



Public Health
England

Protecting and improving the nation's health

The national dried blood spot (DBS) testing service for infants born to hepatitis B infected mothers

Revised September 2017

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: [@PHE_uk](https://twitter.com/PHE_uk)
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Sema Mandal and Amanda Dennis

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Contents

About Public Health England	2
Why test infants of hepatitis B positive mothers for hepatitis B infection?	4
What are the possible methods for testing these infants?	4
Dried blood spot testing	5
What are the advantages of dried blood spot (DBS) testing?	5
How the service works	6
Expectations of coordinators and local area teams	6
PHE testing and reporting of results	7
Education and training	8
Queries and further support	8
Roles and Responsibilities	9
Who do I contact to join the service?	11

Why test infants of hepatitis B positive mothers for hepatitis B infection?

- infants with hepatitis B infection are usually asymptomatic and do not display signs of infection at the time of testing
- testing infants at 12 months of age is important to enable a timely assessment, reducing the risk of long term complications and disease in later life
- if the infant's blood test is negative, the result provides reassurance to parents that transmission has been avoided and no further action is required
- offering the test enables healthcare professionals to monitor the delivery and impact of immunisation programmes
- recommendations to immunise and test infants have been in place since 2000 (HSC 1998/127) and are recommended in the following documents:
 1. National Institute for Health and Care Excellence (NICE), Reducing differences in the uptake of immunisations (2009)
 2. Department of Health, Service specification for the Neonatal hepatitis B immunisation programme (2012)
 3. Department of Health, Hepatitis B antenatal screening and newborn immunisation programme: Best practice guidance (2011)

What are the possible methods for testing these infants?

There are currently two types of tests used to test infants for hepatitis B infection:

- venous blood sample
- dried blood spot testing.

Dried blood spot testing

What are the advantages of dried blood spot (DBS) testing?

The advantages of using the DBS testing service fall into three categories.

1. **Programme** – The DBS offers a simple method of testing and can be conveniently performed in primary care. Referrals to specialist paediatric phlebotomy clinics are not required.
2. **Resources implications** – Ideally, testing should be undertaken at the same time the 12 month dose of hepatitis B vaccine is administered, reducing the need for additional appointments. Testing infants using DBS is free of charge with the costs borne by Public Health England (PHE). Results will be reported to both the GP and the co-ordinator.
3. **Family** – Offering the test in primary care is convenient for the family because the test can be performed locally at the GP surgery, community clinic or at the infant's home address - removing the need to travel long distances to specialist paediatric phlebotomy clinics.

Interested in joining the service?

If you believe the dried blood spot service could help to increase testing in your local area and you are interested in joining the service, you should read the section entitled '**How the service works**' on page 8 of this document. Check that you agree with the PHE expectations of the service and that your organisation is able to meet the roles and responsibilities.

It is important to note that the DBS service is designed to increase testing in **primary care** of all at-risk infants aged 12 months who are born to hepatitis B positive mothers. It is not intended to replace specialist hospital services that are already established within the local area teams and who continue to offer a timely and efficient testing service. It is also not intended (or resourced) for testing infants whose mothers are not hepatitis B positive but have another family/household member (e.g. father) who has hepatitis B. In these scenarios, the infants should be screened and vaccinated according to national guidelines but not using DBS kits provided by PHE Colindale.

How the service works

Expectations of coordinators and local area teams

PHE will liaise with a single named local coordinator identified by the screening and immunisation lead (SIL). The named local coordinator will be responsible for implementing the service locally, providing operational support to ensure that infants born to hepatitis B positive mothers are tested at the age of 12 months in the primary care setting.

Local area teams (NHS England) will have formal responsibility for commissioning the dried blood spot service for infants born to hepatitis B positive mothers.

Local area teams will need to identify a clinical pathway for the neonatal hepatitis B immunisation programme and ensure agreement at a strategic level with key stakeholders, such as midwives, paediatricians, general practitioners and community practice nurses. The named coordinator will maintain a list of infants, in the population they are responsible for, whose mothers were identified as hepatitis B positive during pregnancy.

The targeted hepatitis B vaccination programme for all at-risk infants is extremely important because it helps to prevent transmission of the virus from mother to baby.

Post exposure vaccinations should be administered following the schedule for infants which has been amended following the introduction of the hexavalent vaccine (DTaP/Hib/HepB), Infanrix hexa® into the routine childhood immunisation programme (see Green Book). Infants should now receive monovalent vaccine at birth and 4 weeks of age, followed by three doses of Infanrix hexa® at 8, 12, 16 weeks of age. They should then receive a booster of monovalent hepatitis B vaccine at 12 months of age and at the same time should be tested to exclude chronic infection.

All named coordinators are expected to provide data on the annual estimated number of infants eligible for testing. Once these data are received, Public Health England will send kits free of charge to the named local coordinator responsible for the operational management of the service. DBS testing kits will be delivered to cover an agreed time period.

The named coordinator will be responsible for re-ordering DBS testing kits from PHE. Distributions of DBS testing kits are not automatic and coordinators should contact PHE to replenish local stocks. The named coordinator will be required to co-ordinate the testing kits in their locality; ensuring kits are available to the tester in primary care in time for the test to be undertaken at 12 months of age. It is recommended that the test is undertaken at the same visit as the fourth dose of hepatitis B vaccine is administered.

The named coordinator should ensure that testing kits are made available to primary care for all at-risk infants in their area, including both high and low risk infants. It is the coordinator's role to remind healthcare professionals in the local area that infants require testing at 12 months of age.

Coordinators should remind the person taking the DBS test to complete the laboratory request form fully and return it with the DBS sample in the envelope provided. Complete information on the mother's serology, the infant's immunisation history with dates, and GP details is needed to process the test, assist with the interpretation of results, and to check the reports are sent to the correct GP.

PHE will monitor number of kits sent out and completion of documentation (request form). As required, PHE may i) request for number of DBS tests performed and ii) send out a line list of infants on whom information is missing for coordinators to complete.

The lancet supplied in the kit is designed for 6 month - 24 month old babies. If as part of a catch-up exercise for children who have missed vaccination, DBS testing support is requested from PHE the local coordinator will be responsible for sourcing age-appropriate lancets for use.

Hepatitis B immunisation data should continue to be reported separately by local teams to the COVER system.

PHE testing and reporting of results

Dried blood spot samples received by the Reference Laboratory at PHE Colindale will be tested if the sample is adequate and all documentation (laboratory request form) is supplied.

PHE will send the infant's GP a laboratory report outlining the test results, interpretation and recommended further public health actions.

The target turnaround for test results is approximately 2 weeks from receipt of the sample, but this may be longer depending on demand and capacity. This test is not being done for urgent clinical management so this should not have adverse clinical consequences.

An electronic copy of the report will also be made available to the named coordinator and Health Protection Team. All named coordinators will be given access to e-reporting when joining the service.

For babies with hepatitis B positive results, the named coordinator is responsible for liaising with the GP to ensure a timely referral to a paediatrician/ hepatology specialist.

Education and training

PHE has developed a range of education materials which are available online for use by screening and immunisation teams to support introduction of DBS in the primary care setting.

While no formal DBS training programme is required or provided by PHE It is important that all healthcare professionals undertaking DBS are competent and confident in their ability to carry out the procedure. Many practice nurses are already “trained” to take blood with automated lancets (e.g. for diabetes).

DBS training materials can be accessed at:

<https://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants>

which is part of :

<https://www.gov.uk/government/collections/hepatitis-b-guidance-data-and-analysis>

Information on the introduction of hexavalent vaccine into the routine childhood and selective neonatal immunisation programmes is available at:

<https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance>

Queries and further support

General enquiries, further support and information can be accessed during working hours from the DBS team based at the Immunisation Department at PHE Colindale:
HepatitisBBabies@phe.gov.uk

Patient identifiable information (PII) should not be sent to this email address from any non phe.gov.uk email addresses. Please contact the team for information on secure transfer of PII data.

In the unlikely event of a problem or an adverse event associated with the service (for example, a needlestick injury), irrespective of cause, the local coordinator will report this to PHE so that the safety of the service can be monitored, and improvements made as needed.

Co-coordinators who have successfully implemented the service may be asked if they can be contacted by other areas that are planning to introduce DBS testing in their neonatal pathway.

Roles and Responsibilities

Task	Person responsible	Notes
Maintain a list of high-risk* infants of hepatitis B positive mothers	Named coordinator identified by screening and immunisation lead (SIL). PHE will also have a record of infants for whom immunoglobulin has been issued	No change from previous system
Maintain a list of low-risk**infants of hepatitis B positive mothers	Named coordinator identified by SIL	PHE will not have a list of these infants
Agree the local pathway and inform local stakeholders as needed	Local area team of NHS England have formal responsibility	Stakeholders include CCGs, local PHE centres, GPs, practice nurses and other groups
Send batch of DBS test kits to local coordinator	PHE Immunisation department	Number of kits and frequency of dispatch depends on estimated numbers provided by coordinator
Reorder stock of test kits in advance	Named coordinator identified by SIL	Order at least a month before the next batch is required
Distribute test kits to local testers for use	Named coordinator identified by SILs	Kits can sent by post – envelopes are supplied
Ensure local testers are competent to take dried blood spots from at risk infants	Local arrangements. Supported by material from PHE Immunisation department.	All areas have an individual already competent in DBS to take samples for newborn screening.
Take the test in accordance with the instructions	Local tester	
Complete ALL sections of the request form, including information on the mother's serology, the infant's immunisation history with dates, and GP details	Local tester or named coordinator identified by SIL	The information requested allows interpretation of the result and permits monitoring of how the service is operating

*High-risk—have markers of high infectivity listed in Green Book and eligible for HBIG at birth.

**Low-risk—infants of hepatitis B positive mothers who lack markers of high infectivity listed in the Green Book.

Task	Person responsible	Notes
Send out to coordinators (i) a line list containing infants on whom information is missing from the request form and ii) request for number of DBS performed	PHE immunisation team	This will be sent on an ad hoc basis or more regularly if required, following periodic review of data quality
As required, complete (i) a line list spread sheet of missing information on hepatitis B infants, and (ii) report on number of tests performed using DBS.	Named coordinator identified by SIL to complete the line list	This will assist monitoring of the uptake of the test. Data to be held in line with information governance requirements
Report any difficulties with the service in a timely fashion to PHE Colindale	Named coordinators identified by SIL	A low threshold for reporting concerns will allow PHE to deal with them as efficiently as possible
Report any adverse incidents	Named coordinator to report to the DBS team at PHE Colindale	
Report to COVER on vaccine uptake	SIL/named coordinator	This is separate from the data provided on DBS test request form
Test the samples that arrive with an adequately completed request form for hepatitis B infection	PHE Colindale reference lab	The target turnaround is two weeks, but this may be longer at some times of year.
Report the results of the testing to the infant's GP with copy to SIL and HPT For hepatitis B positive results, the named coordinator should liaise with the GP to ensure a timely referral to a paediatrician/hepatology specialist.	PHE Colindale lab and immunisation team	GP information will be taken from the request form so this form should be accurately completed by the tester. The named coordinator and HPT will have access to an electronic report on e-reporting
Issue standard public health advice with the test result, based on test result	PHE Colindale immunisation team	
Supply data as needed for the evaluation and safe running of the service	Named coordinator identified by SIL and local team	To allow monitoring and evaluation
Monitor and evaluate the service as it is rolled out	PHE Colindale with information from named coordinators and SIL team.	To maintain a safe high quality service

Who do I contact to join the service?

To express your interest in joining the service, please email the DBS team at PHE Colindale at hepatitisbbabies@phe.gov.uk. You should include the following information in your email:

- name, organisation address, telephone number and email address of the Screening and Immunisation Lead
- name, organisation address, telephone number and email address of the named coordinator who is responsible for the delivery of the service in the local area
- local population information that includes the estimated number of infants born to hepatitis B positive mothers per year and what proportion of these are classified as high and low risk infants.