To parents

STATENS SERUM INSTITUT

Blood samples from newborn babies

All newborn babies in Denmark are offered blood spot screening, also known as the heel prick test, which can reveal whether the child is suffering from certain serious diseases.

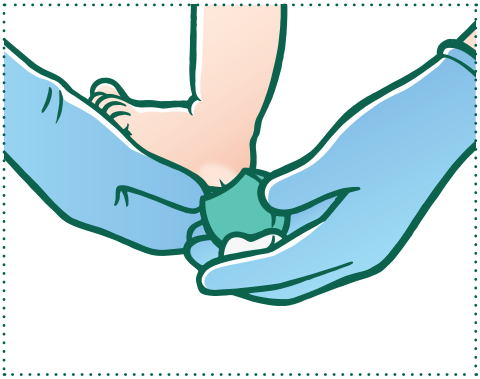
Information about the heel prick test

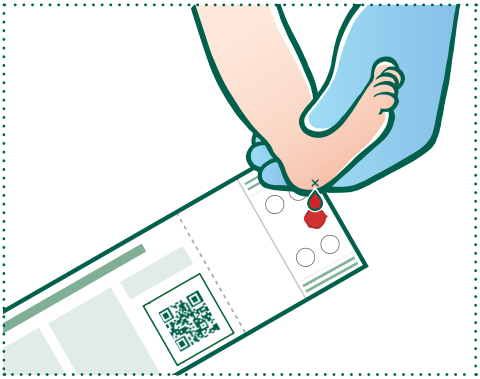
To find out whether your child suffers from a congenital disease, which need to be treated as quickly as possible, a blood sample will be taken 48-72 hours after the birth.

The blood sample depends on you as parents consenting to its being taken. If you do not give your consent, the sample will not be taken.

This folder gives a short description of the purposes of the heel prick test. A more detailed description is available on Statens Serum Institut's website ssi.dk/nyfoedte.

How does it work?
The blood sample consists of a few drops of blood collected on blotting paper taken by 'pricking' the skin on the outer side of one of the child's heels. This rarely causes any great discomfort for the child.





What is the significance of the test for your child?
Even if a child seems totally healthy at birth, in rare cases, he or she may have a congenital disease. The disease may be either insidious or sudden. The longer treatment is delayed, the greater the child's life is at risk, and the greater the chance of permanent mental or physical injury. That is why it is of the utmost importance for the child that the disease is identified so that treatment can be started as soon as possible.

What specific diseases are being screened?
On ssi.dk/nyfoedte, you can find a detailed list of the rare congenital diseases that are currently being screened. On the website, you also read more about the individual diseases. About 1 in 1,000 children are born with one of these 18 diseases. You will also find some examples of the diseases at the end of this leaflet. If you child is suffering from one of the 18 diseases, you will be informed immediately, and the child will be called back for further screening and treatment.

How infallible is the test?
Since it is a screening test, in rare cases, particularly involving prematurely born children, the results may suggest a disease without this actually being the case. A closer examination will immediately be carried out to reveal this. Similarly, the screening cannot eliminate all kinds of congenital diseases. Furthermore, screening is only carried out for diseases where early detection means better treatment options for the benefit of the child.

Storage of the blood sample

After the screening has been carried out, the sample will be stored in frozen condition at the Danish Neonatal Screening Biobank at Statens Serum Institute in locked and secure facilities. See more on ssi.dk/nyfoedte.

The sample is stored for the following purposes:

1st priority: For the use of the child and family. This might involve supplementing with other analyses that were not available at the time of birth and to make certain identification of a person, who later in life becomes the victim of an accident, natural disaster, etc.

2nd priority: To use in the ongoing quality assurance of screening of newborn babies and in the development of new analysis and screening methods.

3rd priority: To use in health research. Use for research purposes always requires the approval of the Danish National Committee on Health Research Ethics. Projects using human biological material must also be conducted in accordance with the rules set out in the Danish Processing of Personal Data Act and on the basis of the requirements laid down by the Danish Data Protection Agency (www.datatilsynet.dk). The biobank's steering committee must also approve the use of sample material for this purpose.

You have control of the sample on your child's behalf until he or she comes of age. If you do not wish the sample to be used in health research for approved purposes, you can inform the Danish Health Authority's Tissue Utilisation Register. For more information, please check sundshedsdatastyrelsen.dk.

If you do not want the sample to be stored at all, you can state this electronically via the citizen portal borger.dk, where you must use your digital signature (NemID) and choose Statens Serum Institut as recipient. The sample will then be destroyed.

Examples of congenital diseases

Immunodeficiencies

Severe combined immunodeficiencies (SCID) and other serious congenital immunodeficiencies cause life-threatening infections in the newborn babies. Without treatment in the form of e.g. bone marrow transplants, children suffering from SCID will die within their first year. Early diagnostics and treatment shortly after birth before the child becomes ill engender the best treatment results. About 1 in 10,000 newborn babies have serious congenital immunodeficiencies. The SCID screening will start on 1 February 2020.

Cystic fibrosis

Cystic fibrosis (CF) is a hereditary disease dominated by the formation of thick, sticky mucus. This causes lung/airway symptoms with repeated infections and problems with digestion. Early treatment involves prevention and intensive treatment of respiratory infections and digestive problems. It prevents serious complications and improves the well-being and prospects of CF patients. About 1 in 4,800 newborn babies have CF.

Metabolic diseases

This covers a large group of congenital diseases caused by the child's inability to convert certain substances or suffering from a low metabolism. The diseases are hard to detect unless they are screened for and may result in organ damage, severely inhibited mental development and infant death. Treatment usually consists of a special diet, which restricts the intake of the nutrient the child cannot tolerate. Medication may be an option. 1 in 3,000 newborn babies have a metabolic disease.

Information til forældrene:

ssi.dk/blodproevefranyfoedte

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14th edition
February 2020
Item no.: 73326