# AMNIOCENTESIS FOR ANTENATAL DIAGNOSIS

## Clinical Guidelines

**Register No:** 08045  
**Status:** Public

Developed in response to:  
NHS Fetal Anomaly Screening Programme  
RCOG Guidelines

Contributes to CQC Standards  
12

### Consulted With:

<table>
<thead>
<tr>
<th>Individual/Body:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Anita Rao/Alison Cuthbertson</td>
<td>February 2018</td>
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<td>Vidya Thakur</td>
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<td>Dr Hassan</td>
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<td>Alison Cuthbertson</td>
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<td>Consultant for Obstetrics and Gynaecology</td>
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<td>Consultant Paediatrician</td>
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<td>Associate Director of Midwifery/Nursing</td>
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<td>Lead Midwife Acute Inpatient Services</td>
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### Professionally Approved By:

| Anita Rao | Lead Consultant for Obstetrics and Gynaecology | February 2018 |

### Version Number

5.0

### Issuing Directorate

Women’s and Children’s

### Approved by

DRAG Chairmans Action

### Approved on

10th April 2018

### Implementation Date

4th May 2018

### EMG Sign Off Date

May 2018

### Next Review Date

April 2021

### Policy to be followed by (target staff)

Midwives and Obstetricians

### Distribution Method

Intranet and Website: Notified on Staff Focus

### Related Trust Policies (to be read in conjunction with)

- 04071 Policy for Standard Infection Prevention precautions
- 04072 Hand Hygiene policy
- 09079 Management of Normal Labour and prolonged labour in low risk patients
- 09062 Maternity Care Guidelines 04272 Guidelines for Maternity Care
- 08046 Interpreting and Acting on Chorionic Villus Sample (CVS) and Amniocentesis Results
- 08056 Management of Human Immunodeficiency Virus in maternity
- 12004 Hepatitis B in pregnancy and the postnatal period

### Document History Review:

<table>
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<tr>
<td>1.0</td>
<td>Yvonne Roder</td>
<td>April 2004</td>
</tr>
<tr>
<td>2.0</td>
<td>Kathleen Bird</td>
<td>October 2008</td>
</tr>
<tr>
<td>3.0</td>
<td>Nicky Leslie</td>
<td>February 2012</td>
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<tr>
<td>3.1</td>
<td>Nicky Leslie – clarification to point 10.7</td>
<td>May 2013</td>
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<tr>
<td>4.0</td>
<td>Nicky Leslie, Antenatal Newborn Screening Coordinator</td>
<td>March 2015</td>
</tr>
<tr>
<td>4.1</td>
<td>Nicky Leslie – clarification to point 10.7 and 13.0</td>
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<td>Emma Neate – Full review</td>
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   Appendix 2: Prenatal samples form
1.0 Purpose

1.1 To ensure that the timing and techniques for these procedures do not vary significantly between practitioners, thereby minimising associated risks.

2.0 Equality and Diversity

2.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

3.0 Background

3.1 Amniocenteses are performed to obtain amniotic fluid for polymerase chain reaction (PCR) or karyotyping and the majority are undertaken from 15 completed weeks (15 weeks and 0 days). This involves aspiration of amniotic fluid.

4.0 Aim

4.1 To obtain amniotic fluid for PCR/ karyotyping for patients who fall into the following categories:

- Received a high-risk screening result (result between 5 -150) from a blood test for 1st trimester or 2nd trimester screening for Trisomy 13 (Patau syndrome) 18 (Edwards syndrome) 21 (Downs syndrome).
- Anomaly scan result show certain features such as heart defect or structural defects which indicate the baby may have a chromosomal abnormality

5.0 Clinical Recommendations

5.1 Formal consent should be obtained before the procedure. This should conform to recommendations on consent as per General Medical Council (GMC)/Royal College of Obstetricians and Gynaecologists (RCOG) guidelines regarding consent.

- Written or oral information should include: how, when and by whom procedure is performed and how their practice is monitored
- What results are possible from the procedure
- Local risks of the procedure
- Analysis and subsequent storage at the local cytogenetics laboratory
- Reporting time
- Rhesus negative patients will require 500 iu anti-D post amniocentesis to prevent the woman from developing antibodies against baby’s blood cells.
- Method of communicating result
- Seeking medical advice after the test with the information leaflet who to contact in emergency
6.0 Risks

6.1 Up to one out of every 100 women who have a CVS or amniocentesis will miscarry. We do not know why some women miscarry after these procedures. Most miscarriages happen within 3 days of the procedure but they can happen up to 2 weeks afterwards.

There is a risk of less than 1 in 1,000 that amniocentesis will cause a serious infection. Women should call the hospital where they had the test, straight away if they experience any of the following symptoms:

- Persistent or severe pain
- A high temperature of 38°C (100.4F) or more
- Chills or shivering
- Heavy vaginal bleeding
- Discharge of clear fluid from the vagina
- Contractions

7.0 Procedure for Singleton Pregnancies

7.1 Amniocentesis should be carried out after 15 completed weeks of gestation

7.2 Amniocentesis should be carried out under direct ultrasound needle tip visualization as this is associated with a higher successful tap and less bloody taps.

7.3 Maximum outer needle gauge size of 0.9 mm (20 gauge) should be used to perform amniocentesis.

7.4 All amniotic fluid samples are placed in a sterile universal specimen pot. The pot is labelled with the woman’s details and checked by the woman. The pot is then sealed with parafilm and placed inside another container. The container is placed inside a box labelled with the destination and the unit from which it has been sent. A laboratory request form is placed in the box with the sample.

7.5 All amniocentesis specimens are sent by courier to arrive at the cytogenetic laboratory the same day:
New address Level 5 Barclay House, 37 Queens Square, London WC1N 3BH

7.6 An email is sent to the laboratory (gos-tr.geneticsspecimenreception@nhs.net), with information about the number and names documented on the samples. This provides a failsafe process, with the laboratory informing the Screening team (refer to Appendix 1 and 2) if a specimen fails to arrive.

7.7 Competency should be maintained by carrying out at least 30 ultrasound guided invasive procedures per annum.

7.8 There should be continuous audit of frequencies of multiple insertions, failures, bloody taps and post procedure losses.
It is crucially important that amniocentesis is not performed until the operator is certain that the fetus and cord are clear of the intended pool of amniotic fluid. When difficulties are anticipated, consideration should be given regarding referring the patient to a more experienced operator.

A more experienced operator should be consulted if two attempts at uterine insertion have failed to produce an adequate sample for analysis.

Expert opinion suggests that an operator’s competence should be reviewed where loss rates appear high and audit should certainly occur where they exceed 4/100 consecutive amniocenteses.

**Procedure for Multiple Pregnancies**

Testing women who are pregnant with twins

Amniocentesis in twin pregnancies is more complex and women should be referred to UCLH Fetal Medicine Unit.

The risk of miscarriage when having an amniocentesis with twins is about twice as high as in single pregnancies. If this occurs, it may lead to the miscarriage of both babies.

**Procedure for Third Trimester Amniocentesis**

Third-trimester amniocentesis does not appear to be associated with any significant risk of emergency delivery. Compared with mid-trimester procedures, complications including multiple attempts and bloodstained fluid are more common.

Mid Essex Hospital Services NHS Trust refer to a tertiary unit for third trimester amniocentesis.

**Risk of Transmission of Infection**

The ultrasound probe should be decontaminated with antiseptic gel during the invasive procedure and separate sterile gel is used.

Invasive prenatal procedures should not be carried out without reviewing available blood borne virus screening tests.

Where patients decline screening for blood borne viruses and are being counselled for prenatal diagnostic procedures, inform and document the potential risk of vertical transmission of infection to the fetus.

Review viral load and treatment regimens prior to invasive prenatal testing in patients with HIV and consider delaying the procedure until there is no detectable viral load if the patient is already on treatment. Discuss with GUM specialist for appropriate regimen prior to amniocentesis on an individual case basis.

(Refer to guideline entitled ‘Management of Human Immunodeficiency Virus in pregnancy’; register number 08056)

Discuss use of antiretroviral therapy with GUM specialist prior to prenatal invasive procedures in women not yet on treatment for HIV.
10.6 Invasive prenatal testing in the first or second trimester can be carried out in patients who carry Hepatitis B or C, the benefits and risks must be assessed by an obstetric Consultant. (Refer to the guideline entitled ‘Hepatitis B in pregnancy and the postnatal period’; register number 12004)

10.7 Rhesus status: the health care professional should only obtain a Kleihauer test for women having an amniocentesis after 20 weeks gestation. Rhesus prophylaxis with anti-D immunoglobulin must be offered following each procedure in line with national recommendations.

11.0 Receiving Results of Amniocentesis

11.1 All results are reported direct to the patient from the Screening team.

11.2 Two laboratory results are obtainable from an amniocentesis test. Polymerase chain reaction (PCR) results 48 hours after testing and a full karyotype 2-3 weeks after testing. The Screening team will contact the patient within 1-2 working days of receiving any results as appropriate.

11.3 PCR testing looks specifically at chromosomes 13, 18 and 21. Some amniocentesis samples may not be suitable for PCR testing. If PCR results are unavailable then a full karyotype will be performed by the laboratory.

12.0 Staffing and Training

12.1 Independent performance of the procedure should be carried out only after adequate training which should include use of a clinical skill model, assessment of interactions with patient and supervised procedures.

12.2 The practitioner carrying out ultrasound as part of the amniocentesis procedure should be trained to the competencies of the RCOG/RCR Diploma in Obstetric Ultrasound or equivalent.

13.0 Infection Prevention

13.1 All staff should follow Trust guidelines on infection prevention by ensuring that they effectively ‘decontaminate their hands’ before and after each procedure.

13.2 All staff should ensure that they follow Trust guidelines on infection control, using Aseptic Non-Touch Technique (ANTT) when carrying out procedures i.e. procedure for amniocentesis.

14.0 Audit and Monitoring

14.1 Audit of compliance with this guideline will be considered on an annual audit basis in accordance with the Clinical Audit Strategy and Policy (register number 08076), the Corporate Clinical Audit and Quality Improvement Project Plan and the Maternity annual audit work plan; to encompass national and local audit and clinical governance identifying key harm themes. The Women’s and Children’s Clinical Audit Group will identify a lead for the audit.
14.2 The findings of the audit will be reported to and approved by the Multi-disciplinary Risk Management Group (MRMG) and an action plan with named leads and timescales will be developed to address any identified deficiencies. Performance against the action plan will be monitored by this group at subsequent meetings.

14.3 The audit report will be reported to the monthly Directorate Governance Meeting (DGM) and significant concerns relating to compliance will be entered on the local Risk Assurance Framework.

14.4 Key findings and learning points from the audit will be submitted to the Clinical Governance Group within the integrated learning report.

14.5 Key findings and learning points will be disseminated to relevant staff.

15.0 Guideline Management

15.1 As an integral part of the knowledge, skills framework, staff are appraised annually to ensure competency in computer skills and the ability to access the current approved guidelines via the Trust’s intranet site.

15.2 Quarterly memos are sent to line managers to disseminate to their staff the most currently approved guidelines available via the intranet and clinical guideline folders, located in each designated clinical area.

15.3 Guideline monitors have been nominated to each clinical area to ensure a system whereby obsolete guidelines are archived and newly approved guidelines are now downloaded from the intranet and filed appropriately in the guideline folders. ‘Spot checks’ are performed on all clinical guidelines quarterly.

15.4 Quarterly Clinical Practices group meetings are held to discuss ‘guidelines’. During this meeting the practice development midwife can highlight any areas for further training; possibly involving ‘workshops’ or to be included in future ‘skills and drills’ mandatory training sessions.

16.0 Communication

16.1 A quarterly ‘maternity newsletter’ is issued and available to all staff including an update on the latest ‘guidelines’ information such as a list of newly approved guidelines for staff to acknowledge and familiarise themselves with and practice accordingly.

16.2 Approved guidelines are published monthly in the Trust’s Staff Focus that is sent via email to all staff.

16.3 Approved guidelines will be disseminated to appropriate staff quarterly via email.

16.4 Regular memos are posted on the Guideline and Audit notice boards in each clinical area to notify staff of the latest revised guidelines and how to access guidelines via the intranet or clinical guideline folders.
17.0 References


NE Thames Regional Genetics Service
Laboratory

PRENATAL/TISSUE CYTOGENETIC TEST REQUEST FORM

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<thead>
<tr>
<th>Surname:</th>
<th>First Name:</th>
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<th>Address for Report</th>
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<th>Date/Time Received</th>
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**Reason for Referral**
Please give clinical details, including previous genetic investigations.

**Prenatal Tests**

- [ ] CVS
- [ ] QF-PCR Only
- [ ] Amniotic Fluid
- [ ] QF-PCR + Microarray or Karyotype

NHS patients will routinely be tested in line with NHS (London Region) prenatal testing policy. Microarray or karyotyping will be actioned in addition to QF-PCR testing in line with this policy, dependent upon the clinical details provided and the QF-PCR results obtained.

<table>
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<tr>
<th>Down's Screen Risk</th>
<th>Gestation at Sampling</th>
<th>Size of NT</th>
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**Solid Tissue Tests (Pregnancy Loss)**

- [ ] MLPA and QF-PCR

**Type of Sample:**

- [ ] Sex (If Known): Male/Female

If products of conception or a fetal/placental sample need to be returned for sensitive disposal please ensure that this is clearly indicated on the referral form and that an appropriate consent form is attached.

**Solid Tissues (Live Patient)**

- [ ] Karyotyping
- [ ] Mosaicism Screen
  (please provide reasons above)
- [ ] DNA Storage

In submitting the sample the clinician confirms that consent for testing and possible storage has been obtained. Please use the alternative request form (available on our website – see overleaf) for postnatal or molecular prenatal referrals.
## INSTRUCTIONS:

<table>
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<th>Quantity</th>
<th>Container</th>
<th>Must be received in lab</th>
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<tr>
<td>Amniotic fluid</td>
<td>20ml*</td>
<td>Universal container</td>
<td>Same day, by 5pm</td>
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<tr>
<td>Chorionic villus biopsy</td>
<td>14-50ng*</td>
<td>Universal container containing 0.9% w/v saline</td>
<td>Same day, by 3pm</td>
</tr>
<tr>
<td>Skin biopsy (live patient)</td>
<td>Skin punch 2mm², full thickness</td>
<td>Contact laboratory secretary (020 7829 8870) for specimen container and transport medium</td>
<td>Same day, by 3pm</td>
</tr>
<tr>
<td>Fetal skin biopsy (post-termination/post-morrem)</td>
<td>1cm³ skin biopsy, full thickness</td>
<td>Universal container Send dry if possible but in sterile 0.9% saline if delay anticipated</td>
<td>Same day</td>
</tr>
<tr>
<td>Products of conception</td>
<td>With chorionic villi or fetal tissues if identifiable</td>
<td>Universal container Send dry if positive but in sterile 0.9% saline if delay anticipated</td>
<td>Same day</td>
</tr>
<tr>
<td>Placental biopsy at cord insertion site</td>
<td>1cm³ with chorionic villi or placental membrane</td>
<td>Universal container Send dry if positive but in sterile 0.9% saline if delay anticipated</td>
<td>Same day</td>
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*Testing may be compromised if a sub-optimal sample is received resulting in a delayed or failed result.

Please FAX patient details of any pre-booked prenatal sample for testing to the FAX number below.

**Sample must be labelled with:**
- Patient's full name (surname and given name)
- Date of birth and NHS number
- Referring Hospital Number
- It is desirable to have the date and time sample was taken and/or location

**Samples MUST BE PACKAGED ACCORDING TO UN PACKING REQUIREMENT 602 and be sent to the address below.**

**Address to:**
Specimen Reception  
Level 5, Barcley House  
Great Ormond Street Hospital  
37 Queen Square  
London WC1N 3BH  
Tel: 020 7829 8870 Fax: 020 7813 8578

For details of all referral criteria and policies please see our website: [www.labs.gosh.nhs.uk/laboratory-services/ genetics](http://www.labs.gosh.nhs.uk/laboratory-services/ genetics)

For Lab Use Only

Version Number: 3  
Index Code: RGF SAB0002
To: North East London Regional Cytogenetic Laboratory
   02078298870 / 02078138561, gosh.geneticslab@nhs.net,
   gos-tr.geneticsspecimnreception@nhs.net

From: Broomfield Screening Office, Broomfield Hospital
   01245513433

PRENATAL SAMPLES

AMNIO/CVS Date................................. Re-Booked to.................................

Cancellation ☐

Name
Hospital Number
DOB
Consultant
Gestation at Amnio

Previous Pregnancies (Insert Number)
LB ☐ SB ☐ MISC ☐ TOP Other ☐ TOP Social ☐ NND ☐

Reason for Prenatal Screening:
Age ☐ MAT SERUM ☐ Abnormal Scan ☐ Other Reason ☐

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Downs Risk 1 in.................