

Red cell Immunohaematology

Request for Supply

Antenatal Microbiology Screening Services

Statement of Work

Version 1.0

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# Executive Summary

**Request for supply of antenatal microbiology confirmatory testing**

NHS Blood and Transplant (NHSBT) is a Special Health Authority, dedicated to saving and improving lives through the wide range of services we provide to the NHS.

As part of the development of our Red Cell Immunohaematology (RCI) blood testing services for fetal and maternal health, NHSBT is intending to provide an antenatal serology and microbiology screening service for pregnant women from April 2016.

In order to fully offer this service NHSBT is seeking a laboratory partner to offer antenatal microbiology confirmatory testing for samples that register as screen reactive.

The aim of this confirmatory testing is threefold

* To ensure that women with hepatitis B, HIV and syphilis are identified as early in pregnancy as possible to facilitate appropriate assessment and management of their health
* To reduce the risk of mother to child transmission of these infections
* To facilitate appropriate neonatal referral and management

In summary the supplier would be providing a service that ensures all antenatal microbiology samples, found by NHSBT to be screen reactive for the agreed markers receive appropriate confirmatory testing and follow up care in line with relevant published guidelines.

**Tests to be performed:**

Confirmatory Testing and reporting of screening samples showing reactive to identify:

Syphilis

Hepatitis B

HIV 1 & 2

Hepatitis C (on request)

NHSBT is looking for a cost-effective provider with whom it can work closely to develop the best NHS antenatal screening service in England.

The procedures and management of antenatal screening within the UK are well established based on GUIDELINE FOR BLOOD GROUPING AND ANTIBODY

TESTING IN PREGNANCY (2006)1 British Committee for Standards in Haematology

Blood samples taken and used for both serology and micro biology testing as outlined in the Background below.

1. **Background**

1. **Antenatal serology screening:**

The blood sample taken at 12-16 weeks gestation (known as the “booking sample”), is tested to establish the ABO and RhD blood groups and for the presence of red cell antibodies. If no antibodies are detected a repeat sample for the same tests is requested in the third trimester, ideally at 28 weeks gestation. Similarly, since many antibodies do not harm the baby, in cases where clinically non-significant antibodies are detected only one more test, at 28 weeks, is normally recommended.

A very small number of women are found to have antibodies which are more likely to affect the baby and more frequent samples will be requested and tested if these red cell antibodies are present, or if there is any other cause for concern regarding the baby’s well-being.

1. **Microbiology screening**

The purpose of microbiology screening is to identify infections which can result in congenital or perinatal infections, which can present a risk to the baby and which, with appropriate management, can be controlled. These are normally performed on the booking sample.

All screening is performed in compliance with the Infectious Diseases in Pregnancy Screening Programme Standards, UK National Screening Committee (September 2010)2

The antenatal microbiology screening tests are intended to identify markers for syphilis, hepatitis B, HIV and rubella. Hepatitis C may be requested as an additional screening test. Should the initial screen prove reactive then the sample needs confirmatory testing by a local diagnostic virology laboratory. The confirmatory tests required are for:

Syphilis

Hepatitis B

HIV 1 & 2

Hepatitis C

The testing laboratory needs to be responsible for supplying all relevant clinical advice to the relevant maternity unit as part of follow-up, and ensure notification of results to referring midwife/GP/Consultant and statutory reporting bodies.

Early detection of these infections is necessary in order to ensure appropriate treatment to protect the foetus from infection, robust follow up and reporting systems need to be in place to ensure that such reports are acted upon promptly.

1. **NHSBT Requirements**

NHSBT will offer both serology and microbiology screening services through our testing laboratories but is now seeking provision of a supplier of antenatal microbiology confirmatory testing for samples which are identified as reactive at time of screening.

The details of the required service are outlined in the attached Schedule, but in summary the supplier will need to offer a service to NHSBT which meets national guidelines, has the ability to report results accurately within agreed timescales, has national coverage and has resilience to guarantee a continuation of service despite adverse events.

The successful supplier must offer the following:

* a proven track record in the provision of virology testing
* robust reporting systems to ensure Public Health and local clinical requirements are met
* National coverage with local clinical follow up
* A standard price for carrying out the testing based on current forecasts
* Ability to meet guideline turnaround times.

Please review the schedule for detailed requirements

**Key Guidelines and reference**

1GUIDELINE FOR BLOOD GROUPING AND ANTIBODY

TESTING IN PREGNANCY (2006)

British Committee for Standards in Haematology

2 <https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards>

Further details and information can be obtained from:

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**4. Schedule of Services**

**Tests to be performed:**

Confirmatory Testing and reporting of screening samples showing reactive to identify:

Syphilis

Hepatitis B

HIV 1 & 2

Hepatitis C

**Turnaround time**

Results to be reported within 5 days of receipt of samples from NHSBT

**Laboratory operating schedule**

Hours of operation (for sample receipt) to be specified by supplier

**Laboratory coverage**

The provider must have coverage throughout England to receive samples from NHSBT and have a clinical relationship with hospitals within the area local to testing in order to provide timely and effective support

**Sample validation**

Identified procedure for notifying NHSBT of samples that are not suitable for testing and require a repeat sample

**Testing methods**

Must be compatible with NHSBT antenatal screening tests and accredited to ISO15189 or equivalent

**Reporting**

Content of report and reporting method to hospitals to be specified by supplier.

Data analysis to be reported to NHSBT on a regular and agreed basis

**IT Connectivity**

The supplier must work with NHSBT to develop electronic requesting and reporting systems as well as appropriate electronic failsafe systems.

**Clinical Consultant support**

A description of consultant clinical support and coverage available should be supplied, It is expected that all the supplier’s testing laboratories can provide cover to follow up positive/significant results directly with the referring hospital or clinic. Availability of on-call cover is to be specified.

**Pricing**

To be specified for inclusive service (testing, reporting, clinical support) based on samples delivered to the suppliers laboratory

**Invoicing to NHSBT**

Monthly with listing of volume and locations of tests carried out

**Supplier capability**

Prospective suppliers must supply an outline technical specification of their testing protocols to demonstrate operational capability and conformance to regulatory requirements.

**Detailed process and sample flow mapping to be agreed with successful supplier**

**Anticipated volumes**

Confirmatory testing volumes are based on screening referral numbers. As a guide only NHSBT are anticipating serology referral volumes as follows:

|  |  |  |
| --- | --- | --- |
|  | Total microbiology screens carried out by NHSBT | Estimated confirmatory referrals |
| Year 1 | 15k | 180 |
| Year 2 | 30k | 360 |
| Year 3 | 50k | 600 |
| Year 4 | 50k | 600 |

 The referral volumes are based on historic referral rates and are indicative only

Regional breakdown of the forecast is currently not available but NHSBT will hold six- monthly review meetings to assess future volumes and future prospects