EARLIER DETECTION FOR A HEALTHIER FUTURE

GSP® Newborn screening system - the most advanced system for screening NBS disorders

Brochure not for distribution in the US
GSP – THE MOST ADVANCED SOLUTION FOR SCREENING NBS DISORDERS

Every life is exceptional and every child is unique. That's why your screening program should deliver exceptional performance when it matters most – at the beginning of a child's life.

As the most advanced platform for screening of NBS disorders, the GSP Newborn screening system offers outstanding screening accuracy and reliability, coupled with high efficiency and user-friendliness. It brings the future of neonatal screening to your laboratory, helping you provide children with a healthier start to life.

WHAT MAKES THE GSP AN ALL-IN-ONE SCREENING SYSTEM

- Fully automated from plate loading to results output - reduced hands-on stages and reduced risk of error
- Reliable dried blood spot measurement with several control steps - designed for DBS measurement
- Intuitive interface design and easy-to-learn functionalities - less time on training and workflow management
- Widest selection of neonatal assays - high accuracy and confidence in results
- Continuous sample and reagent loading - all analytes can be run together in any preferred order

GIVE LIFE AN EXCEPTIONAL START

Every life is exceptional and every child is unique. That's why your screening program should deliver exceptional performance when it matters most – at the beginning of a child's life.

As the most advanced platform for screening of NBS disorders, the GSP Newborn screening system offers outstanding screening accuracy and reliability, coupled with high efficiency and user-friendliness. It brings the future of neonatal screening to your laboratory, helping you provide children with a healthier start to life.
USER-FRIENDLY AT EVERY STAGE

1. **LOAD REAGENTS**
   Load bulk reagents and kit reagents as needed. It is not necessary to work out in advance the estimated use of reagents, since they can be loaded in excess or added whenever they run low.

2. **PREPARE WORKLIST**
   If the worklist has not been generated automatically by the punching device, you can create it using GSP Workstation running on an adjacent computer.

3. **LOAD PLATES**
   Load a magazine with plates into the input stacker and an empty magazine into the output stacker. The instrument will start the assay runs automatically.

4. **CHECK STATUS**
   The touch screen allows you to prioritize the running order of your plates as you wish and see instantly the status of your assays, consumables, reagents and waste capacity.

5. **VIEW RESULTS**
   When the assay is complete results are delivered to you at the GSP Workstation computer. You can check the calibration curve, quality control levels, possible notifications about the run, accept the assay and export and print results.

For a more detailed description, please check out the step-by-step GSP training video at https://perkinelmeremea.box.com/GSP-training-video

THE GSP INSTRUMENT. AN ANALYZER LIKE NO OTHER.

WHAT THE GSP INSTRUMENT CAN DO FOR YOUR SCREENING PROGRAM

**More flexible workflow**
The GSP instrument is optimized for continuous sample loading. The loaded plates are processed automatically or users can prioritize the order in which plates are processed.

**Safer and more convenient**
The GSP platform can be connected directly to a deionized water supply and waste line, so you no longer need to add water and drain the waste. The cooled reagent compartment also eliminates the need to unload reagents after assay runs and improves screening accuracy.

**Laboratory friendly**
The GSP instrument is easy for laboratory staff to learn to use, and is controlled via an intuitive touch-screen interface. The instrument requires minimal user training and supports effective staff rotation.

**Reduced risk of error**
Plates, reagents, QC materials and lot specific QC certificate information are all barcoded to support improved traceability and ease of use.

**Improved results management**
The GSP Workstation software tracks your laboratory workflow effectively, so you obtain reliable, quality controlled results with maximum efficiency.

For a more detailed description, please check out the step-by-step GSP training video at https://perkinelmeremea.box.com/GSP-training-video
BEST-IN-CLASS INFORMATICS
THE GSP WORKSTATION COMPRISSES FOUR MODULES, EACH DESIGNED TO IMPROVE WORKFLOW EFFICIENCY AND QUALITY MANAGEMENT.

1. KITLOT EDITOR
Kitlot Editor is an easy way to enter kitlot information. It also allows to edit cut-off limits and build reference curves from existing calibration curves. You can also edit default plate maps by changing sample or control definition.

2. PLATE GENERATOR
Plate Generator can be used to generate worklists if they are not generated directly through connected punchers.

3. RESULT VIEWER
Result Viewer allows you to browse assay runs and related data in plate or worksheet formats. The screen layout can be customized to meet your laboratories' specific requirements.

4. QUALITY CONTROL PROGRAM
Quality Control Program supports effective long-term management and follow-up of quality control data. Store and graphically review results for the controls and monitor the level of a quality control sample. You can also specify quality control run definitions and materials, as well as QC multirules.

FUNCTIONAL VERSATILITY.
FROM TOP TO BOTTOM.

Cooled reagents storage
- Temperature controlled storage for assay reagents
- Room for 13 reagent cassettes
- Enables continuous loading

Stacker modules
- Modules used to load plates to GSP and unload them after completion of the assays
- Each stacker can hold up to 26 plates

Liquid module
- Prepares Wash solution from the Wash concentrate
- Handles the waste solutions

Measurement module
- xy-conveyor to move the plate under the measurement head
- Enables time resolved fluorescence, prompt fluorescence and absorbance measurements

Plate Manipulator
- "Elevator" for transferring plates between different modules of the GSP
- Forms the body of the instrument

Disk remover, washer and bulk dispenser

Incubator and Shakers
- Heated incubator operates at 37°C and can hold up to 12 plates
- Three non-heating shakers can each hold up to 6 plates

DESIGNED FOR DBS MEASUREMENT
GSP is designed to measure reliably dried blood spot samples by using several control steps. The used control steps are specified in the assay protocol. In case a control step is not passed, a notification message is reported.

1. Elution control
Detects missing sample or poorly eluted disks in the wells. In case a missing disk is suspected, a notification message is reported.

2. New measurement technology
New measurement step avoids outliers caused by unspecific fluorescence and reduces variation in results. With GSP G6PD assay results are received even with floating disks.

3. Floating disk control
Detects floating disks that may influence screening results.

4. Disk detection
Detects the removal of disks in DELFIA assays from the wells before measurement.
Neonatal screening is a highly complex workflow involving numerous process stages and continuous attention to quality control. Each link in the screening process must be as reliable and efficient as the next one.

By combining the GSP Newborn screening system with other PerkinElmer products, you can manage your entire screening program, from sample preparation and collection to analysis and results management.

**PERKINELMER HAS AN ANSWER TO EVERY STAGE IN THE SCREENING PROCESS**

1. **SAMPLE COLLECTION AND PREPARATION**
   - PerkinElmer 226 Sample Collection Device is a 100% pure cotton linter filter paper optimized for DBS sampling.
   - When combined with Panthera-Puncher™ or DBS Puncher you will get automatic worklist generation and transfer to GSP.

2. **ANALYSIS AND MEASUREMENT**
   - The GSP instrument is the device of choice for medium to large laboratories. It uses several measurement techniques for screening of NBS disorders and it supports the widest range of analytes and assay techniques.
   - The GSP workstation software is designed to follow laboratory workflow to obtain reliable, quality controlled results with maximum efficiency.

3. **RESULT MANAGEMENT AND REPORTING**
   - SpecimenGate® software is PerkinElmer’s dedicated informatics for newborn screening laboratories.
     - Connects punchers and analysis instruments seamlessly and gathers results into one database
     - Enables punchers to identify specimen-specific requests and responds accordingly (Smart Positive ID)
     - Historical result-based cutoff values (Cutoff analyzer)
     - Demographic-based cutoffs (latter requires Screening Center)

**NBS DISORDERS SCREENED BY THE GSP SYSTEM**
- Congenital Hypothyroidism
- Galactosemia
- Congenital Adrenal Hyperplasia
- Cystic Fibrosis
- Phenylketonuria
- Biotinidase deficiency
- Duchenne Muscular Dystrophy (DMD)
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency

Learn more at [https://perkinelmeremea.box.com/NBS-today](https://perkinelmeremea.box.com/NBS-today)
<table>
<thead>
<tr>
<th>GSP TSH</th>
<th>GSP T4</th>
<th>GSP 17-OHP</th>
<th>GSP IRT</th>
<th>GSP CR-MM</th>
<th>GSP BTD</th>
<th>GSP PKU</th>
<th>GSP TGAL</th>
<th>GSP GALT</th>
<th>GSP GAPI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technology</strong></td>
<td>DELFIA</td>
<td><strong>Combina- tion of DELFIA and Enzymatic</strong></td>
<td>Enzymatic</td>
<td></td>
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<tr>
<td><strong>Assay duration</strong></td>
<td>4 h 9 min</td>
<td>2 h 56 min</td>
<td>3 h 56 min</td>
<td>2 h 43 min</td>
<td>4 h 50 min</td>
<td>4 h 13 min</td>
<td>2 h 28 min</td>
<td>1 h 33 min</td>
<td>2 h 50 min</td>
</tr>
<tr>
<td><strong>On board stability</strong></td>
<td>14 days</td>
<td>14 days</td>
<td>14 days</td>
<td>14 days</td>
<td>14 days</td>
<td>14 days</td>
<td>4 days</td>
<td>48 hours</td>
<td>14 days</td>
</tr>
<tr>
<td><strong>Measuring range</strong></td>
<td>1.13 (µg/dL serum) - 22.9 (µg/dL serum)</td>
<td>0.81 (µg/dL serum) - 15.2 (µg/dL serum)</td>
<td>0.3 (µg/dL serum) - 9 (µg/dL serum)</td>
<td>9 (µg/dL serum) - 59 (µg/dL serum)</td>
<td>0 (µg/dL serum) - 600 (µg/dL serum)</td>
<td>0 (µg/dL serum) - 1110 (µg/dL serum)</td>
<td>0 (µg/dL serum) - 2.4-130 U/dL blood</td>
<td>6-8000 ng/mL</td>
<td>14.8-325 ng/mL serin</td>
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<tr>
<td><strong>Fully automated</strong></td>
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<tr>
<td><strong>Calibrator and Controls in Dried Blood Spot Format</strong></td>
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<td><strong>Fluorescence</strong></td>
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<td><strong>New Measurement Technology</strong></td>
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<td><strong>Automatic Plate Washer</strong></td>
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<tr>
<td><strong>Reagents, Plates and QC Material Barcoded</strong></td>
<td>✔</td>
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<tr>
<td><strong>24 h Solid Calibration Curve</strong></td>
<td>✔</td>
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<tr>
<td><strong>Reagents Ready to Use</strong></td>
<td>✔</td>
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<tr>
<td><strong>Plates Included</strong></td>
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</table>

*The measurement/control step is not required for the specific assay.

**For Congenital Hypothyroidism**

**GSP Neonatal THSH and GSP Neonatal Thyroxine (T4) Kits**

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.

- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time only 3.5h and 2h

**The 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.

**The 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.

**For Congenital Adrenal Hyperplasia**

**GSP Neonatal 17α-OH-Progesterone Kit**

This kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the GSP instrument.

- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time 3h

**The GSP Neonatal 17α-OH-Progesterone Assay**

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

This kit is intended for the semi-quantitative determination of galactose-1-phosphate uridylyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency using the GSP instrument.

- Faster assay – incubation time now only 2 h
- Provides results in today’s preferred unit, U/dl blood
- Floating disks control

THE 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 is reduced to NADPH, a fluorescent substance that can be measured with excitation at 355 nm and emission detection at 460 nm.

Galactose-1-phosphate + UDP-glucose → Glucose-6-phosphate + Galactose

GSP TOTAL GALACTOSE KIT

This kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia using the GSP instrument.

- The first fully automated Total Galactose assay for galactosemia screening
- The reconstituted reagent stability is improved from one hour in the manual kit to several days
- Resorufin step added for improved performance

THE GSP NEONATAL TOTAL GALACTOSE (TGAL) ASSAY

The GSP Neonatal Total Galactose kit makes use of a fluorescent galactose oxidase method. The assay measures total galactose, i.e. both galactose and galactose-1-phosphate. The fluorescence is measured using an excitation wavelength of 505 nm and an emission wavelength of 580 nm.
**INSTRUMENT SPECIFICATIONS**

**Physical dimensions**
- Height: 1960 mm (77.2”)
- Width: 1310 mm (51.6”)
- Depth: 760 mm (30.0”)
- Weight: 610 kg (1345 lb)

**Power requirements**
- Power consumption: 1500 VA
- Mains voltage: 100 - 240 V, 50 - 60 Hz

**Environmental conditions**
- Operating temperature: 18 - 30 °C
- Temperature range: 18 - 27 °C
- Relative humidity: 10 – 80 %
- Temperature range: 28 - 30 °C
- Relative humidity: 10 – 65 %
- Noise: < 60 dB

**The water used for preparing wash solution and for rinsing has to be deionized.**

**Samples**
- Sample type: Blood disks from dried blood spots punched into 96-well plates
- Sample identification: Barcode reader or keyboard input

**Loading**
- Continuous sample loading
- Continuous reagent loading
- Continuous bulk reagent loading

**Bulk Reagents**
- Washing and rinsing
  - Wash solution: Automatic dilution of Wash concentrate from a mains water line (deionized) or from an external bottle outside the instrument
  - Rinse water: Automatic filling from a mains water line (deionized) or from an external bottle outside the instrument

**Liquid waste**
- Waste capacity: Automatic disposal if connected to a waste line OR manual disposal 16 L (15 plates)

**Performance specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Capacity</strong></td>
<td>Sample capacity</td>
</tr>
<tr>
<td></td>
<td>Reagent capacity</td>
</tr>
<tr>
<td></td>
<td>Heated incubator module</td>
</tr>
<tr>
<td></td>
<td>Shaking module</td>
</tr>
<tr>
<td></td>
<td>Wash concentrate capacity</td>
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<tr>
<td></td>
<td>Manual water filling or waste emptying</td>
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<tr>
<td></td>
<td>Automatic water filling and water emptying</td>
</tr>
<tr>
<td><strong>Low volume reagent pipette</strong></td>
<td>Volume range: 5 - 50 µl</td>
</tr>
<tr>
<td></td>
<td>Precision (CV%): &lt; 1.5 % within ± 8 %</td>
</tr>
<tr>
<td><strong>High volume reagent pipette</strong></td>
<td>Volume range: 25 - 200 µl</td>
</tr>
<tr>
<td></td>
<td>Precision (CV%): &lt; 1.5 % within ± 4 %</td>
</tr>
<tr>
<td><strong>Measurement unit</strong></td>
<td>Measurement modes: TRI, FL, Abs</td>
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<tr>
<td></td>
<td>Signal with 1 nM Eu</td>
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<tr>
<td></td>
<td>1 000 000 cps ± 17%</td>
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<tr>
<td><strong>Humidity</strong></td>
<td>Plate storage area: &lt; 60 %</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>Temperature inside the instrument: 25 ± 2 °C</td>
</tr>
<tr>
<td></td>
<td>Reagent storage temperature: 10 ± 2 °C</td>
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<tr>
<td></td>
<td>Heated incubator module: 37 ± 1 °C</td>
</tr>
</tbody>
</table>

**For Phenylketonuria**

**GSP NEONATAL PHENYLALANINE KIT**

This kit is intended for the quantitative determination of phenylalanine concentrations in blood specimens dried on filter paper as an aid in screening newborns for phenylketonuria by using the GSP instrument.

- Incubation time only 2 x 1 h
- Resorufin step added for improved performance
- Also bulk kit with reagents for 5760 tests (60 plates) available (3308-0018)

**THE GSP NEONATAL PHE ASSAY**

In the first reaction of GSP Neonatal Phenylalanine assay, phenylalanine dehydrogenase converts phenylalanine in sample to phenylpyruvate generating NADH. In the presence of NADH, resazurin dye is reduced to fluorescent resorufin, which is measured using an excitation wavelength of 505 nm and an emission wavelength of 590 nm.

**For G6PD deficiency**

**GSP NEONATAL G6PD KIT**

This kit is intended for the quantitative in vitro determination of glucose-6-phosphate dehydrogenase (G6PD) activity in blood specimens dried on filter paper as an aid in screening newborns for G6PD deficiency using the GSP instrument.

- The first fully automated assay for G6PD deficiency screening
- Reliable sample results even with floating disks

**THE GSP NEONATAL G6PD ASSAY**

The assay is based on the oxidation of glucose-6-phosphate by the G6PD enzyme present in the sample. At the same time NADP+ is reduced to a fluorescent resorufin, which is measured with excitation wavelength at 340 nm and an emission wavelength at 505 nm.
ORDERING INFORMATION

2021-0010 Genetic Screening Processor

The Genetic Screening Processor includes GSP instrument and GSP Workstation.

The GSP instrument includes:

- High volume reagent tips (960)
- Low volume reagent tips (960)
- Cassette pack (3x) for tips and reagents, each containing:
  - Reagent cassette (6x)
  - Low volume tip cassette (1x)
  - High volume tip cassette (1x)
  - Waste tip cassette (1x)
- Anti-evaporation caps (3 x 10)
- Magazine for 25 plates, input / output (2x)
- External barcode reader
- External keyboard with touchpad
- Installation kit containing necessary cables and tubing
- Service kit containing parts for routine maintenance of the GSP instrument
- User manual (English paper version and other available language versions on a CD)
- Instrument manual (English)

2021-3010 GSP Workstation includes:

- Computer with GSP Workstation software
- GSP Workstation Quality Control manual (English paper version and other available language versions on a CD)
- GSP Workstation Result Viewer, Kitlot Editor and Plate Generator manual (English paper version and other available language versions on a CD)

Kits outside the US

<table>
<thead>
<tr>
<th>Kits outside the US</th>
<th>3301-0010</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>GSP Neonatal hTSH kit</td>
</tr>
<tr>
<td>3302-0010</td>
<td>GSP Neonatal Thyroxine (T4) kit</td>
</tr>
<tr>
<td>3303-0010</td>
<td>GSP Neonatal GALT kit</td>
</tr>
<tr>
<td>3305-0010</td>
<td>GSP Neonatal 17α-OH-progesterone kit</td>
</tr>
<tr>
<td>3306-0010</td>
<td>GSP Neonatal IRT kit</td>
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<tr>
<td>3307-0010</td>
<td>GSP Neonatal Biotinidase kit</td>
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<tr>
<td>3308-0010/3308-001B</td>
<td>GSP Neonatal Phenylalanine kit</td>
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<tr>
<td>3309-0010</td>
<td>GSP Neonatal Total Galactose kit</td>
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<tr>
<td>3310-0010</td>
<td>GSP Neonatal G6PD kit</td>
</tr>
<tr>
<td>3311-0010</td>
<td>GSP Neonatal Creatine Kinase -MM kit</td>
</tr>
</tbody>
</table>

All the kits include reagents for 12 plates (1152 assays) except the 3308-001B GSP Neonatal Phenylalanine kit which includes reagents for 60 plates (5760 assays)

Consumables

<table>
<thead>
<tr>
<th>Consumables</th>
<th>3304-0010</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>DELFIA Inducer</td>
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<tr>
<td>4080-0010</td>
<td>GSP Wash concentrate</td>
</tr>
<tr>
<td>4076-0010</td>
<td>Clear microplates for GSP Neonatal GALT kit or GSP Neonatal G6PD kit (50 plates)</td>
</tr>
<tr>
<td>4091-0010</td>
<td>Clear U-bottomed microplates for GSP Neonatal Phenylalanine kit or GSP Neonatal Total Galactose kit (100 plates)</td>
</tr>
</tbody>
</table>

Products in this brochure may not be available in all countries. Confirm availability with your local PerkinElmer representative.