





PerkinElmer is the global market leader in neonatal screening, currently serving customers in more than 90 countries. We are 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.

Since 1985, allmost 500 million babies have been screened with our products. Every day 63 babies around the world get a healthier start to life thanks to the early detection of a serious disorder.

EARLIER DETECTION WITH COMPLETE RANGE OF SCREENING ASSAYS FOR NBS DISORDERS

Early detection is critical to the treatment of many congenital newborn disorders. PerkinElmer's assays help you find affected children in time and determine the best course of care.

DISORDERS	ANALYTES				ISTRUMENT			
		GSP®	AutoDELFIA®	VICTOR2 ™D	TQD MSMS	VICTOR EnLite™	Resolve®	Sebia CAPILLARYS 2 Neonat Fast™
Congenital hypothryroidism	hTSH	✓	✓	✓				
	T4	✓	✓	✓				
Congenital adrenal hyperplasia	17-OHP	✓	✓	✓				
Cystic fibrosis	IRT	✓	✓	✓				
Phenylketonuria	Phenylalanine	✓ *		✓				
Galactosemia	GALT	✓		✓				
	TGAL±	✓		✓				
G6PD deficiency	G6PD*	✓		✓				
Biotinidase deficiency	Biotinidase	✓±		✓				
Hemoglobinopathies	Hb Variants						✓	✓
Metabolic and amino acid disorders	AA/AC				✓			
Severe combined immunodeficiency	TREC					✓		

^{*}Product not available in the USA or Canada +Product not available in Canada

Some of the PerkinElmer products mentioned on this page may not be available in all countries. For information on availability in your country please contact your local PerkinElmer representative.

Analysis and Measurement

Analytical performance is the foundation of effective newborn screening. That is why we manufacture all our instruments and reagents to highest quality and performance standards, and source key components and technology from trusted suppliers.

Informatics

Newborn screening generates vast amounts of data that require continuous tracking. With effective information management, you can increase processes throughout and reduce costs. Our dedicated informatics solutions for newborn screening laboratories keep vital information flowing from sample to result and beyond.

Support

Our specialists help you set up and manage your screening process from start to finish. Our ultimate goal is to maximize instrument uptime and ensure that your screening results are accurate.

FROM SAMPLE TO RESULT. WE COVER THE ENTIRE SCREENING PROCESS

1 SAMPLE COLLECTION





PerkinElmer 226 Sample Collection Device is a dried blood spot collection card comprised of 100% pure cotton linter filter paper validated for even and uniform sample distribution. PerkinElmer can custom-print and manufacture a device format that meets your specialized newborn screening requirements.



DBS Puncher® Instrument is a semiautomatic device for punching dried blood spot samples into microtitration plates. The 2-plate capacity puncher is an easy-to-use, robust option for lower capacity screening.



Panthera-Puncher^{TM9} Instrument is the next- generation semi-automatic dried sample punching device with an automatically adjusting punch pattern. Thanks to its outstanding ergonomics, enhanced traceability and unique 9-plate capacity, Panthera-Puncher instrument allows you to process sample materials with optimum efficiency and performance.

ANALYSIS AND MEASUREMENT PLATFORMS



TQD MSMS Screening System is the system-level tandem mass spectrometry solution for comprehensive screening of metabolic disorders in neonates. Together with the nonderivatized Neobase kit and dedicated screening software, TQD MSMS Screening System delivers exceptional scan speed and sensitivity, as well as the right tools for easy interpretation of screening results.

Disorders: Metabolic and amino acid disorders



Sebia CAPILLARYS 2 Neonat Fast™ Instrument is the innovative screening platform for hemoglobin disorders. Exclusive capillarys elecrophoresis technology for high resolution separation and complete walk-away automation from hemosylate preparation to final color-coded result.

Disorders: Hemoglobinopathies

GSP® Instrument is the most advanced screening platform for neonatal dried blood spot assays and the system of choice for medium to large laboratories. Performing all assay stages automatically with superior accuracy and traceability, GSP instrument supports our complete range of analytes and employs several measurement techniques for screening of core NBS disorders. From plate loading to results output, GSP instrument offers laboratories outstanding efficiency and confidence throughout the screening process.

Disorders: Congenital adrenal hyperplasia, congenital hypothryroidism, galactosemia, phenylketonuria*, cystic fibrosis, biotinidase deficiency±, G6PD deficiency*

AutoDELFIA® Instrument is a fully automatic neonatal screening platform for sensitive and precise quantitation of four assays based on DELFIA chemistry. Combining versatility with ease of use, AutoDELFIA instrument also supports prenatal screening. For medium to large laboratories that perform 1,000 – 2,000 DELFIA tests per day.

Disorders: Congenital adrenal hyperplasia, congenital hypothryroidism, cystic fibrosis



VICTOR2 TMD Instrument is the ideal measurement platform for low volume laboratories. Easy to use and reliable, Victor2 provides start-up screening programs with the right balance of cost-effectiveness and control

Disorders: Congenital adrenal hyperplasia, congenital hypothryroidism, galactosemia, phenylketonuria, G6PD deficiency*, phenylalanine, cystic fibrosis, biotinidase deficiency±





Trinest™ Incubator shaker instrument



DELFIA® Washer-diskremover



DELFIA® Plateshake instrument

*Product not available in the USA or Canada

±Product not available in Canada

Some of the PerkinElmer products mentioned on this page may not be available in all countries. For information on availability in your country please contact your local PerkinElmer representative.



Resolve® IEF System is our diagnostic testing system for hemoglobinopathies. The system allows positive identification of the hemoglobin types, confirming the presence or absence of sickle cell diseases or thalassemia. Interpretation of gels may be aided by an imaging system such as PerkinElmer's dedicated IsoScan gel imaging system for IEF.

Disorders: Hemoglobinopathies



EnLiteTM Neonatal TREC Instrument is PerkinElmer's platform for molecular screening of severe combined immunodeficiency (SCID). This complete system includes ready-to-use reagents, a Victor EnLite instrument and dedicated software. Combined with continuous support and effective training, Enlite Neonatal TREC system stands out as the practical approach to SCID screening.

Disorders: Severe combined immunodeficiency



As the global leader in newborn screening, PerkinElmer was wellpositioned to develop the world's first laboratory information management system specifically intended for newborn screening. Specimen Gate® is the result of years of continuous development, and the product is widely used in all parts of the world.

Specimen Gate® software modules providing control and monitoring tools for the entire screening process:



LABORATORY®

For managing the laboratory processes. Specimen Gate Laboratory Enterprise Edition software allows two-way communication with PerkinElmer punching devices and instruments, and interfaces to third-party instruments too. It models the processes involved in punching; allows electronic gathering of test results from all instruments; flags analytes and disorders based on site-specific logic; and includes both Quality Control data management as well as Cutoff Analysis tools.

- Models the punching
- Gathers test results from all instruments
- Flags analytes and disorders

SCREENING CENTERTM

Specimen Gate® Screening Center™ software focuses on the overall management of newborn screening programs. It allows smooth handling of patient demographics and patient reports; offers the ability to enter and track patient and contact information; and supports creating of business rules to govern the content of patient reports. Ad-hoc guerying and statistical information to monitor the performance of the program is provided.

- Easier handling of patient demographics and patient reports
- Entry and tracking of patient and contact information
- Business rules for patient reports

PATIENTCARETM

For follow up of screen-positive patients and unsatisfactory specimens. Specimen Gate® PatientCare™ software allows users to define and monitor the processes used to follow up a positive determination. Cases are created within PatientCare™ software, allowing users to track the tasks associated with follow up. Users can define procedure templates for each disorder in the test panel. Each template is made up of individual tasks and includes automatic followup workflow procedures reminding of necessary actions.

- Every case requiring follow up is monitored
- Electronic updating of tasks performed
- Reminds of necessary actions

eREPORTS™

Specimen Gate® eReports™ software allows end users to view patient reports online. Remote data entry of patient de mographics is available. The application is hosted on a server rovided by the customer to ensure that customers retain control over the information to which end-users have access

Reports created by the laboratory using Screening Center™ and/or PatientCare™ software are available 24h/7d through the secure web connection.

- End-users can use eReports to send demographic data or test results back to the laboratory
- Cost and time savings are immediately realized



BENEFITS

TO CONSIDER

nopathies screening.

Low setup costs, low maintenance costs, reliable results.

This solutions demands manual assay preparation, which reduces

traceability and increases risk of human errors. This laboratory

might consider Resolve IEF system for cost effective hemoglobi-

EVERYTHING YOU NEED FOR EFFICIENT NEWBORN SCREENING

PerkinElmer provides you with the tools you need to run a successful and cost-effective neonatal screening program. We offer a broad range of systems and solutions for every type of laboratory from manual low cost alternatives to more sophisticated fully automated

Some general examples of solutions for different laboratory needs are given below. To find the optimal solution for your laboratory, please contact your local PerkinElmer representative.

FOR LOW VOLUME LABORATORIES

- when costs must be kept down, but performance must not be compromised

FOR LOW TO MEDIUM VOLUME LABORATORIES

- when your panel or volume expands

FOR MEDIUM TO LARGE **VOLUME LABORATORIES**

- when you value automation and traceability

RATIONALE

HIGH VOLUME EXPANDED **LABORATORIES**

Panthera-Puncher™ 9 Punching up to 9

– when high automation, full traceability, seamless integration and instruments with two-way communication are your standards

TESTS

TSH

IRT

• 170HP

GALT

Biotinidase

SCID

VOLUME

600 specimens/day

4200 tests/day

Expanded

screening

including PKU

RATIONALE

assays in parallel

2 punch sizes

Consolidated

platform for all core

solution for expanded

IVD assay for SCID

Full automation

Comprehensive

screening

screening

SOLUTIONS RATIONALE TESTS RATIONALE TESTS SOLUTIONS DBS Puncher® ≤ 2 Parameters TSH Panthera-Puncher™ Punching up to 9 TSH • 170HP instrument 1 Punch size PKU instrument assays in parallel/ 8 IRT 2 different punch sizes PKU MCAD Hb Variants AutoDELFIA® Automated VICTOR 2™ D Manual platform for platform for DELFIA instrument instrument all core disorders assavs VOLUME VOLUME TQD MSMS System Expanded screening SpecimenGate™ Browser based for PKU + possible Essentials software informatics software for additional parameters (In development**) core newborn screen- 600 specimens/day 400 specimens/day ing result management | 1200 tests /day 2000 tests/day Sebia CAPILLARYS 2 Automated solution Neonat Fast™ for screening for hemoglobinopathies instrument W111 **SpecimenGate Essentials software is in development, release contingent on satisfy-Specimen Gate™ Informatics solution ing country specific regulatory requirements. Laboratory Enterprise integrating instruments This product does not conform to 98/79 EC Edition software seamlessly, providing In Vitro Diagnostic Medical device directive control and monitorand cannot be placed on the market or put ing tools for the entire into service until they have been made to screening process incomply cluding patient reporting and follow-up

BENEFITS

Automation of immunoassavs and screening for hemoglobinopathies, good traceability of the punching process. Two-way communication between instruments.

TO CONSIDER:

AutoDELFIA instrument is limited to DELFIA assays. GSP instrument can be considered an option for AD as a fully automated/higher capacity solution compatible with future expansions to include enzymatic assays.

Panthera-Puncher™ 9 Punching up t assays in paral 2 different pur sizes



SOLUTIONS

assavs



TO CONSIDER:

performance and workflow.

The GSP workstation software is a stand alone solution for ba- 400 specimens/day sic data management | 2000 tests/day and quality control

High traceability in the sample processing process, consolidated

This laboratory might consider including Specimen Gate™

Laboratory® software solution for seamless communication

between instruments and better monitoring of the laboratory

platforms, full automation and high capacity.

Punching up to 9 assays in parallel / 2 different punch sizes	•	TSH PKU 17OHP TGAL G6PD
Consolidated platform for all core assays		

TESTS

VOLUME

Victor™ Enlite

SOLUTIONS

GSP® instrument

TQD MSMS System

instrument



Specimen Gate™ Informatics solution



Laboratory Enterprise integrating instruments seamlessly, providing control and monitoring tools for the entire screening process including patient reporting and follow-up

BENEFITS

Full traceabaility throughout the process, consolidated platforms. full automation and high capacity. Two-way communication between instruments and easy patient reporting system.

TO CONSIDER:

With the addition of Sebia CAPILLARYS 2 Neonat Fast™ instrument this laboratory would enable screening for hemoglobinopathies.

Products on this page may not be available in all countries. Please check availability with your local PerkinElmer representative.



BETTER SUPPORT. MORE EFFECTIVE PROCESS.

Through our experts in newborn screening, we can help you to create service programs that meet the standards of even the most demanding screening laboratories. Our global presence and holistic understanding of newborn screening enables our screening solutions to share both innovation and know-how effectively.



Consultation	Training	Service Excellence	Customer Support	
PerkinElmer develops, manufactures and supports a market leading ange of instruments, reagents, and consumables to the screening community.	Our training team offers diagnostics product training courses for customers. Training is conducted by product managers and specialists from customer and technical support, software	PerkinElmer's dedicated diagnostics service team comprises trained and certified engineers who have an average of 15 years of experience maintaining PerkinElmer and partner equipment.	Our product specialist and technical support teams provide country and regional support. That's why PerkinElmer is able to provide the best service in thindustry.	
Providing unparalleled knowledge and depth of expertise with over 75 rears of experience, PerkinElmer is a company you can count on to be here when you need us.	services and R & D. We aspire meet your training expectations and to give you the best possible training experience.			

PerkinElmer, Inc. 940 Winter Street Waltham, MA 02451 USA P: (800) 762-4000 or (+1) 203-925-4602 www.perkinelmer.com



For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs $\,$

Copyright ©2015, PerkinElmer, Inc. All rights reserved. PerkinElmer® is a registered trademark of PerkinElmer, Inc. All other trademarks are the property of their respective owners.

1244-1216-16, November 2015