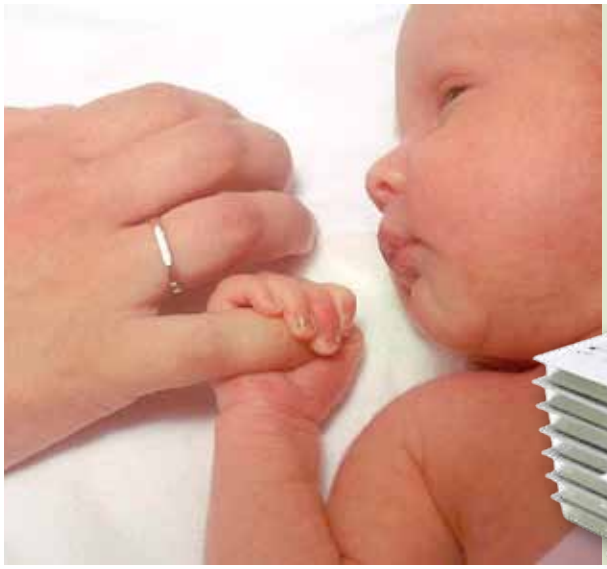
HUMAN HEALTH

ENVIRONMENTAL HEALTH

RELIABLE RESULTS – EFFICIENTLY

GSP® NEONATAL ASSAYS
for CH, galactosemia, CAH and CF screening

PerkinElmer®
For the Better



GSP® NEONATAL KITS

DELFIA® or enzyme-based fluorescence assays

GSP® is the new, automated neonatal screening system from PerkinElmer. It has multi-technology capability, which means that both DELFIA® and prompt fluorescence assays can now be run on a common platform. Its versatility and speed help it to accommodate present and future screening needs.

Kits already available are

- **GSP Neonatal hTSH and GSP Neonatal Thyroxine (T4),** for congenital hypothyroidism (CH) screening
- **GSP Neonatal GALT,** the first automated assay for galactosemia screening
- **GSP Neonatal 17α-OH-progesterone,** a GSP version of PerkinElmer's widely used screening assay for congenital adrenal hyperplasia (CAH)
- **GSP Neonatal IRT** for cystic fibrosis screening

In addition, several new kits are currently in development as we continue to expand the GSP assay portfolio.

Work with the leader in Newborn Screening

PerkinElmer is the global market leader in neonatal screening, currently serving customers in some 74 countries.

The company is a total solution provider offering complete systems based on a broad range of high quality, validated products, including newborn screening kits, consumables, instruments and software. Our global presence and comprehensive support philosophy mean that our expertise is available to you at all times.

46 babies saved every day

The first DELFIA neonatal kit was developed in 1985, to allow dried blood spot measurement of hTSH. In 2010, for this analyte alone PerkinElmer sold kits in 70 countries.

By 2010, some 350 million babies had been screened with PerkinElmer products. For every day of the year serious disorders are revealed in 46 babies so that treatment may be applied in time.

GSP® NEONATAL ASSAYS

Reduced risk of error

All contents of GSP Neonatal kits, including reagents, plates, QC material and lot specific QC certificates are barcoded to reduce the risk of errors.

Less work – faster results

To minimize the pre-analytical work, for most GSP assays, all reagents are ready to use. On the instrument itself, there are direct access water and waste lines, with automatic dilution of wash concentrate. The reagent storage compartment is temperature controlled to provide extended on board stability, and relieve the need to unload reagents once loaded.

For further time efficiency, a single calibration curve can be used for up to 24 hours. This enables more samples to be run on plates and easier reruns. Additionally, all calibrators and controls come in cassette format to support automatic punching.

SCREENING FOR CONGENITAL HYPOTHYROIDISM

using GSP Neonatal hTSH and GSP Neonatal Thyroxine (T4) assays

Congenital hypothyroidism (CH) occurs in 1 in 4,000 to 1 in 3,000 newborns.[1] CH results from a failure of the thyroid glands to produce thyroid hormones in adequate amounts. The condition can easily be treated with daily doses of thyroid hormones but clinical diagnosis is difficult to establish and the disease may continue unrecognized for a long time causing irreversible brain damage. However, increased thyroid stimulating hormone (hTSH) and decreased thyroxine are clear signs of CH, which have led to the establishment of large scale screening programs.

The PerkinElmer GSP Neonatal hTSH and GSP Neonatal Thyroxine (T4) assays are used with dried blood spot specimens as an aid in screening newborns for congenital hypothyroidism.

- The incubation time is only 3.5 h for hTSH, and 2 h for T4
- Sensitive, robust DELFIA chemistry for confidence in results
- The kits contain reagents and plates for 1152 tests (12 plates)

GSP Neonatal hTSH assay

The GSP Neonatal hTSH assay is based on a direct sandwich technique where two monoclonal antibodies recognize separate antigenic determinants on the hTSH molecule. The fluorescence signal is proportional to the analyte concentration in the sample (see diagram on page 7).

GSP Neonatal Thyroxine (T4) assay

In the GSP Neonatal Thyroxine (T4) assay the analyte competes with europium-labeled T4 for the binding sites on T4 specific monoclonal antibodies and the fluorescence signal is inversely proportional to the analyte concentration in the sample (see diagram on page 6).

SCREENING FOR GALACTOSEMIA

with GSP Neonatal GALT – the first automated GALT assay

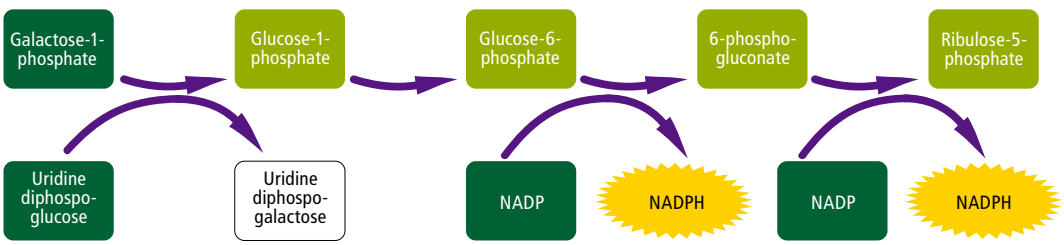
Galactosemia is an inherited disorder caused by a deficiency of one of three enzymes responsible for the metabolism of α-D-galactose. The most common form of the disease, galactose 1-phosphate uridyltransferase (GALT) deficiency occurs in approximately 1 in 47,000 newborn infants.[2] This disorder is often referred to as classic galactosemia. If not diagnosed and treated within the newborn period, it can lead to diarrhea, dehydration, jaundice, hepatic failure, hypoglycemia, cataracts, developmental retardation, and death within a few weeks. Treatment of the disease consists of withdrawal of all foods containing lactose and galactose from the diet.

The GSP Neonatal GALT assay is used as an aid in screening newborns for classic galactosemia.

- Faster assay - incubation time now only 2 h
- Improved precision compared to manual assays
- Provides results in today's preferred unit, U/dL
- Contains reagents for 1152 tests (12 plates), clear microplates should be ordered separately in a bulk pack of 50.
- Floating disks control

GSP Neonatal GALT assay

In the GSP Neonatal GALT assay, GALT in the blood sample catalyzes a reaction between galactose-1-phosphate and uridine diphosphoglucose contained in the assay substrate reagent. In the course of further reactions NADP (nicotinamide adenine dinucleotide phosphate) also contained in the assay substrate reagent is reduced to NADPH, a fluorescent substance that can be measured with excitation at 355 nm and emission detection at 460 nm.



SCREENING FOR CONGENITAL ADRENAL HYPERPLASIA

with GSP Neonatal 17α-OH-progesterone

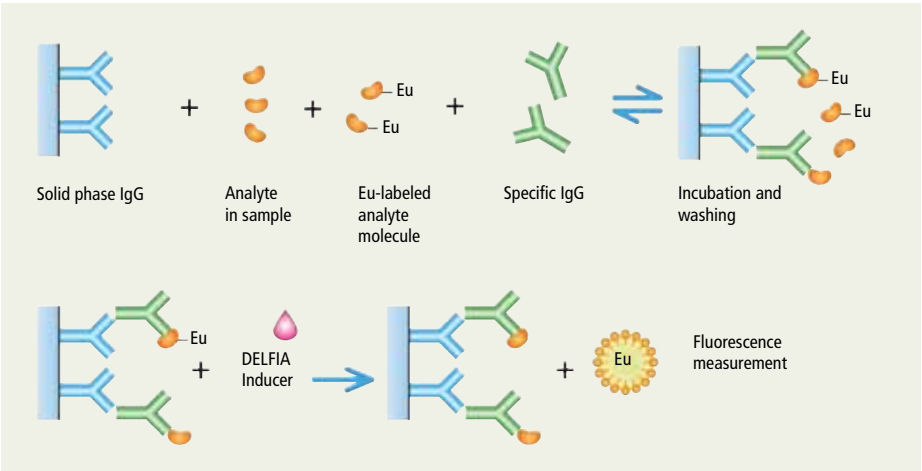
Congenital adrenal hyperplasia (CAH) is a genetic disorder affecting approximately 1 in 16,000 live births in North America[1], and the most severe form of the disease can lead to a life threatening condition during the first weeks of life. The disease is caused by enzyme defects in steroid biosynthesis, the most frequent types being 21- and 11a-hydroxylase deficiency. These types represent 95% of CAH cases and in both, the 17α-OH-progesterone (17OHP), a precursor of cortisol, is increased. The determination of 17OHP is thus a useful screening method for 95% of all CAH cases.

The GSP Neonatal 17α-OH-progesterone assay is intended for the quantitative determination of 17OHP in dried blood spot specimens as an aid in screening newborns for CAH.

- Incubation time 3 h
- Sensitive, robust DELFIA chemistry for confidence in results
- Contains reagents and plates for 1152 tests (12 plates)

GSP Neonatal 17α-OH-progesterone assay

The GSP Neonatal 17α-OH-progesterone assay is based on the competitive binding of europium-labeled 17OHP and 17OHP in the sample to 17OHP-specific antibodies. The fluorescence signal is inversely proportional to the analyte concentration in the sample.



Competitive assay design as used in the GSP Neonatal assays for T4 and 17OHP

SCREENING FOR CYSTIC FIBROSIS

with GSP Neonatal IRT

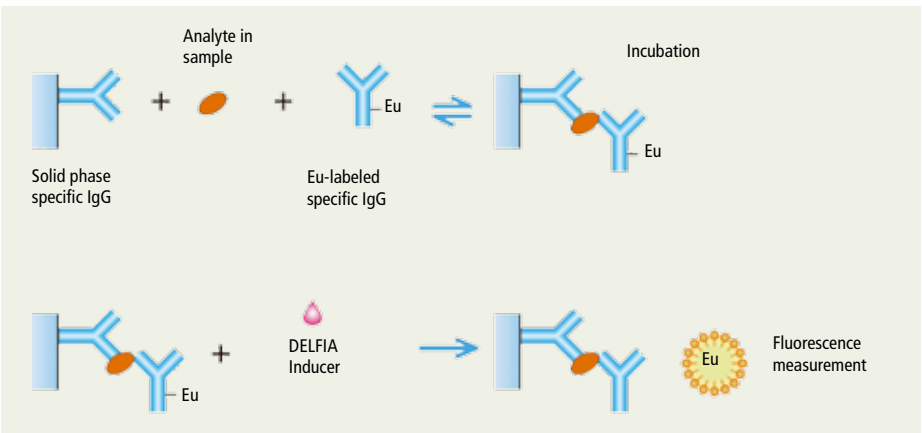
Cystic fibrosis is a common genetic disorder affecting approximately 1 in 3,500 white newborn infants[1]. The diagnosis is often based on the symptoms which may cause considerable delays in the disease intervention, and evidence indicates that early attention may be important in determining the clinical outcome. The amount of the pancreatic enzyme, immunoreactive trypsin(ogen) (IRT) has been shown to be increased in blood of CF patients especially during the first weeks after birth.

The GSP Neonatal IRT assay allows the quantitative determination of IRT from dried blood spot specimens, and is intended as an aid in screening for cystic fibrosis.

- Linear calibration curve fitting - improved precision
- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time 2 h
- The kit contains reagents and plates for 1152 tests (12 plates)

GSP Neonatal IRT assay

The assay is based on a direct sandwich technique where two monoclonal antibodies bind to different epitopes on the target molecule. The fluorescence signal is proportional to the analyte concentration in the sample.



Sandwich-type assay design as used in the GSP Neonatal assays for hTSH and IRT

ORDERING INFORMATION

3301-001U	GSP Neonatal hTSH kit
3302-001U	GSP Neonatal Thyroxine (T4) kit
4076-0010	Clear microplates for GSP Neonatal GALT kit (50 plates)
3303-001U	GSP Neonatal GALT kit excluding plates, reagents for 12 plates
3305-001U	GSP Neonatal 17α-OH-progesterone kit
3306-001U	GSP Neonatal IRT kit
3304-0010	DELFIA Inducer
4080-0010	GSP Wash concentrate

References:

[1] Kaye, CI. and the Committee on Genetics (2006) **Newborn Screening Fact Sheets.** *Pediatrics 118; 934-963. DOI: 10.1542/peds.2006-1783.*

[2] National Newborn Screening and Genetics Research Center. **National Newborn Screening Report: 1999.** *Austin, TX: National Newborn Screening and Genetics Research Center; 2002.*

For the better

At PerkinElmer, we're working to improve the health and safety of people and their environment. From safer water to cleaner air to healthier babies, our solutions touch every part of your life.

This brochure is intended for distribution in the USA and describes products offered for sale in this country. For information on the availability of PerkinElmer neonatal screening products in other countries, please contact your local representative.

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1244-9928-03, June 2011, Printed in USA