



Public Health  
England



# NHS Infectious Diseases in Pregnancy Screening Programme Laboratory Handbook 2016 to 2017

Public Health England leads the NHS Screening Programmes



## About Public Health England

Public Health England (PHE) exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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## About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the United Kingdom National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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[www.gov.uk/topic/population-screening-programmes](http://www.gov.uk/topic/population-screening-programmes)

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Prepared by NHS Infectious Diseases in Pregnancy Screening Programme team

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# Introduction

This document presents the revised Laboratory Handbook for the NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme 2016 to 2017. It was developed in collaboration with laboratory advisers and members of the IDPS Laboratory Task Group (Appendix 1).

The first edition of the Handbook for Laboratories was published in 2010 and updated with minor modifications in 2012. It brought together the various policies, standards and guidance for laboratories that undertake screening for infectious diseases in pregnancy and established a uniform national framework for the testing protocols.

The aim of this handbook is to guide screening laboratory teams that process specimens for the IDPS Programme and highlight the requirements for screening. It is linked to the wider programme standards and service specifications and will be of relevance to service providers, commissioners and those responsible for quality assurance in the operational delivery of the screening pathway.

The handbook has been cross-referenced to International Standards Organisation **ISO 15189** 'Medical laboratories – requirements for quality and competence', to reduce duplication of effort and resources for laboratory quality assurance.

## Related documents

The handbook is part of a suite of documents that are reviewed and updated annually.

1. **Service specification** 2016-17 (No.15). This document outlines the service and quality indicators expected by NHS England in line with the recommendations and standards of the United Kingdom National Screening Committee (UK NSC).
2. **Programme standards**. This document focuses on process standards to enable providers and commissioners to continuously improve the quality of the screening programme. It defines a set of variable standards with metrics relating to screening for HIV, hepatitis B and syphilis. The standards view the entire screening pathway and are based on the 10 themes that assess the whole pathway.
3. **IDPS programme handbook**. This handbook provides operational guidance to inform and support best clinical practice in the delivery of the IDPS programme. This practical guidance supports healthcare professionals and stakeholders in the operational delivery of the screening pathway.

# NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme

## General principles of screening

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition. Further information regarding the general principles of screening can be found on [GOV.UK](https://www.gov.uk).

An antenatal and newborn screening [timeline](#) illustrates the screening tests that are offered and the optimum times for testing.

## Screening policy

[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 UK NSC recommends that systematic, population screening in pregnancy is offered and recommended to all eligible women for:

- HIV
- hepatitis B
- syphilis

The IDPS programme aims to:

- ensure equal access to uniform and quality assured screening across England
- 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 at all or 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, are seen by the IDPS multidisciplinary team (MDT) within specified timescales

## Standards, accreditation and quality assurance

All commissioners and service providers should refer to the public health functions agreement (Section 7A) **IDPS service specification (No 15)**, and supporting **standards** and **handbook** to ensure a programme is set up correctly and meets the standards set by the national screening programme.

Laboratories offering screening for the IDPS programme must:

- be accredited to ISO- 'Medical laboratories – requirements for quality and competence (**ISO 15189**)' or be CPA accredited and actively transitioning towards ISO 15189
- participate in EQA schemes accredited to ISO- 'Conformity assessment. General requirements for proficiency testing schemes (ISO 17043)'
- meet IDPS programme screening quality assurance requirements

The **UK Accreditation Service (UKAS)** will assess both the ISO and the screening requirements on behalf of **PHE Screening Quality Assurance Services (SQAS)** and the **IDPS Programme**.

## Risk management, audit and external quality assurance

The laboratory must have effective procedures to assess and manage safety and performance, including:

- documented risk management policy for the laboratory as part of the overall risk management arrangements for the screening pathway
- audit schedule in line with screening risks and performance requirements
- procedures to audit and ensure screening is completed, from point of receipt of the sample to communicating all results to clinicians
- compliance with the NHS Screening Programmes **guidance for managing safety incidents**
- provision of **KPI** data and screening activity data to NHS Screening Programmes
- participation in ISO accredited external quality assurance schemes

## Organisation, leadership and responsibilities

The initial screening tests for any of the three infections, HIV, hepatitis B and syphilis, must be performed in a single laboratory or within a single multidisciplinary pathology department to ensure efficient coordination of the results for each woman. The laboratory must have robust oversight and leadership of screening, including:

- senior leadership for screening in the laboratory with a named senior member of staff at consultant or clinical scientist level accountable for the IDPS screening service at all times
- contingency plans for screening
- participation in cross-organisational and multidisciplinary arrangements, including the IDPS MDT as described in the screening programme handbook
- management review of screening and contribution to the provider's annual screening report

## Communication and collaboration

The laboratory must have good communication and collaboration with other services in the screening pathway, including:

- documented procedures for communication with other services
- formal service level agreements and standard operating procedures with referral laboratories for confirmatory testing
- incorporation of screening into the laboratory quality management system
- standard operating procedures to track samples from point of receipt to authorization and reporting of screen positive results to clinical services
- inclusion of users in assessment and review

## The IDPS Multidisciplinary Team

“...a well-functioning team is much more fun to work in!”

Peter Kohn, Director – Office of CCGs

A **multidisciplinary approach** is vital to:

- improve health and well-being outcomes for women and their babies
- ensure women are seen by the most appropriate clinician in a timely manner
- ensure the delivery of person-centred coordinated care
- empower women in managing their condition
- facilitate and enable informed choice
- reduce health inequalities by equity of access to co-ordinated MDT services
- make best use of finite resources, avoiding duplication

Accurate and timely communication and handover between all professionals involved in the screening and clinical pathways in acute and primary care settings is essential to reduce the potential for errors and ensure a seamless pathway for service users. It is important that named clinical responsibility remains clear at all times and that the clinical responsibility is clarified at handover of care.

Current clinical guidelines (**BHIVA** page 43 and **BASHH** page 734) on the care of pregnant women with HIV and syphilis, endorse the MDT approach to the screening and clinical pathways. This approach provides the opportunity for the management of women with more than one infection and also to manage more effectively any social issues that many of these women have.

An MDT approach involves use of knowledge, skills and best practice from multiple disciplines and across service provider boundaries. An effective MDT depends on robust working relationships. The membership of the IDPS MDT will vary locally and may include some or all of the professionals in Figure 1. The screening coordinator/team should oversee the screening programme and act as a link between other members of the IDPS MDT.

The laboratory team is integral to the delivery of the screening pathway and functions of the IDPS MDT. There must be representation from the laboratory team on trust screening governance groups.

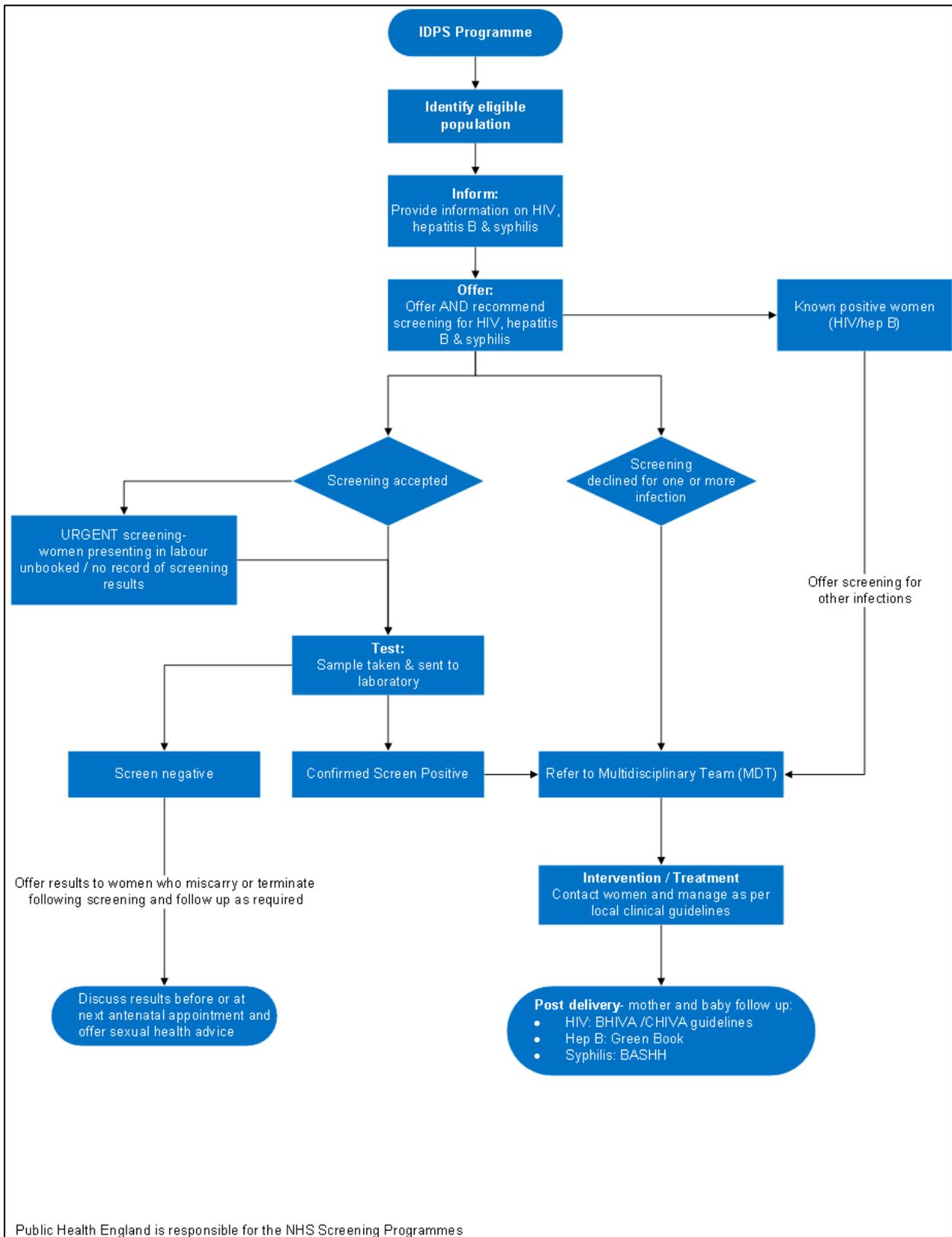
**Figure 1. Membership of the IDPS multidisciplinary team**



The screening MDT should:

- demonstrate knowledge of the range of local health and care services including the voluntary and community sector
- take responsibility for coordinating the care planning process and ensuring that identified activities and interventions take place as agreed
- liaise with other providers to ensure delivery of the care plan
- monitor and review care plans and agreed outcomes in partnership with the woman and to evaluate outcomes
- provide direct care and support where appropriate throughout the pregnancy

# The screening pathway



Each condition has a **screening pathway** that describes a woman's 'step by step' journey from booking to delivery. The pathway goes from identification of the eligible population and the offer of screening through to timely referral and entry into care and specialist services. The pathway correlates with the themes of the **programme standards**. Healthcare professionals must be familiar with these pathways and the timeframes for referring women in line with the programme service specification.

This section highlights the areas of the pathway relevant to the screening laboratory.

## Offer

**Offer:**  
Offer and recommend screening for HIV, hepatitis B and syphilis

All women booking for antenatal care should be offered and recommended screening for each of the 3 infections: HIV, hepatitis B and syphilis. The screening tests must not be offered as a suite of tests.

There should be a local process in place to identify and follow up women who have declined screening including:

- documenting acceptance or decline for each of the individual screening tests in the patient held record / maternity notes (paper or electronic) and on the laboratory request form or electronic requesting system
- clearly identifying the specific infection(s) requested on the laboratory request form
- the midwife booking and offering the screening and/or the laboratory should notify the screening coordinator / screening team as soon as possible to facilitate the formal reoffer by 20 weeks' gestation
- notifying the screening coordinator / screening team directly to follow up any women who decline screening for all three infections



If the woman declines the formal reoffer of screening, the MDT will be responsible for further management in line with local protocols. The onus of the reoffer is to facilitate an informed choice, not to coerce women to accept screening.

Known positive women (HIV / hep B)

A screening test is not necessary if a woman discloses that she is positive for HIV or hepatitis B. However, this information must be recorded in the maternity notes and on the laboratory request form irrespective of local policy concerning retesting of known positive women.

This should be recorded as 'known positive' on the laboratory request form and reported accordingly to the screening coordinator to ensure timely referral to the local MDT. The local service should offer the woman screening for the other infections and refer her directly to the local MDT for assessment and management of her condition within 10 working days as per IDPS **screening standard No 5**.

A system should be in place to ensure tests are offered and performed for all women presenting in labour who are either unbooked or with no reliable laboratory evidence of screening results.

Urgent screening-women presenting in labour/unbooked/no record of screening results

If this has not happened on delivery suite, screening should be offered prior to discharge from maternity services.

1. The maternity service should liaise directly with the laboratory to ensure the laboratory has the necessary clinical information to inform prompt analyses.
2. Point of care tests should not be used for routine screening purposes.
3. There should be robust processes to ensure all results are obtained, reported and managed appropriately.
4. The screening coordinator / specialist midwives should be informed of any woman screened on delivery suite/postnatal wards to ensure appropriate tracking and follow-up.

## Request process

Test  
Sample taken and sent to laboratory

Screening laboratories must be able to identify antenatal samples as distinct from other samples they receive and should be able to match these samples to a specific maternity service.

In particular:

- the specimen must be clearly identified as an antenatal screening sample
- the request form or electronic data request fields must be compliant with the minimum data fields (Table 1).

**Table 1. IDPS Minimum Data Fields for Laboratory Request Forms/Electronic Requesting**

No	Data category	Data fields	Rationale for inclusion (service specification / ISO 15189 and IDPS)																								
1.	Type of sample	<b>ANTENATAL SAMPLE</b>	ISO 15189 5.4.3. (c) IDPS programme requirement, must distinguish antenatal from other samples.																								
2.	Identification of the pregnant woman	<ul style="list-style-type: none"> <li>NHS Number</li> <li>Hospital Number</li> <li>Forename</li> <li>Surname</li> <li>Estimated Date of Delivery (EDD)</li> <li>Address- first line and postcode</li> <li>Date of Birth</li> <li>GP name and/or GP Code</li> </ul>	ISO 15189 Request Information. 5.4.3. (a) Must have sufficient information to allow unequivocal identification of the pregnant women.																								
3.	Name / location of requesting individual and where to send the results	<ul style="list-style-type: none"> <li>Name of person completing the request</li> <li>Location of requestor - ANC / GP surgery etc.</li> <li>Maternity unit booked for delivery</li> <li>Results &amp; report to: name and location (if different from above)</li> </ul>	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	<ul style="list-style-type: none"> <li>Name and location of person taking the sample</li> <li>Date and time of sample collection</li> </ul>	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	<ul style="list-style-type: none"> <li><b>INITIAL</b> antenatal screening sample</li> <li><b>REPEAT</b> antenatal screening sample (inadequate first sample)</li> <li><b>REPEAT</b> sample to exclude recent infection</li> <li><b>INITIAL</b> sample taken after previous decline</li> </ul>	ISO 15189 5.4.3 (g) IDPS requirement. Must be clear to enable sample status, tracking and monitoring turnaround times.																								
6.	Examinations requested	<table border="1"> <thead> <tr> <th rowspan="2">(to complete)</th> <th colspan="2">Status unknown</th> <th colspan="2">Known positive</th> </tr> <tr> <th>Accepted</th> <th>Declined</th> <th>Accepted</th> <th>Declined</th> </tr> </thead> <tbody> <tr> <td><b>Hepatitis B</b></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>HIV</b></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>Syphilis</b></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	(to complete)	Status unknown		Known positive		Accepted	Declined	Accepted	Declined	<b>Hepatitis B</b>					<b>HIV</b>					<b>Syphilis</b>					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.
(to complete)	Status unknown			Known positive																							
	Accepted	Declined	Accepted	Declined																							
<b>Hepatitis B</b>																											
<b>HIV</b>																											
<b>Syphilis</b>																											
7.	Clinically relevant information	Clinical indications for urgent sample request	ISO 15189 5.4.3 (e) Must be able to ensure urgent samples processed as soon as possible.																								

## Sample reception

Samples received in the screening laboratory must be 'logged' as antenatal samples and assigned a laboratory accession number. If screening is not undertaken for all 3 infections in 1 laboratory department or on one site then there must be a process to ensure samples are tracked and that all the requesting information is sent with the sample.

## Management of samples

Local protocols should be in place and agreed between the laboratory and maternity service to facilitate communication and timely management of:

- incomplete information on the request form
- declines for 1 or more of the screening tests
- requests for repeat samples for inadequate screening samples
- recording known positive status for women with HIV and hepatitis B even in trusts where there is a policy to retest

# The screening tests

The laboratory must adopt the screening algorithms and protocols as defined by the national screening programme. These define the conditions to be tested for and the analytical methods that must be used, together with any national action limits and the diagnostic sensitivity and specificity that must be achieved. The laboratory must submit its assays on the **UKAS** Accreditation Category (AC) form and be UKAS accredited for those assays.

## Generic issues

The initial screening test for all three infectious diseases should be performed in a single laboratory or within a single multidisciplinary pathology department.

1. Specimens for confirmatory tests may be sent to a reference laboratory or performed by the screening laboratory as long as quality and turnaround times are maintained.
2. There should be a process in place to track samples sent to the reference/referral laboratory including live tracking, confirmation of receipt at the

reference lab and failsafe to follow up/ensure results are available within the specific timeframe.

3. Positive results should only be reported on the screening specimen for HIV, hepatitis B and syphilis following confirmation of the result using appropriate analytical methods by a competent laboratory with relevant expertise.
4. Interpretation of screen positive results and management advice should be available from staff with the required level of experience and competency.
5. If a screening specimen is reported as screen positive for HIV, hepatitis B and syphilis, a second specimen should be taken to confirm the screening result and to perform additional diagnostic tests as agreed with the appropriate clinical specialty.
6. This second specimen could be taken in the maternity setting if there is a written protocol agreed with those specialist clinicians regarding which tests are required, or it could be taken in the specialist clinical area if there is an agreed referral pathway for the woman after the screening result is obtained.
7. The results from the screening specimen and the confirmatory specimen should both be available to the specialist clinical services to avoid delays in treatment.
8. A second specimen taken purely to confirm the original screening results before referral to clinical services is not considered necessary. Local policies should specify the procedure for obtaining the second specimen and exactly how the woman will be referred to the appropriate clinical service.

## Sample storage

When the tests have been completed an aliquot from the screening specimen must be stored frozen at a minimum temperature of  $-20^{\circ}\text{C}$  for at least 2 years. The volume stored must be enough to allow further testing if necessary. If there is insufficient volume to store a sample then a local process should be in place to document this in the notes and manage this, for example by requesting a second sample notifying the women on the rationale.

## HIV

The recommended screening tests must detect HIV-1 antibodies, HIV-1 p24 antigen and HIV-2 antibodies.

1. Assays must have a high sensitivity (>99.9%) and specificity (>99.5%) and be able to detect all the major subtypes of HIV-1 and HIV-2.
2. No report should be issued until the confirmatory tests outlined below are performed and a conclusion reached about the complete set of screening results. Interim reports and presumptive positive reports must not be issued as they can cause confusion and mislead recipients.

### Confirmation of the screening test results

All results considered to be positive in the screening assay must be confirmed on the initial specimen by 2 further independent assays, using different methodologies, 1 of which should discriminate between HIV-1 and HIV-2. This is to confirm that the reactivity is specific for HIV and reduce the possibility of non-specific reactions giving false positive results.

1. A second specimen is required after referral to clinical services to establish positive HIV status.
2. Confirmatory assays must discriminate between HIV-1 and HIV-2 infections. p24 antigen assays, or as an alternative HIV RNA assays, must be used to identify acute HIV infection, for example, where screening assays are positive and antibody only tests are negative.
3. A rapid service for confirmatory testing must be provided to avoid delays in reporting and to meet the standard for turnaround times. Confirmed positive screening tests must be reported directly to the IDPS MDT within 8 days of receipt of the sample in the screening laboratory (**standard 4**). This is to enable recall of the woman within 10 working days of the positive result or known status being reported to maternity services (**standard 5**).
4. If a positive result in the screening assay is not substantiated by confirmatory tests, the results are inconclusive. The sample should undergo further investigation in-house or via the reference laboratory before a confirmed screening test result is issued or a repeat sample requested.

## Hepatitis B

The recommended screening test for hepatitis B is an immunoassay to detect hepatitis B surface antigen (HBsAg).

1. This must have an analytical sensitivity of at least 0.05IU/ml and a cut-off defining a diagnostic sensitivity of greater than 99.9% and a diagnostic specificity of greater than 99.5%. Screening assays that detect common escape mutations are preferred to minimise false negative results.
2. The screening test is designed to detect women who have an acute or chronic infection with hepatitis B virus.
3. Tests for HBsAg are very sensitive and may detect women who are in the early incubation phase of an infection. The further tests used to assess infectivity will identify such cases.
4. No report must be issued until the confirmatory tests outlined below are performed and a conclusion reached about the complete set of screening results. Interim reports and presumptive positive reports must not be issued as they can cause confusion and mislead recipients.

### Confirmation of a positive screening test result

All specimens that are positive for the HBsAg screening test must be confirmed using a neutralisation assay or an alternative HBsAg test of equivalent analytical sensitivity.

1. A second specimen is required after referral to clinical services to establish positive hepatitis B status.
2. A rapid service for confirmatory testing must be provided to avoid delays in reporting and to meet the standard for turnaround times. Confirmed positive screening tests must be reported directly to the IDPS MDT within 8 days of sample receipt of the sample in the screening laboratory ([standard 4](#)). This is to enable recall of the woman within 10 working days of the positive result or known status being reported to maternity services ([standard 5](#)).

## Assessment of infectivity

There must be an agreed local IDPS MDT and clinical hepatology protocol for the management of screen positive women and their babies. The functions of the screening MDT are further defined in the [screening programme handbook](#).

Confirmed positive screening tests are followed with an assessment of hepatitis B infectivity and other clinical markers as determined by the clinical specialist. Some laboratories and maternity services have a process to test infectivity markers on the initial screening sample. These processes must not delay timely referral to the IDPS MDT and subsequent clinical services.

Tests for the markers: AntiHBc (total), AntiHBc IgM, HBeAg, AntiHBe and measurement of viral load will be included to inform the appropriate triage of all newly positive women and known positive women. This will also inform the ordering and coordination of the infant HBIG ([standards 6 and 7](#)).

## Syphilis

The screening test for syphilis is an enzyme immunoassay (EIA) that detects antibodies to *Treponema pallidum*, or an alternative immunoassay of equivalent analytical sensitivity. A total EIA, that can detect both treponemal IgG and IgM antibodies, is recommended because of the test's high diagnostic sensitivity.

1. A cut-off value for the assay to differentiate between the negative and positive specimens is defined and provided in the manufacturer's instructions.
2. These first line serological screening tests rely on a woman having mounted an antibody response to their infection and may be insensitive in very early treponemal infection.
3. No report must be issued until the confirmatory tests outlined below have been performed and a conclusion reached about the complete set of screening results. Interim reports and presumptive positive reports must not be issued as they can cause confusion and mislead recipients.

## Confirmation of screening test results

A rapid service for confirmatory testing must be provided to avoid delays in reporting and to meet the standard for turnaround times. Confirmed positive screening tests must be reported directly to the IDPS MDT within 8 days of sample receipt of the sample in the screening laboratory (standard 4). This is to enable recall of the woman within 10 working days of the positive result or known status being reported to maternity services (standard 5).

1. All EIA positive results should be confirmed using the same assay to confirm reproducibility. Repeating the assay may be omitted if other confirmatory assays are to be performed in the same laboratory.
2. A second specimen is required after referral to clinical services to establish positive syphilis status.
3. A *Treponema pallidum* particle agglutination (TPPA) or *Treponema pallidum* haemagglutination (TPHA) assay must be performed as a confirmatory test on the same screening specimen. These assays are sensitive and specific and a combination of a positive result with both EIA and TPPA/TPHA gives a strong likelihood for past or current treponemal infection.
4. A positive or equivocal result with EIA but negative with TPPA/TPHA are discordant and needs further investigation in a reference laboratory before a confirmed screening test result is issued. False positive results on the initial screening test may be caused by cross-reacting antibodies in the woman's blood. In low prevalence populations, such as pregnant women in the UK, most initial screen reactive results will be false.
5. If after further analysis, the results are still inconclusive then a repeat specimen is required to rule out the presence of cross reacting antibodies. A confirmed positive result on the repeat specimen requires immediate referral to the IDPS MDT.
6. Specimens which are equivocal on both EIA and TPPA/TPHA assays, or equivocal on the EIA but positive on TPPA/TPHA, require further investigation and should initially be repeated on a second sample. If the result remains inconclusive, it should be referred for further investigation in a reference laboratory before a confirmed screening test result is issued.

# Reporting and releasing results

## Generic

The laboratory must have a standard operating procedure for reporting screen positive and inconclusive results to the IDPS MDT, including:

- the laboratory must issue the results of the screening test(s) as a single report for every woman screened
- an authorisation process for results including contingency arrangements
- the laboratory must issue the result within the timescale stipulated by the IDPS programme:  $\leq 8$  working days of sample receipt in the laboratory (based on local working arrangements)
- the format of the laboratory report must specify whether the result is screen positive, screen negative, decline or known positive

## Screen positive results

Results must not be communicated, either written or electronic, to the maternity service until confirmatory tests are completed on the screening sample.

Confirmed screen positive

The laboratory should directly inform the designated lead within the IDPS MDT (for example, screening coordinator / specialist midwife) of a confirmed screen positive result.

A local protocol should be in place between the laboratory and IDPS MDT to log receipt of screen positive results.

## Screen negative results

Reports with negative results for the infections screened must be communicated to the requester and the woman must be informed of the results at her next antenatal visit.

Screen negative

## Inconclusive results

There must be an agreed process in place between the laboratory and the screening coordinator / specialist midwife to alert them to an inconclusive result. Laboratories

require a sample 2 weeks later to exclude a recent infection at the time of the initial sample.

Refer to MDT

If the repeat sample is also inconclusive then advice and/or referral should be sought from the infectious disease clinicians for future management.

Women who have a confirmed screen positive result or those already known to be positive should be invited for specialist assessment within 10 working days of the positive report being received from the laboratory, or known positive status reported to the screening coordinator ([standard 4](#)).

## Screening quality assurance services (SQAS)

Each English screening programme has a defined set of standards that providers have to meet to ensure local programmes are safe and effective. **Quality assurance (QA)** is the process of checking that these standards are met and encouraging continuous improvement across screening and referral pathways, in order to ensure pregnant women and their babies have access to a high quality service wherever they live.

QA is essential to minimise harm and maximise benefits. Formal QA visits to a local screening programme provide the forum for a review of the whole multidisciplinary screening pathway, and an assessment of the effectiveness of team working within the screening centre and associated referral sites.

### Screening safety incidents

An incident for screening programmes is defined as an actual or possible failure at any stage in the pathway of the screening process which exposes the programme to unknown levels of risk, for example where screening or assessment have been inadequate, with potentially serious consequences for the clinical management of individuals.

The **guidance documents** explain the incident management procedures for NHS screening programme providers and commissioners and provide a form for notifying incidents to the SQAS. This guidance should be read alongside NHS England's **Serious Incident Framework**.

The **Screening Incident Management Resource** is available for health professionals working in NHS population screening. The e-learning resources examine why screening incidents occur, the steps that can be taken to avoid them, how to manage them, learn from them, and optimise the quality of the patient experience.

# Data collection and reporting

## Programme standards

A formal IDPS programme was established in 2007 and has been part of the population screening programmes within the PHE Health and Wellbeing Directorate since 2013. The **IDPS programme standards 2016 to 2017** have been updated into a new format with clear metrics to support QA processes. The scope is standards that assess the screening process and allow for continuous improvement. This enables providers and commissioners to identify where improvements are needed.

The programme has 7 standards for 2016 to 2017 (Table 1). These will be reported via national systems and local data collection processes. The laboratory and maternity service should have an agreed process in place to coordinate and ensure timely collation and submission of data.

**Table 1. IDPS Programme Standards 2016 2017**

<b>IDPS Standard</b>	<b>Data collected by</b>
1. HIV coverage (KPI ID1)	Maternity service
2. Hepatitis B coverage	Maternity service
3. Syphilis coverage	Maternity service
<b>4. Test result turnaround time</b>	<b>Screening laboratory</b>
5. Timely assessment for screen positive and known positive women	Maternity service
6. Timely assessment of women with hepatitis B (KPI ID2)	Maternity service
7. Hepatitis B – timely neonatal vaccination	Maternity service

## Key performance indicators

Key performance indicators (**KPIs**) for the NHS screening programmes were introduced to provide a way of measuring how well the screening programmes are doing in important areas. They contribute to the quality assurance of screening programmes but are not, in themselves, sufficient to quality assure or performance manage screening services. They help local screening services identify potential problems so they can be put right. They have led to

changes in practice and the implementation of measures to prevent errors occurring in the screening pathway.

The IDPS programme currently collects matched cohort **KPI data** on HIV coverage and data on hepatitis B referrals. There are plans to pilot 2 new coverage metrics for the other conditions (hepatitis B and syphilis).

## Standards data collection process

Surveillance data for the IDPS Programme was previously collected by the National Antenatal Infections Surveillance Monitoring (NAISM) team via the PHE regional Field Epidemiology Service (FES) teams (formerly the Health Protection Agency).

Data has been collected since 2004, supported by regional health protection teams and epidemiologists, and the pre-PHE regional antenatal and newborn screening teams. Since 2006 this data has been used to produce the annual health protection **reports**.

The programme has identified a need to:

- reduce duplication between data requested by NAISM and the screening team within PHE
- collate matched cohort data across the screening pathway
- ensure consistency of reporting, whether regional or national against the programme standards to support QA processes
- simplify the process and reduce the effort of data duplication for screening coordinators in trusts

From 2016, the IDPS programme will coordinate data collection in line with the other antenatal and newborn screening programmes. A new data dictionary and data submission tool has been produced to facilitate data collection from screening coordinators and laboratories. Data will be submitted annually with a submission deadline of 30 June for the previous year (1 April to 31 March).

Data will be submitted to the programme annually and will be received, stored and analysed by the programme centre and an agreed data extract sent to PHE Centre for Infectious Disease Surveillance and Control to include in their health protection reports. (**PHE CIDSC HIV & STI department**). A data report will also be produced by the IDPS programme for NHS Screening Programmes.

## Screening outcomes

Collation and analyses of screening outcome data is essential to:

- monitor the performance of the screening programme
- identify areas for further audit and research
- review all positive cases to inform screening programme pathways and standards

The IDPS programme commissions the Infections Group in the Population Policy and Practice Programme at University College London (UCL) Institute of Child Health to collect data on screening programme outcomes. The IDPS programme is undertaking a review of data collection processes and systems in order to establish a single submission and governance structure.

Current projects include:

- enhanced HIV in pregnancy audit through the National Study of HIV in Pregnancy and Childhood (NSHPC)
- surveillance of antenatal syphilis screening (SASS) study
- hepatitis B in pregnancy audit

The IDPS team also supports the continued monitoring of congenital rubella cases through the British Paediatric Surveillance Unit rare conditions active reporting scheme.

All trusts should continue to report HIV confirmed pregnancies to the NHSPC. A process should be in place to review the outcomes for their local population to inform local screening processes. Local data on outcomes can be requested directly from the NHSPC team at UCLH.

## Appendix 1. Acknowledgments

The IDPS programme would like to acknowledge the significant contribution and support from the IDPS laboratory advisers and members of the IDPS laboratory task group.

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