

## Parent information – Newborn Screening Programme in Bavaria

Dear Parents,

Most children are born, and remain, healthy. However, there are rare congenital disorders which cannot yet be recognised by external symptoms in newborn babies. If left untreated they can lead to serious impairments in the child. To protect against this, a vital screening programme is recommended for all newborns in Germany during their first few days post natum. Costs for these tests are covered by the health insurance and participation is voluntary with the exception of the newborn hearing test.

### **Newborn screening for congenital metabolic and hormonal disorders**

Rare congenital metabolic or hormonal disorders can lead to serious disabilities or even death if left untreated. If recognised early, in most cases, medication or a specialised diet can prevent or moderate the effects of the disorder. The test is best undertaken on the second or third day post natum with a couple of drops of blood collected on a piece of filter paper and sent to the laboratory. You can find a full description of the test and individual disorders from page 6 onwards [in the German brochure].

### **Newborn screening for cystic fibrosis (CF)**

The same blood sample can also be used to test your child for cystic fibrosis. Children with cystic fibrosis suffer from a build-up of thick mucus in the lungs and other organs which leads to long-term infection. As a consequence, children are often underweight and struggle to grow. In severe cases, the lung functions can be considerably impaired. The goal of this test is early diagnosis so that treatment can be started as soon as possible, improving the quality of life and life expectancy of the child. In accordance with the legal requirements of the German Genetics Diagnostics Act, a consultation with a doctor is necessary before a routine screening for cystic fibrosis. More information about the disorder and test can be found from page 8 onwards [in the German brochure].

Your child's blood sample will be destroyed after the tests are completed.

### **Hearing tests for newborns**

Around two in every 1000 children born in Germany have a hearing defect which requires treatment. Without a hearing test for newborns, this impairment is recognised late in most children, often in their second, third, or even fourth year, when they fail or struggle to learn to speak. Children can only learn to speak when they can hear and therefore copy speech. The longer the hearing impairment remains undiagnosed, the more difficult it becomes for the child to catch up with the delay in speech development. Today, screening, early support and modern hearing aid technologies can prevent these issues.

The newborn's hearing will be examined in their first few days with a TEOAE or AABR device. The examination is completely painless and in no way detrimental to your baby. It is part of the compulsory preventative examinations in Bavaria (U1 to U9), and is described in greater detail on page 11 [in the German brochure].

### **For Bavarian children, there is an extra service, so that no child is left behind (tracking)**

In Bavaria, the public health service offers a special service - the screening centre in the Bayerischen Landesamt für Gesundheit und Lebensmittelsicherheit (LGL) [Bavarian Office for

Health and Food Safety]. The LGL ensures that these tests are offered to all newborns, and any necessary check-ups are carried out promptly.

If you agree to the transfer of your data, then the name and address of the newborn, as well as the findings will be sent from the laboratory or in the case of the hearing test, directly from the maternity or paediatric clinic, to the screening centre. There, the data will be processed under the supervision of a physician and with medical confidentiality. Any checks, processing and use of personal data necessary for this will be handled according to the applicable data privacy laws.

The screening centre will send a list with the names and addresses of the screened children to the responsible local health authority (without details of findings). The local health authority compares the names of the screened children with the registration office's birth notifications to track down any unscreened children, therefore guaranteeing that any children whose parents would like them to be screened, really are screened. This approach allowed that more than 2500 children were able to be screened subsequently in the last few years. Parents who don't agree with the data transfer will still be contacted by the local health authority, as no screening information is available for their child. After a maximum of twelve weeks, the local health authority will delete the data.

If a check-up is needed, the screening centre will check whether the results are communicated in a timely manner. If the results are not shared, the screening centre will approach the sender (usually the maternity or paediatric clinic) or the parents, to find out the status of the check-up. This ensures security for you as parents and guarantees that you will be informed either way if a necessary examination is forgotten. Thanks to this tracking process, 40% of hearing tests and 18% of metabolism tests which required monitoring could be quickly clarified in the past years!

### **What happens to the data?**

Agreeing to the data transfer is voluntary. If you do not wish to consent, there will be no legal disadvantages to you or your child. However, you will not be able to benefit from the advantages of the tracking system. In this case, you should inquire with the sender of the test results and arrange further tests yourself if required. Personal data will be deleted after two years or, in case of abnormal findings, once the diagnosis has been completed. The anonymised data are used to ensure the quality of the screening and for scientific analyses. In case you wish to cancel your data transfer consent, you can request for your child's personal data to be deleted from the screening centre at any time with a short letter. Your cancellation notice can be sent to the screening centre at the below address.

### **How will I receive the information concerning abnormal results?**

If a hearing test cannot ascertain whether a child can hear in both ears, then the parents will be informed before discharge. The results will be noted in the child's yellow medical check-up booklet.

If blood tests reveal an abnormal result, then the laboratory will usually inform the doctor who arranged the test, usually a gynaecologist or paediatrician. The doctor will then inform the parents. For this reason, it is important to provide a telephone number where you can be reached.

In Bavaria there is also the possibility that parents can be called by a paediatrician who is specialised in one of the disorders. This doctor can then explain the disorder which your child may have to you, and discuss further steps with you. If you would like this, you can sign for it separately on the consent form.

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**Screening centre address:**

Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit [Bavarian Office for Health and Food Safety], Screening Centre, Veterinärstraße 2, 85764 Oberschleißheim

**Tel: 09131 6808-5204 / -5131**

Monday to Thursday from 8am to 4pm and Friday from 8am to 1pm

[screening@lgl.bayern.de](mailto:screening@lgl.bayern.de)

Further information can be found at:

<http://www.lgl.bayern.de/gesundheit/praevention/kindergesundheit/index.htm>

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## Declaration of consent

**If you would like your child to undergo all of the available tests, and agree to the transfer of the relevant data, please complete and sign this page.**

Name of child: \_\_\_\_\_ -

Name of mother: \_\_\_\_\_ -

Address: \_\_\_\_\_ -

**Tel:** \_\_\_\_\_ -

We have been informed about the newborn screening for congenital metabolic and hormonal disorders, newborn screening for cystic fibrosis and newborn hearing tests as well as about the collection, processing and utilisation of personal data, and our right to withdraw. -

We consent to these tests and to the transfer of data to the relevant screening centre until the findings have been reviewed. -

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Place, date

signature of at least one legal guardian

We agree that if the test results require follow-up, they and our contact data will be passed to an appropriately specialised paediatrician and that we will then be further informed directly by them.

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Place, date

signature of at least one legal guardian

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Place, date

signature of the person obtaining informed consent

If you only wish for your child to undergo some tests, or disagree with the transfer of data, please complete and sign the declaration on the reverse [in the German brochure].

Contact address: Screening Centre, Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Veterinärstraße 2, 85764 Oberschleißheim Tel: 09131 6808-5204 or -5131