

# STANDARD OPERATING PROCEDURE

## Antenatal Trisomy Screening:

### Obtaining, recording, transporting, tracking and reporting samples.

<b>PREPARED BY : Monika Mills</b>	<b>DATE: 11<sup>th</sup> May 2022</b>
<b>RATIFIED BY : Perinatal Governance Group</b>	<b>DATE: Rapid ratification 19.5.22</b>
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<b>PURPOSE</b>
<p>The purpose of this Standard Operating Procedure (SOP) is to ensure that all relevant staff understand how Combined and Quadruple blood samples are collected, transported, tested, tracked and reported.</p>
<b>OBJECTIVE</b>
<p>To be able to provide safe Trisomy screening service to all eligible population. This includes:</p> <ul style="list-style-type: none"> <li>Combined blood test (CBT) samples up to 13+6 gestation,</li> <li>Quadruple (QUAD) bloods samples (T21 only) from 14+2 till 20+0 gestation</li> <li>PAPP-A only samples for women who decline screening but accept PAPP-A for the purpose of Tommy's app assessment.</li> </ul>
<b>SCOPE</b>
<p>This guidance is relevant to following staff groups:</p> <ul style="list-style-type: none"> <li>All staff working within Maternity including Midwives, Obstetricians, Maternity Support workers and Student Midwives.</li> <li>All staff working to manage the patient pathway - Ultrasound, phlebotomy and all clerical staff involved in the process of maternal antenatal screening</li> </ul>
<b>COMPETENCIES</b>
<ol style="list-style-type: none"> <li>1. In obtaining blood samples – Midwives, sonographers and MSWs</li> <li>2. Understating of Trisomy screening</li> <li>3. Ability to use BadgerNet.</li> <li>4. Screening team to have access and to be able to use LifeCycle Web portal.</li> </ol>
<b>PROCESS</b>
<p><b><u>1. Background</u></b></p> <p>All women attending for antenatal care before 20 weeks gestation will be offered antenatal screening for Down's, Edward's and Patau's syndromes.</p> <p>Screening is offered in 2 forms depending on gestation and technical ability to obtain certain images and measurements during USS examination.</p> <ol style="list-style-type: none"> <li>1. <b>Combined test-</b> Up to 13+6 (or Crown Rump Length of 45mm-84mm) and NT measurement, with accompanying blood serum of Beta hCG and PAPP-A. This test offers screening for Down's, Edward's and Patau's Syndromes. Recommended test for multiple pregnancies.</li> <li>2. <b>Quadruple test-</b> From 14+2 (or Head Circumference of 101 to 170mm) a blood serum of Beta hCG, AFP and uE3 and Inhibin A. This test offers screening for Down's Syndrome only. Refer to Ultrasound Guideline</li> </ol> <p>The woman may choose:</p>

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- To have screening for all 3 conditions (T21, T18, T13)
- To have screening for Down's syndrome only (T21)
- To have screening for Edward's and Patau's syndromes only (T18, T13)
- To decline all screening
- To accept PAPP-A only

## **2. Obtaining and recording samples**

- The NHS England and Improvement "*Screening Tests for You and Your Baby*" QR Code is sent to the woman by the Maternity Ultrasound Department with the scan appointment. Consent is obtained at either Booking appointment or scan and recorded on BadgerNet and viewpoint by Booking Midwife or Sonographer. Copies can also be downloaded in other languages from <https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby> Languages available include: Arabic, Bengali, Chinese, French, Latvian, Lithuanian, Polish, Portuguese, Punjabi, Romanian, Somali, Urdu. An Easy-Read version and mp3 files are also available.
- Blood sample request form is generated by the sonographer during 1<sup>st</sup> trimester scan.
- **A screening blood sample must always be taken first if a full blood count is being taken at the same time. It is important that the correct order of draw is followed.**
- Samples taken at St. Peter's will be processed by Berkshire & Surrey Pathology Services (BSPS) (located at St. Peter's Hospital). Samples taken at Ashford will be processed by Berkshire & Surrey Pathology Services at Frimley Park Hospital. Both labs will send samples to John Radcliffe Oxford University Hospital (OUH) laboratory for testing.
- PAPP-A only sample forms must have the yellow sticker stating "PAPP-A ONLY Declined CBT"
- All must be recorded as taken and by whom on BadgerNet.

## **3. Transporting Samples**

OUH provide Mon-Fri transport from Wexham Park Hospital (WPH) to OUH at 12pm.

The Oxford Screening Laboratory  
Room 4812  
Clinical Biochemistry  
Level 4  
John Radcliffe Hospital  
Headington  
Oxford  
OX3 9DU

### **ASHFORD HOSPITAL SAMPLES**

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Monday – Thursday: All samples taken are collected by BSPS shuttle and transported daily to Frimley Park Hospital (FPH). These are then transported by BSPS together with FPH samples to WPH on a daily 9 am transport. Samples are placed to the OUH box by the sendaway staff in the WPH laboratory. BSPS have SOP in place.

Friday: samples are sent to FPH laboratory where they are spun and stored until Monday morning before being sent to WPH at 09:00 (then onwards to Oxford at 12:00pm).

### ST. PETER'S HOSPITAL SAMPLES

Monday -Thursday pm: All collected samples are packed up by the BSPS Sendaway team at St. Peter's Hospital laboratory to catch the 4 pm transit from SPH to Wexham Park for onward transit to Oxford the next day at 12:00pm.

Friday: samples to be sent to FPH late pm to be held over the weekend with FPH samples to then join up with Mon 9 am transit from FPH to WPH (then onwards to Oxford at 12:00pm).

### 4. Tracking samples and failsafe

Screening team checks that all women having first trimester scan and consenting for screening on the previous working day have had bloods taken or there is a documented reason why not - e.g. declined.

CBT	QUAD	DECLINES
The screening team to complete CBT tracking every morning	The screening team to complete Quad Test tracking every Monday.	The screening team to complete Quad Test tracking every Monday.
Run Viewpoint " <b>AN screening NT search</b> " for previous days date to generate tracking list	Run Viewpoint " <b>HNC-Quad Search</b> " for previous Saturday to Friday dates to generate tracking list	Run Viewpoint " <b>AN Screening CBT Decliners</b> " for previous Saturday to Friday dates to generate tracking list

To ensure that all samples have been taken and sent to OUH by the laboratory:

- a) Cross-check tracking list with barcode list from SPH BSPS Sendaway department, e-mailed to [asp-tr.anscreening@nhs.net](mailto:asp-tr.anscreening@nhs.net) daily, showing bloods that have been sent to OUH.
- b) Cross-check tracking list with forms sent from Frimley BSPS Sendaway department lab (Ashford samples), e-mailed to [asp-tr.anscreening@nhs.net](mailto:asp-tr.anscreening@nhs.net) daily, showing bloods that have been sent to OUH.

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If all blood samples are accounted for- write "*all accounted for*", sign & date & file in FASP Tracking Screening file.

Investigating discrepancies for any woman with no matching blood sample:

**Viewpoint:** Check for explanatory notes on scan/ comments/messages.

**Badgernet:** Check 'Full Notes'- Blood Tests Section/ Clinical Notes N.B. Samples taken late in the day or at Ashford may be sent on following day.

- The screening team will contact any woman, who has not had blood taken as expected, by the end of the next working day.
- Community midwife to be informed if unable to get hold of woman, and a letter to be sent to woman by first class post.
- Tracking lists with outstanding queries are to be filed in raised position, to draw attention to them. Tracking lists to be returned to normal position once all issues resolved and signed/dated.
- Arrange for blood to be taken if she still wants testing.
- If test declined, add to decliner list on CBT database & make entry on Viewpoint and BadgerNet.
- Annotate list with action taken.

Once samples arrive at OUT data will be entered on web based portal called LifeCycle.

<https://lifecycle.oxnet.nhs.uk/>

(LifeCycle 7 is software provided by PerkinElmer; patient demographics and pregnancy details are recorded in the software, linked to the accompanying biochemistry specimen and a chance for trisomy calculated.

It allows screening team to:

- Lookup completed screening reports (and download if required)
- Review samples in process in the laboratory
- Review samples on 'hold' – these may require: Confirmation of details that are unclear on the request card o Completion of missing details or Confirmation of IVF dates and US date/measurement if the gestation calculated by scan measurement and IVF details differ by >6 days – See incomplete request forms below.
- Review increased chance samples that require actioning.
- Review increased NTs (>3.5mm) – optional search, utilised by some screening teams)

Screening team has access to this portal and will check that all samples arrived by crosschecking the laboratory sent list with the received on LifeCycle. This is to ensure that all samples are accounted for and registered for testing.

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### Incomplete request forms

- Sonographer is responsible for checking that form is complete before it is given to the woman.
- If any essential data is missing from request form, OUH laboratory will put the sample on “**Hold**” and this will be highlighted in LifeCycle. Sample will not be processed until the query is resolved. Screening team will check LifeCycle daily and will resolve any queries identified.
- All incomplete forms to be recorded on specific database which is shared with scan team quarterly. This highlights if there are individuals who are repeatedly missing info from forms.

## 5. Reporting results

All results will be available to view and download on LifeCycle.

**LOW CHANCE results** will be published on LifeCycle. Screening team will review these daily and enter results on maternity system BadgerNet for the woman to be able view her results. A letter with the low chance results will be automatically sent to the woman from OUH.

**HIGH CHANCE results** will also be published on LifeCycle. Additionally the OUH laboratory will send an email to [asp-tr.anscreening@nhs.net](mailto:asp-tr.anscreening@nhs.net) to alert the screening team of a high chance result. The screening midwife will contact the woman with the results. For further process details see Fetal Anomaly Screening Programme Policy.

Only after the woman is informed and counselled as per FASP policy will the results be published to BadgerNet.

If a risk is calculated for a women who did not opt for screening (ie pappA only requested), a DATIX should be completed so that learning can be embedded. The family must be contacted and a Duty of Candour performed.

### TERMINOLOGY

BSPS	- Berkshire Surrey Pathology Services
CBT	- Combined Blood Test
FASP	- Fetal Anomaly Screening Programme
FPH	- Frimley Park Hospital
NT	- Nuchal Translucency
QUAD	- Quadruple Blood Test
OUH	- Oxford University Hospital
SOP	- Standard Operating Procedure
SPH	- St. Peter's Hospital
WPH	- Wexham Park Hospital

### RESPONSIBILITIES and CONTACTS

All staff involved in Trisomy screening are responsible for complying with this SOP

NAME	POSITION	LOCATION	CONTACT
Monika Mills	ANNBS Coordinator	ASPH NHS Foundation Trust	01932 726152 <a href="mailto:asp-tr.anscreening@nhs.net">asp-tr.anscreening@nhs.net</a>
Sarah Watkins	ANNBS Support Midwife	ASPH NHS Foundation Trust	01932 726448 <a href="mailto:asp-tr.anscreening@nhs.net">asp-tr.anscreening@nhs.net</a>

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Katie Symons	ANNBS Failsafe Officer	ASPH NHS Foundation Trust	01932 722903 <a href="mailto:asp-tr.anscreening@nhs.net">asp-tr.anscreening@nhs.net</a>
Ultrasound Dept.		ASPH NHS Foundation Trust	01932 722665 <a href="mailto:asp-tr.maternityreferrals@nhs.net">asp-tr.maternityreferrals@nhs.net</a>
Ian Smith	Screening and Point of Care Testing Manager	Oxford University Hospital Foundation Trust	01865 221638 Ian.Smith@ouh.nhs.uk
Rhiannon Marr	Senior Biomedical Scientist	Oxford University Hospital Foundation Trust	01865 220488 <a href="mailto:Rhiannon.marr@ouh.nhs.uk">Rhiannon.marr@ouh.nhs.uk</a>
Sendaway Dept. SPH		BSPS Laboratory SPH	Ext. <a href="mailto:bloodsciences@nhs.net">bloodsciences@nhs.net</a>
Sendaway Dept. FPH		BSPS Laboratory FPH	01276 604196 <a href="mailto:michaela.munday@nhs.net">michaela.munday@nhs.net</a> ; <a href="mailto:evangeline.wilcox@nhs.net">evangeline.wilcox@nhs.net</a>
<b>AUDIT</b>			
This SOP will be reviewed after three years or sooner as a result of audit findings or as any changes to practice occurs.			

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