Infectious Disease in Pregnancy Screening (IDPS) Programme

BWC Microbiology, Birmingham Children’s Hospital

For screening enquiries contact
Phone number 0121 333 9803

Check the Birmingham Women’s and Children’s Hospitals web site:
https://bwc.nhs.uk/laboratories
1 Introduction to Infectious Disease in Pregnancy Screening Programme at BWC

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Service user feedback is welcomed and any problems regarding the quality of the service should be brought to the attention of Philip Milner (Head Biomedical Scientist) on extension 9809 or email philip.milner@bch.nhs.uk

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1 Introduction to Infectious Disease in Pregnancy Screening Programme at BWC

Services Provided

The Microbiology laboratory provides the Infectious Disease in Pregnancy screening (IDPS) programme at Birmingham Women’s and Children’s NHS Foundation Trust.

The UK National Screening Committee (UK NSC) policy for the IDPS programme is to offer and recommend screening to all eligible women. This is to enable early detection and treatment for infections in pregnancy in order to significantly reduce the risk of mother to child transmission of infection.

The IPDS programme aims to:

- Ensure equal access to uniform and quality assured screening
- Provide women with high quality information so they can make an informed choice about their screening options and pregnancy choices. Some women may choose not to be screened for to accept screening for some of the infections and it is important that this choice is respected.
- Provide assurance that all women who screen positive for HIV, hepatitis B or Syphilis, or are already known to be positive for HIV and Hepatitis B, are seen by the IDPS MDT within specified timescales.

A blood test is offered as early as possible in pregnancy to ensure timely referral and management of care.

Service Scope

The IDPS programme currently screens for:

- HIV
- Hepatitis B
- Syphilis

Service Standards/Quality Assurance

The IDPS programme at BWC is run by the Microbiology department located at Birmingham Children’s Hospital. Both the department and the IDPS programme have been assessed for their competency by UKAS in accordance with Medical Laboratories – requirements for quality and competence (ISO 15189:2012) and have the accredited medical laboratory number 9896.

The full schedule of accreditation is found here:

https://search.ukas.com/#/tabbed/search?q=Birmingham%20Women's &ati=1

The Microbiology department recognises its responsibility as a provider of quality services. To this end, the laboratory has developed and documented a quality management system to better satisfy the needs of its users and to improve management of the organisation. The quality system complies with UKAS International Accreditation ISO standards 15189:2012.

We aim to be a model of excellence in the delivery of a clinical Microbiology service. In order for this to be achieved, we are committed to the following:

- Service user involvement
- Good professional practice & evidence-based practice
- Efficient utilisation of resources
- Valuing our staff in order to realize their full potential
• Commitment to the health, safety and welfare of our patients, staff and visitors

• Keeping a safe environment in compliance with current environmental legislation

• Working as teams and partnerships

• Continuous improvement

All staff working within the department are fully qualified, specialised and experienced, providing a quality service.
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) Scheme:

- UK NEQAS for Blood donor screen

**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 Infectious Disease in Pregnancy Screening Programme laboratory service including test repertoire, specimen requirements and details on accessing our service.

It also provides

- Laboratory contact details
- Location of laboratory
- Opening hours (including the out of hours service)
- Details of services provided
- Instructions for completing sample and request form information
- Arrangements for transporting samples to the laboratories

**Intended Audience**

All users of Microbiology laboratory services at Birmingham Women’s Hospital

Service user feedback is welcomed and any problems regarding the quality of the service should be brought to the attention of Philip Milner (Head Biomedical Scientist) on extension 9809 or email philip.milner1@nhs.uk
## Useful Contacts

<table>
<thead>
<tr>
<th>Microbiology Contacts</th>
<th>Phone No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Enquiries</td>
<td>9803</td>
</tr>
<tr>
<td>Pathology Manager</td>
<td>9835</td>
</tr>
<tr>
<td>Microbiology Section Lead</td>
<td>9809</td>
</tr>
<tr>
<td>Quality Lead / Senior Biomedical Scientist</td>
<td>6187/9802/9803</td>
</tr>
<tr>
<td>Training Lead / Senior Biomedical Scientist</td>
<td>9802/9803</td>
</tr>
<tr>
<td>Main Laboratory (please use General Enquiries number for results)</td>
<td>9802</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultant and Advanced Laboratory Practitioners</th>
<th>Phone No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Jim Gray</td>
<td>9815</td>
</tr>
<tr>
<td>Dr Mitul Patel (Clinical Lead)</td>
<td>9814</td>
</tr>
<tr>
<td>Registrar</td>
<td>9818</td>
</tr>
<tr>
<td>Mr Phil Milner</td>
<td>9809</td>
</tr>
<tr>
<td>Infection Control</td>
<td>9968/9966</td>
</tr>
<tr>
<td></td>
<td>Bleep 55047</td>
</tr>
</tbody>
</table>
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
Patient Information

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


This Information booklet is available on


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

Infectious Diseases in Pregnancy Screening Programme website

Antenatal Results and choices website

https://www.arc-uk.org/tests-explained/infectious-diseases
5 Service Location & Availability

Location of the Department
The laboratories at Birmingham Children’s Hospital are located on Whittall Street. The Microbiology laboratory is located on the second floor of the Laboratory Block, next to Histopathology. The Laboratory Block is signposted off the Rainbow corridor connecting the laboratories with the Main Hospital Corridor.

Laboratory postal address
Dept. of Microbiology
Paediatric Laboratory Medicine
Birmingham Children’s Hospital
Steelhouse Lane
Birmingham
B4 6NH

Delivery address for couriers
Pathology Reception
Dept. of Microbiology
Paediatric Laboratory Medicine
Birmingham Children’s Hospital
Whittall Street
Birmingham
B4 6DH

Service Hours
Microbiology operates a 7-day service. However, tests for IDPS screening are not run outside normal working hours.

Normal Working Hours
The Microbiology department is open from
- Monday to Friday, 8:30 to 20:00.
- Saturday, Sunday and Bank Holidays 8:30 to 5:00

Please note that at weekends only two technical staff are present in the laboratory and on weekdays only one technical staff member is in after 17:00. Therefore please do not make telephone requests for patient results unless absolutely necessary-utilise ICE wherever possible.

Out of Hours Service
Tests for IDPS screening are not run out of hours.
6 Specimen Collection, completion of the request form and management of urgent and additional requests

Consent

The IDPS programme aims to provide women with high quality information so they can make an informed choice about their screening options and pregnancy choices.

Some women may choose not to be screened or to accept screening for some of the infections and it is important that this choice is respected. The screening tests must not be offered as a suite of tests.

It is the responsibility of the midwife / clinician to discuss the options with the patient and to confirm consent.

The consented screening tests are indicated on the request form by tick boxes. Failure to indicate 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.

The request form must be signed by the person obtaining consent for testing and the infectious diseases screening box ticked.

Specimen Collection (including the preparation of the patient)

It is the responsibility of clinical staff ordering tests, taking samples, or sending samples to the ward to:

- Be familiar with and comply with Policy for Labelling and Transporting Laboratory Specimen and associated procedures.
- Be aware of the hazards to themselves and others that would exist through noncompliance with the Policy for Labelling and Transporting Laboratory Specimens policy
- When requesting specimens for analysis that may present a high risk of infection, ensure that staff who may take or handle the specimen are warned of the risk so that appropriate additional precautions can be taken

The identity of the patient must be confirmed prior to sampling and a signature supplied on the request form to ensure that these checks have been made.

Disinfect the skin of the patient at the venepuncture site prior to sampling. Blood should be taken into a sterile blood tube containing no additives (at BWH these are a brown topped tube) Ensure that the tube is sufficiently labelled with patient identifiers.
Instructions for the completion of the request form

There is a request form specifically for IDPS samples, this must be used and completed. Where a repeat sample is required later in the pregnancy a routine request form should be used to distinguish the specimen. 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. The following is taken from the current Infectious Disease in Pregnancy Screening Programme Laboratory Handbook (2016-17)


<table>
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<tr>
<th>No.</th>
<th>Data category</th>
<th>Data fields</th>
<th>Rationale for inclusion (service specification / ISO 15189 and IDPS)</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Type of sample</td>
<td>ANTENATAL SAMPLE</td>
<td>ISO 15189 6.4.3. (c) IDPS programme requirement, must distinguish antenatal from other samples.</td>
</tr>
</tbody>
</table>
| 2.  | Identification of the pregnant woman | • NHS Number  
• Hospital Number  
• Forename  
• Surname | ISO 15189 Request Information. 5.4.3. (a) Must have sufficient information to allow unequivocal identification of the pregnant woman. |
| 3.  | Name / location of requesting individual and where to send the results | • Name of person completing the request  
• Location of requestor - ANG / GP surgery etc.  
• Maternity unit booked for delivery  
• Results & report to: name and location (if different from above) | ISO 15189 Request Information. 5.4.3. (b) 'name or other unique identifier of clinician, healthcare provider or other person legally authorised to request examinations or use medical information, together with the destination for the report and contact details.' |
| 4.  | Name, date and time of specimen collection | • Name and location of person taking the sample  
• Date and time of sample collection | ISO 15189 Date and time of sample collection. 5.4.3. (f) Data required for governance, management and audit of safety and performance. |
| 5.  | Identification of priority status | • INITIAL antenatal screening sample  
• REPEAT antenatal screening sample (inadequate first sample)  
• REPEAT sample to exclude recent infection  
• INITIAL sample taken after previous decline | ISO 15189 Examinations requested. 5.4.3. (d) & (e) Must be able to identify status of every sample requested, for governance and audit of safety and performance. |
| 6.  | Examinations requested | | ISO 15189 Examinations requested. 5.4.3. (d) & (e) Must be able to ensure urgent samples processed as soon as possible. |
| 7.  | Clinically relevant information | Clinical indications for urgent sample request | |

Rationale for inclusion:
- ISO 15189 6.4.3. (c) IDPS programme requirement, must distinguish antenatal from other samples.
- ISO 15189 Request Information. 5.4.3. (a) Must have sufficient information to allow unequivocal identification of the pregnant woman.
- ISO 15189 Request Information. 5.4.3. (b) 'name or other unique identifier of clinician, healthcare provider or other person legally authorised to request examinations or use medical information, together with the destination for the report and contact details.'
- ISO 15189 Date and time of sample collection. 5.4.3. (f) Data required for governance, management and audit of safety and performance.
- ISO 15189 Examinations requested. 5.4.3. (d) & (e) Must be able to identify status of every sample requested, for governance and audit of safety and performance.
- ISO 15189 Examinations requested. 5.4.3. (e) Must be able to ensure urgent samples processed as soon as possible.
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

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 there is an absence of one or both signatures.

If information is missing from a request, the requestor will receive an e-mail asking for this information.

Add-on Tests / Verbal requests

An aliquot of each sample is retained for 2 years as per IDPS guidelines and may be retrieved for comparative testing on request by prior arrangement with the Consultant Microbiologist.

Late Bookers

Any patient presenting for booking at >20 weeks is classified as a late booker and results must be available within 24 hours. The laboratory will process these samples urgently so they must be identified on the request form. Ensure that the gestational age is also specified.

Un-booked Patients

These are patients who present at the hospital either in labour or at the late stages of the pregnancy not having booked. A routine request form is completed. A rapid HIV test is available at Haematology at BWH and can be performed by prior arrangement. The remainder of the tests will be followed up at BCH within 24 hours.

Repeat testing

Repeat samples on patients whom have previously tested positive during the pregnancy are taken as normal and sent on a routine request form. Please indicate that the patient has previously tested positive and that this is a follow-up sample. If the patient is receiving treatment at another Trust this must also be indicated as it may affect the referral location.
7 Transportation of samples to the laboratory

Specimens must be delivered to Specimen Reception at Birmingham Women’s Hospital who will arrange transportation for testing on the Children’s Hospital site. Where a delay in transportation is unavoidable samples should be stored in the fridge on delivery suite or in antennal clinic. 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.

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.
8 Examinations offered by the laboratory

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<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>HIV</td>
<td>5ml</td>
<td>A rapid test may be performed on unbooked patients by prior arrangement with the laboratory. Patients known to be positive should be indicated with Biohazard tape.</td>
<td>Delay in receipt of specimen in the laboratory may lead to haemolysed samples which cannot be processed.</td>
<td>Values &lt; 1 are negative. Values ≥1 are referred for confirmation.</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>5ml</td>
<td>Patients known to be positive should be indicated with Biohazard tape.</td>
<td>Delay in receipt of specimen in the laboratory may lead to haemolysed samples which cannot be processed.</td>
<td>Values &lt; 1 are negative. Values ≥1 are referred for confirmation.</td>
</tr>
<tr>
<td>Syphilis</td>
<td>5ml</td>
<td></td>
<td></td>
<td>Values &lt; 1 are negative. Values ≥1 are referred for confirmation.</td>
</tr>
</tbody>
</table>
9 Reports, turnaround times and availability of clinical advice

Reports
Paper copies of reports are sent to requestor and an electronic copy is available on the hospital reporting system, ICE.

Turnaround Times
All results should be available within 8 days of receipt of the sample in the screening laboratory. This data is collated and reported to PHE (see standard 4). This is to enable the recall of the woman within 10 working days if the result is positive.

The nationally set achievable target for turnaround of results is that 97% of results will be available within eight days of receipt in the laboratory, with an acceptable target set at 95%.

Availability of Clinical Advice
Clinical Advice is available from the laboratory during normal opening hours.

Work Referred Away
All results to be considered to be positive, tested at BWC, must be confirmed with further testing. This is currently performed at the Public Health Laboratory at Heartlands Hospital.

Communication Pathways

The Antenatal team is notified by email of any specimen that is unprocessed or has a discrepancy on the request form. They are also notified of any samples that have one or more tests declined.
10. Frequently asked questions

How do I deal with an inconclusive result?

- A Repeat sample is requested when the result is reported.
- Where results are still inconclusive discuss with the Consultant Microbiologist.