **Second trimester – all cases.** Send blood and request form for quad test (FASP guidance)

Triplet/Higher order pregnancies – fall outside the remit of the screening programme. Chance cannot be calculated for triplet/higher order or demised triplet/higher order pregnancies.
Reports, turnaround times and availability of clinical advice

Reports

Reports are e-mailed back to requestors via NHS mail or made available through the laboratory web based software (SSD). Please contact the laboratory to arrange access and training if required.

Patient letters are provided to Units in the West Midlands. It is the responsibility of the requestor to confirm that the address on the letter is correct before sending.

Increased chance reports are e-mailed back to the requestor separately.

Turnaround Times

Turnaround times quoted are the anticipated times between specimen receipt in our laboratory and reporting under normal operating conditions. The turnaround times of all tests are monitored.

The nationally set target for turnaround of results is that 97% of results will be available within three working days of receipt in the laboratory.

Availability of Clinical Advice

Clinical Advice is available from the laboratory during normal opening hours. We strongly recommend that this is done through e-mail as this allows the advice given to be recorded and referred to at a later date. It also allows ensures that advice will be given by the most appropriate person. Please e-mail enquiries to bwc.clinchem@nhs.net.

Work Referred Away

Work is not referred away by the Foetal Anomaly Screening laboratory except in unusual cases where assay interference is suspected. In these cases, the requestor will be informed that there is likely to be a delay in reporting the result and the specimen will be referred to an accredited provider of a screening service.

A report from the referring laboratory will be issued if appropriate.
10. Frequently asked questions

Can screening be performed in triplet pregnancies?

No – triplet and higher order pregnancies fall outside the remit of the screening programme. The laboratory software is not configured to allow a calculation in these cases as there is insufficient evidence to allow the prior chance to be estimated.

The gestational age on the report is different to that calculated locally – should the report be amended?

If the scan measurement, date of scan and date of sample are correct then the chance will not be recalculated based on gestational age. The gestational age calculation is based on the papers approved by BMUS and is an automatic calculation which has been verified. You should investigate any discrepancies by first confirming that local GA calculations are using the correct equations and if so, the discrepancy should be raised with the company responsible for the software. Occasionally, GA may differ by a day because the two calculations round some smaller numbers to a different degree.

The equations that should be used to convert scan measurements to gestational age are as follows –

\[ \text{GA}_{\text{CRL}} = 8.052 \times \sqrt{\text{CRL} \times 1.037} + 23.73 \]

\[ \log_{10} \left( \text{GA}_{\text{HC}} \right) = 0.010611 \times \text{HC} - 0.000030321 \times \text{HC}^2 + 0.43498 \times 10^{-7} \times \text{HC} + 1.848 \]

They are taken from Loughna P, Chitty L, Evans T, Chudleigh T. Fetal size and dating: charts recommended for clinical obstetric practice. Ultrasound 2009;17:161–7 and have been agreed by FASP, BMUS and the FMF.

What action should be taken if the courier does not arrive?

Occasionally the couriers may be delayed by heavy traffic or adverse weather conditions. In these cases please store specimens in a refrigerator. The FASP laboratory handbook states that whole blood specimens are stable at 4 degrees for 5 days. This is confirmed by data collected over three years at BWH.

What arrangements are made over Bank Holidays?

Specimens will be collected on every working day (Mon-Fri) except for Bank Holidays. Please ensure that all specimens taken on the day before a Bank Holiday are ready in time for the courier collection. Those that are not should be referred to a local laboratory where they should be spun and stored refrigerated until the next collection. Serum (separated) specimens for screening are stable for up to 14 days when stored refrigerated (FASP lab handbook).

Arrangements have been made with some Trusts to collect specimens on Saturday. Where this happens, the Saturday collection on a Bank Holiday weekend will continue as normal unless Christmas Day, New Year’s Day or Boxing Day falls on that Saturday.

Where is my result/have you received a specimen?

Please consider the time taken to transport specimens to the laboratory when chasing results and potentially missing samples. Where the courier collects directly from the antenatal clinic, samples arrive in Birmingham on the same day but will not be booked into the lab system until the following day. Where specimens are sent to a local laboratory first, there may be longer delays depending on how your laboratory deals with these specimens. Chasing results and samples too soon may lead to women being bled unnecessarily.
99% of results are reported either on the day received or the day after receipt. Results are reported in batches so that all samples received at the same time are reported at the same time. We would suggest where possible waiting until other results from the same time are received before contacting us regarding missing specimens.

**We have noticed an increased/decreased number of increased chance results – is there a problem?**

We run internal QC daily, participate in external QA programmes and monitor our overall screen positive rate and the mean patient values for a number of different variables on a weekly basis. We are fairly confident that our results are monitored sufficiently to ensure that no problems would arise. Most likely, an increase or decrease in the number of increased chance results that you see is a statistical anomaly – possibly caused by a higher than usual number of older or younger women being screened, or even simply by a number of true positive women around the same time. All results are calculated by the software using the same set of equations and appear automatically on the report.

**However** we would still encourage you to question any strange patterns of results that you may see. It is always possible that we have missed something and you may not be the only Unit that has seen something amiss. We can check your Unit’s screen positive rate and compare to the overall rate and make sure that there have been no analytical changes in the period of concern.

**Can we offer a repeat screening test?**

If a result has been reported then we do not offer a second screening test. A screening test should not be used as confirmation of another screening test.

If an increased chance result is reported from the original test –

The repeat may also be increased chance – there was therefore no point in repeating.

The repeat may be low chance –

If the woman chooses to have diagnostic testing then there was no point in repeating the test as the choice is only influenced by the first test.

If the woman chooses not to have diagnostic testing then there is the possibility that the repeat test was a false negative.

If a woman has had a private screening test then she is entitled to have an NHS screening test. It is still not good practice to have results from multiple screening tests and we would discourage this. If a woman does have private screening and then is screened at BWH we will only offer interpretation and recommendations for action based on our result.