

Trust Guideline for the Management of Antenatal & Newborn Screening Blood Results

Document Control:

For Use In:	Norfolk and Norwich University Hospital NHS Foundation Trust		
	Obstetrics		
Search Keywords	Antenatal Screening, Booking bloods, Screening bloods, Infectious diseases, haemoglobinopathies, Antenatal bloods, Blood results, Screening, Needlephobia.		
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Approved By:	Maternity Guidelines Committee and Nursing, Midwifery and Clinical Professional (NMCP) Forum		
Ratified By:	NM&CP Board		
Approval Date:	14/07/2023	Date to be reviewed by: This document remains current after this date but will be under review	14/07/2026
Implementation Date:	14/07/2023		
Reference Number:	AO15 Trust Docs ID 853		

Version History:

Version	Date	Author	Reason/Change
V14	2020	Alison Evans	Updated guideline
V15	2023	Charlotte Aldous	Booking bloods to be repeated for those who transfer in to NNUH, attendance criteria to clinic settings. Re-offering serology screening during pregnancy. Inclusion of eligibility for neonatal Hepatitis B vaccination.

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Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
Management of routine blood tests in Obstetrics including Antenatal and Newborn screening results	October 2015
Guideline on the management of results	July 2008
Guideline for the management of results in Obstetrics and Gynaecology	March 2012
Guideline for the management of results in Obstetrics and gynaecology	July 2015
Management of results in Obstetrics	June 2018
Management of results in Obstetrics and gynaecology	June 2016

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:
Antenatal Screening Coordinator, Consultant Obstetrician, Consultant Gynaecologist, Consultant Haematologist

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to individual Trust; please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

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1. Introduction

1.1. Rationale

It is important to the quality of patient care that there is a robust system to deal with all tests initiated, so that the results are relayed to the relevant staff and the necessary action taken within the appropriate timescale.

1.2. Objective

The objective of the clinical guideline is to ensure that there is a robust system for the management of results from routine blood tests, with particular reference to antenatal and newborn screening results. There must be clear responsibility for checking results and abnormal results must be brought to the attention of the relevant clinician in a timely manner. Once alerted this clinician can then take responsibility for acting on that result appropriately, using this document as a reference point. Each clinical area will have different processes in place due to the nature of tests being undertaken. This document will only deal with tests offered routinely throughout pregnancy and in the neonatal period.

1.3. Scope

The purpose of document is to provide direction on the management of Antenatal and Newborn Screening Bloods Results. The scope of the document covers patients who have Antenatal and Newborn Bloods screening at the Norfolk and Norwich Hospital or transfer their care to this trust. This guideline should be reviewed by all medical staff and implemented to prevent incidents occurring.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
ANSC	Antenatal & Newborn Screening Coordinator
UKNSC	UK National Screening Committee
ANC	Antenatal Clinic
IVDU	Intravenous Drug Use
NT	Nuchal Translucency

2. Responsibilities

All health care professionals to fully comply with this guideline to ensure timely review and management of results.

3. Policy Principles

3.1. Antenatal Investigations – routine

A wide range of routine diagnostic and screening tests are offered and performed antenatally. The majority of these tests are initiated in the community and recorded in the handheld and electronic maternity records; however, some of these tests may be initiated in hospital if the patient is attending for other reasons.

Responsibility for interpreting the results of these tests and taking the appropriate action rests with the doctor or midwife requesting the tests. There is a designated

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Antenatal & Newborn Screening Coordinator (ANSC) responsible for actioning all positive results for each of the UK National Screening Committee (UKNSC) antenatal screening programmes.

Ideally, women should have access to information about screening before she is consented for the test. The UKNSC booklet “Screening tests for you and your baby” should be accessible to women at the point of making her booking appointment. A link on the Trust’s pregnancy self-referral page takes women to further information about screening tests and the UKNSC “Screening tests for you and your baby” booklet. This booklet is available in English, a number of different languages in HTML versions and other formats including Easy read versions and audio downloads.

3.1.1. Booking bloods

At first presentation in a pregnancy a series of blood tests are offered to the woman despite gestation, including the UKNSC recommended screening tests. This means that women who book late in pregnancy (after the twelfth completed week of pregnancy) are offered the same tests as those booking early in their pregnancy.

These include:

- Full blood count
- Blood group and antibody screen
- Sickle cell and thalassaemia screening
- Infectious disease screening
 - Hepatitis B status
 - HIV status
 - Syphilis status

Screening for Down, Edwards and Patau syndromes is also offered at booking but is gestation dependant. The combined test is offered between 11+2 – 14+1 weeks, offering screening for all three conditions and the Quadruple test is offered between 14+2 and 20+0 weeks screening for Down syndrome only.

At 28-32 weeks the full blood count and blood group and antibody screen are repeated. If any other screening tests have been previously declined they will be re-offered at this point.

NHSE recommend that all patients have antenatal screening results processed within a UKAS accredited laboratory, however not all UK Hospitals achieve UKAS accreditation. It is therefore the recommendation of the NNUH that if a patient transfers their antenatal/intrapartum care to the NNUH from another trust, due to the difficulty in being able to verify laboratory accreditation all patients who have not had their Antenatal Screening tests processed by the NNUH Laboratory are reoffered: Full blood count with Sickle cell and thalassaemia screening, Blood group and antibody screen and Infectious disease screening (Hepatitis B, HIV, Syphilis) at the

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booking assessment. If this offer is declined, the consenting clinician must document this on the electronic maternity record.

Training for antenatal and newborn screening is provided for all midwives as part of their annual mandatory training. Where a midwife is moving out to work in the community setting, part of her induction will include time spent with the ANSC to ensure they are updated and familiar with all tests and processes. This is also part of the Induction programme for any midwife new to the Trust.

3.1.2. Booking bloods – Process for reviewing results

Most of the booking and 28-32 gestation blood tests are initiated in the community. Normal results are accessible on ICE both in the Hospital and community settings. All results are checked daily by Antenatal Clinic (ANC) Midwives and where action is required, such as low haemoglobin, they will ensure the GP is notified. Where a sample has been rejected or not tested for some reason, the ANC Midwives/Antenatal Screening Midwives will inform the community midwife of need to repeat. All rejected Antenatal Screening Programme Bloods should be repeated **within 10 working days (see appendix 1)** and not rebooked to coincide with future appointments. Delay in repeating these samples may delay diagnosis and essential treatment. Women are informed of their normal results at their 16-week appointment with their community midwife when the results are documented in their hand held and electronic records.

3.2. Abnormal or screen positive results – process for review, referral and management

3.2.1. Abnormal red cell antibodies

Abnormal red cell antibody results are sent to ANC for action. A Consultant will review and either the patient will be contacted by the ANC midwife and asked to attend the next appropriate Consultant appointment or the community midwife will be informed re need for repeats and partner testing where required. Where the antibody level is high and requires Fetal Medicine input, the Laboratory contacts the ANSC who will arrange a Fetal Medicine appointment and contact the woman directly.

3.2.2. Vertically transmitted infections

HIV, syphilis, hepatitis B and hepatitis C are all blood borne viruses that can be passed from mother to fetus (vertical transmission). In the UK, HIV and hepatitis B serology tests are performed as part of routine antenatal screening, with the aim of identifying mothers infected with these viruses. The rationale is to identify women infected to offer intervention to improve their own health and reduce the risk of transmission to their child. Children born to mothers known to have a BBV can then be tested for these viruses and offered treatment if required.

Testing for hepatitis C is **not** performed routinely, but should be offered to those at risk: -

- Current intravenous drug use (IVDU)
- Past intravenous drug use
- HIV or hepatitis B infection
- Sharing drug taking equipment i.e. spoons/filters/pipes

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- Having undergone a blood transfusion before 1991
- Having sexual intercourse with someone known to carry HIV, hepatitis B or hepatitis C
- Having medical or dental treatment in parts of the world where the virus is more common (e.g. Africa, Eastern Europe, Central and East Asia) and needles may be reused or equipment not sterilised effectively
- Unsterile body piercings/tattoos/acupuncture

All women receive information about routine screening tests and if the woman understands the risks and benefits of the test, informed consent is obtained and the blood tests taken preferably at the booking appointment. All negative results should be communicated and documented in the woman's electronic and hand held records.

If positive results are obtained, then the ANSC and the obstetrician in charge of the woman's care should be informed of the results to arrange an appointment so the results can be disclosed and explained in person. Mothers found to have hepatitis C should be referred to a specialist hepatitis C treatment service for follow up, regardless whether treatment is considered appropriate or not.

The Microbiology Laboratory will notify any positive infectious disease screening results to the ANSC, the result will be available to the GP on ICE. The result is emailed to the ANSC via a generic screening email address and the Laboratory will phone to confirm it has been sent and received. Women will be contacted directly by the ANSC or deputy and given the appropriate follow up as per the infectious disease pathway (appendix 2) (Appendix 3 syphilis positive pathway). **See guidelines AO33 – hepatitis B screening and AO21 – HIV in pregnancy hyperlink** for more specific guidance. If the woman miscarries, the ANSC will contact the woman either directly or via their GP to ensure appropriate referrals are made. All screen positive results are documented in a spreadsheet kept on the "S" drive, accessible by the Consultant Neonatologist with special interest in blood borne viruses. The Neonatologist uses this to check that a NICU alert has been received and that a plan is in place for delivery and neonatal management. The Chief Biomedical Scientist leading the screening programme in the laboratory will cross check the spreadsheet on a monthly basis. This ensures that all cases have been dealt with within an appropriate timescale.

Where a service-user declines screening for any of the infectious diseases in pregnancy, the ANSC or deputy will meet the service-user at scan or contact via telephone to explore the reasons for declining and at this point will re-offer screening. This is to ensure the woman has made an informed choice and understands the benefits of screening. If the service-user declines a formal reoffer the ANCS or deputy will inform the registered GP via letter that booking bloods have been rejected and inform the responsible consultant to allow care planning. If vulnerabilities place the service user at higher risk, a NICU alert will be completed so the Neonatologists can assess whether to test the baby after birth. For those that decline blood test screening due to a needlephobia, the needlephobia pathway should be initiated (see Appendix 4, Needlephobia Pathway).

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Families with babies born and considered at risk of Hepatitis B will be offered immunisation – these should include babies born to:

1. Primary caregiver(s) with a history of current or previous substance abuse e.g. heroin, crack cocaine
2. Primary caregiver(s) on Methadone Programme
3. Human immunodeficiency virus (HIV) positive mothers
4. Hepatitis C Virus (HCV) positive mothers
5. Mothers from high HBV prevalence area with unknown HBV status (a country has 'high prevalence if the chronic infection rate is >8%. <http://www.medic8.com/travel/viral-hepatitis-b.htm>)
6. Father known hepatitis B carrier.

(Trust Guideline for the Immunisation of Infants at Risk of Hepatitis B Infection Trust Docs 1183).

A woman presenting in labour should be encouraged to have screening for infectious diseases as these women are often vulnerable with higher risk factors. Urgent testing can be performed (see guideline for the management of concealed or undiagnosed pregnancies (ID16848). Delivery Suite staff must inform the ANSC to inform to ensure correct follow up of results.

Screening for infectious disease can be re-offered at any stage of pregnancy if a service-user is deemed to be at risk of contracting a vertically transmitted disease. Repeat tests will be offered and recommended if a woman changes her sexual partner, she or her partner are sexually active with other people, her partner is diagnosed with or suspected to have a sexually transmitted infection (STI), she injects recreational drugs, is a sex worker, or for any woman who requests a test. In addition women must be made aware at the booking appointment about the availability of sexual health testing at any stage of pregnancy and to report any symptoms of genitourinary infection as soon as possible.

At the booking appointment when discussing infectious disease, midwives are to advise women to report any rash or rash-like illness to their midwife or GP as soon as possible to facilitate appropriate management of viral rash in pregnancy. The woman will be advised to avoid attending any clinic setting or contact with other pregnant women until advised it is safe to do so. At this booking appointment, service-users must also be directed to the information on vaccinations in pregnancy.

3.2.3. Sickle cell and thalassaemia

Sickle cell and thalassaemia – screen positives (see **guideline AO35 – Management of haemoglobinopathies in pregnancy** [Trustdocs ID 846](#) for full screening process and the Sickle cell and thalassaemia Antenatal and Linked screening pathways).

Where a woman is identified as a carrier of or being affected by a haemoglobinopathy the ANSC is informed directly by phone from the Laboratory and partner testing is requested. A report will go back to the GP stating that partner

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testing will be instigated by ANC. The woman will be contacted by the ANSC or deputy by phone to discuss the result. An appointment at the hospital will be offered to discuss the result further and offer partner testing if required. If the couple prefer, a blood request form for the partner will be sent with a letter and national sickle cell and thalassaemia screening programme information leaflets so that the partner can be tested locally. Where there are language difficulties, an appointment will be offered for the woman with a face-to-face interpreter present where possible.

All haemoglobinopathy screen positive results are documented in a spreadsheet kept on the "S" drive, accessible by the Laboratory and a separate one for high-risk couples, accessible by the Consultant Neonatologist with special interest in haemoglobinopathies. Documented details include patient details, result, management plan, partner details (when known), partner result and action taken. The Neonatologist uses this to check that a NICU alert has been received and that a plan is in place for delivery and neonatal management.

It is the responsibility of the ANSC or deputy to document the details on the spreadsheet which is then cross-checked on a monthly basis by the Chief Biomedical Scientist leading the screening programme in the laboratory. This ensures that all cases have been dealt with within an appropriate timescale.

3.2.4. Down's, Edward's and Patau's Screening

Down, Edwards and Patau syndrome screening (See guideline AO25 "Antenatal screening for Trisomy 21, Trisomy 18 and Trisomy 13" [Trustdocs Id 836](#) and the Down, Edwards and Patau syndromes screening pathway for detailed information).

Screening for Down, Edwards and Patau screening is performed by the combined test and the Quadruple test, dependant on gestation. Women will be given the option to be screened for all or some of the syndromes depending on the test available.

All combined tests are performed on the Trust site via ANC/ultrasound and phlebotomy. A checklist is kept everyday of women undergoing NT scans or requiring quadruple tests following their dating scans in ultrasound. This is checked against the Laboratory worklist to ensure all expected samples of blood are received. Where a nuchal translucency measurement is unobtainable the woman is advised to see her community midwife for a quadruple test at around 16 weeks. The community midwife is informed by the Antenatal Screening Midwives and a copy of the scan report is put in the Quadruple test folder kept in the Antenatal Screening Office. The Screening Failsafe Officer checks the folder weekly to highlight women where a Quadruple test sample has not been received by 18-19 weeks gestation in order for the woman to be contacted by the ANSC and arrangements to be made if still requested. These systems are to try and ensure all women opting for screening for Down, Edwards and Patau syndromes, receive it.

Women having the Quadruple test have the test performed, ideally, at 15 to 16 weeks gestation. The majority of these tests will be performed by the community midwife. Any request forms that reach the laboratory but have missing data (i.e. weight or scan data), will be sent by email to the Antenatal Screening team so that the additional information can be obtained and added in order for the result to be correctly calculated. If missing data has not been received within 3 working days the

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laboratory contacts the ANSC directly. For either test, women are advised to contact the ANSC or ANC if they have not received their results within 10 -14 working days of being tested.

Copies of all combined test results are collected daily by the Screening Failsafe Officer who cross checks against women who have had tests to ensure all results are received in a timely manner. Low chance results are shredded as they are stored electronically; Quadruple test results will be emailed to the NNUH Laboratory by Antenatal Screening Laboratory, Addenbrookes where they are performed. These are then stored on the "S" drive and are accessible to the ANSC and Screening Failsafe Officer in order to ensure all results are received.

Women are informed of their "low chance" result by letter sent directly from the laboratory.

All "higher chance" results, both combined and quadruple tests, are emailed to the antenatal screening team. Upon receipt of the email, the ANSC or deputy is responsible for checking the hospital notes and confirming the details on the result are correct e.g. ultrasound scan date and measurements. If any details are incorrect the laboratory is asked to re-calculate the risk assessment based on the correct information.

Once all details are confirmed, the woman is contacted directly by phone by the ANSC or deputy. The patient is informed of the result and counselled over the phone concerning her options. She will be offered an appointment at the hospital for non-invasive pre-natal testing, invasive testing or simply to discuss the result in more detail at a Fetal Medicine Clinic appointment. Where it has not been possible to contact a woman during office hours the details are given to a community midwife who informs the woman of her result and offers a Fetal Medicine appointment, usually the next day, to attend the hospital to be counselled. See **guidelines AO24 Prenatal Testing for Fetal Chromosome Abnormality** [Trustdocs id 874](#) for full screening and prenatal testing guidelines (Down, Edwards and Patau syndromes screening pathway – appendix 3). If a woman declines prenatal diagnosis the GP and community midwife are informed of the result and a NICU alert is completed to enable swift examination of the baby after birth.

All "higher chance" results and action taken are documented on a spreadsheet on the "S" drive accessible by the Screening team and the laboratory. This spreadsheet is checked weekly by the ANSC or deputy, and Chief Biomedical Scientist leading the screening programme in the laboratory, ensuring higher chance results have been dealt with within an appropriate timescale.

3.2.5. Newborn Bloodspot Screening Test

See **The Trust Guideline for the Newborn Bloodspot Screening test (MID10v3)** for full details. [Trustdocs Id No: 796](#)

All babies are offered a Newborn Blood Spot screening test to identify a number of rare genetic disorders as recommended by UKNSC. These include:-

- Phenylketonuria (PKU)

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- Congenital Hypothyroidism (CHT)
- Sickle cell disease (SCD)
- Cystic Fibrosis (CF)
- Medium Chain acyl-CoA dehydrogenase deficiency (MCADD)
- Maple Syrup Urine Disease (MSUD)
- Isovaleric acidaemia (IVA)
- Glutaric Aciduria Type 1 (GA1)
- Homocystinuria (pyridoxine unresponsive) (HCU)

Any relevant history should be noted on the Newborn Blood Spot sample e.g. mother of baby is HbAS carrier.

Normal results are reported to Child Health Department who inform the parents by letter. The Newborn Screening Laboratory contacts the ANSC via a generic screening email if a repeat sample is needed with the reason noted. The community midwives are informed of the need for repeat by the Screening Failsafe Officer

The Trust uses the National Newborn Blood Spot IT Failsafe System which flags up babies where samples have not been received by day 12 of age. This is checked by the Screening Failsafe Officer who informed the ANSC/deputy of any delayed tests. The Team responsible for the care of the baby is informed ensuring a sample is sent.

3.2.6. Abnormal results – process for review

There is a named Paediatric Consultant responsible for providing care for each condition identified on Newborn Bloodspot Screening. The Newborn Screening Laboratory contact the named consultant directly by phone with an abnormal result, followed up by a hard copy. The named consultant or one of their team will contact the parents directly and offer an appointment, usually the next day, to discuss the result and organise care. The Laboratory email the ANSC for information.

Abnormal blood results for haemoglobinopathies should be entered into the Newborn Outcomes System to support referral of screen positive infants from screening laboratories into treatment services by the named paediatric lead (see trust doc 846).

3.3. Safety Screening Incidents

Due to the nature and characteristics of screening tests, safety incidents within screening programmes require special attention and management. (Ref. no. 6) Where an incident occurs along any of the UKNSC screening pathways the ANSC should be informed and the UKNSC document “Managing Safety Incidents in NHS Screening Programmes; August 2017” referred to.

The UKNSC guidance defines screening safety incidents as including:

- Any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme

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- Harm or a risk of harm because one or more persons eligible for screening are not offered screening

Occasionally a safety incident needs to be declared as a Serious Incident. The UKNSC guidance defines a Serious Screening Incident as,

“where the consequences ...are so significant to individuals, families and carers, populations, staff or organisations, or represent such significant potential learning for the NHS, that a heightened level of response is warranted.”

In the event of an incident being identified the ANSC will refer to the guidance document and use the relevant section to report the incident to NHS and Public Health England and Regional UKNSC Quality Assurance teams. Advice will be sought from them as to the classification of the incident. The ANSC will ensure a DATIX is completed for the Trust and will investigate the incident. All incidents will be discussed at the Trust Antenatal and Newborn Screening Steering Group so lessons can be learned and changes made to processes and pathways if required.

4. Training & Competencies

Please refer to the Maternity Training Needs Analysis [Trust Docs ID 8649](#).

5. Related Documents

Guideline Number	Title	Trust Docs ID
Guideline AO35	Management of haemoglobinopathies in pregnancy	Trust Docs ID 846
Guideline AO33	Hepatitis B Screening in Pregnancy and Neonatal Vaccination	Trust Docs ID 847
Guideline AO21	HIV in pregnancy	Trust Docs ID 1185
	Management of Syphilis in pregnancy	Trust Doc ID 18707
Guideline AO25	Antenatal screening for Trisomy 21, Trisomy 18 and Trisomy 13	Trust Docs ID 836
Guideline AO24	Prenatal Testing for Fetal Chromosome Abnormality	Trust Docs ID 874
Guideline MID10	Newborn Bloodspot Screening Test	Trust Docs ID 796
Guideline Mid 37	Maternity Training Needs Analysis	Trust Docs ID 8649

6. References

1. Antenatal Care – NICE guidance: routine care for the healthy pregnant woman (March 2008)
2. Fetal anomaly screening programme: Down’s syndrome, Edwards’ syndrome and Patau’s syndrome screening Handbook for Laboratories. August 2018
3. Managing Safety Incidents in NHS Screening Programmes: August 2017
4. PHE Fetal Anomaly Programme Standards 2015-16
5. PHE Infectious Disease Screening in Pregnancy Programme Handbook 2016 to 2017
6. PHE Sickle Cell and Thalassaemia Screening Programme: Antenatal Screening Guidance 2018

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7. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Population Screening HIV at NNUH uptake	Quarterly review and submission to NHSE	ANNBS Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Population Screening Hepatitis B at NNUH uptake	Quarterly review and submission to NHSE	ANNBS Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Population Screening Syphilis at NNUH uptake	Quarterly review and submission to NHSE	ANNBS Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Avoidable Repeat NNST quarterly	Quarterly review and submission to NHSE	ANNBS Team	Antenatal and Newborn Steering Group Meeting	Quarterly
Population Screening SCT at NNUH uptake	Quarterly review and submission to NHSE	ANNBS Team	Antenatal and Newborn Steering Group Meeting	Quarterly

The audit results are to be discussed at relevant governance meeting such as Clinical Governance, Antenatal and Newborn Steering Group Meeting and externally at NHSE Antenatal and Newborn Screening Board Meetings. These groups will review the results and recommendations for further action. Then sent to the relevant committee or Sub-Board who will ensure that the actions and recommendations are suitable and sufficient.

8. Appendices

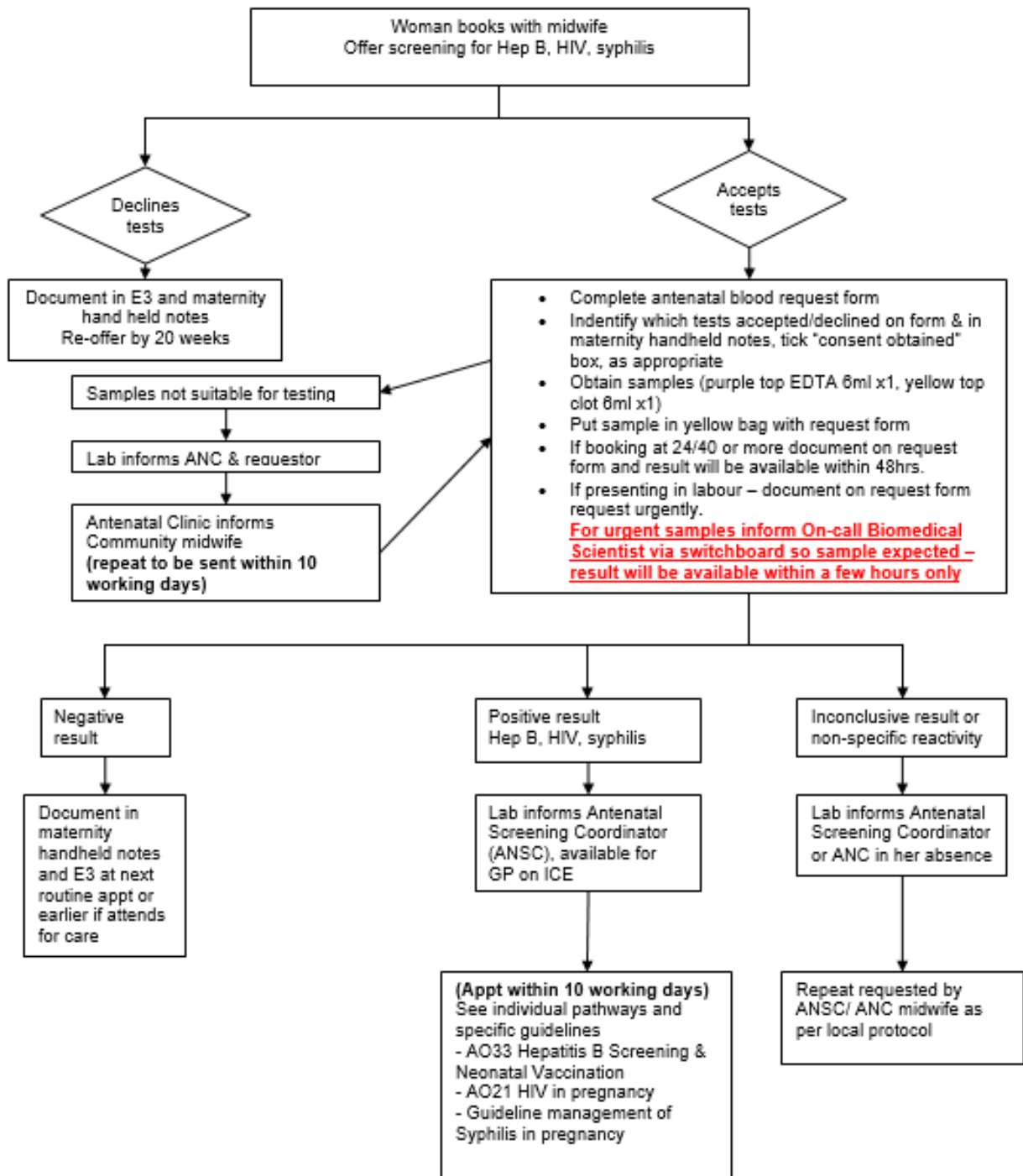
1. SOP for rejected Antenatal Screening Programme blood tests
2. Infectious disease screening pathway
3. Syphilis positive pathway
4. Needlephobia in pregnancy pathway

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Appendix 1- SOP for rejected Antenatal Screening Programme blood tests

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Appendix 2- Infectious Disease Screening Pathway



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Appendix 3- Syphilis Positive pathway

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Appendix 4- Needlephobia in pregnancy pathway

Below action to be taken when service user discloses needlephobia.

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9. Equality Impact Assessment (EIA)

Type of function or policy	Existing
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Division	Women and Children	Department	Maternity and Gynaecology Care
Name of person completing form	Charlotte Aldous	Date	23/11/2022

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	None	N/A	No
Pregnancy & Maternity	None	None	N/A	No
Disability	None	None	N/A	No
Religion and beliefs	None	None	N/A	No
Sex	None	None	N/A	No
Gender reassignment	None	None	N/A	No
Sexual Orientation	None	None	N/A	No
Age	None	None	N/A	No
Marriage & Civil Partnership	None	None	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?	N/A			

<ul style="list-style-type: none"> A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service The policy or function/service is assessed to be of high significance
IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED
<p>The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.</p>