HUMAN HEALTH

ENVIRONMENTAL HEALTH

# COST-EFFICIENT SYSTEM FOR NEWBORN SCREENING

**The semi-automated system for optimized newborn screening**

Brochure not for distribution in the US

PerkinElmer®
*For the Better*

# EFFECTIVE DETECTION FOR A HEALTHIER FUTURE

# THE TRUSTED SYSTEM FOR AFFORDABLE AND EXPANDABLE NEWBORN SCREENING

PerkinElmer is the global market leader in neonatal screening, currently serving customers in more than 90 countries. Almost 500 million babies have been screened with our products. Every day 65 babies around the world get a healthier start to life thanks to the early detection of a serious disorder.

Since 1999, the semi-automated system has been used in over 200 NBS laboratories all over the world. The large number of users is a testament to the quality and reliability of the platform: nearly 10 million newborns are screened with Victor™ 2D each year. The semi-automated system is a robust, cost-efficient solution for screening of seven NBS disorders: congenital hypothyroidism, phenylketonuria, congenital adrenal hyperplasia, galactosemia, cystic fibrosis, biotinidase deficiency and G6PD deficiency.

## WHY CHOOSE THE SEMI-AUTOMATED NBS SYSTEM?

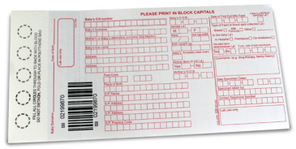
- ☑ Ideal solution for small to mid-size and start-up laboratories
- ☑ Fully expandable when needs in the laboratory change – adding new parameters or increasing sample volume is easy and cost-efficient
- ☑ Total solution guarantees excellent support and service throughout the whole workflow
- ☑ All instruments and assays are CE marked
- ☑ Over 200 satisfied NBS customers globally

# OPTIMIZED PRODUCTS FOR BEST RESULTS

All products and instruments are especially optimized for use with PerkinElmer kits. They may be supplied alone or as part of a complete semi-automatic system for performing DELFIA and other assays.

## VICTOR™ 2D FLUOROMETER

- Easy to use and reliable measurement device
- Preset protocols for neonatal assays based on
  - Time-resolved fluorescence (TSH, T4, 17-OHP, IRT)
  - Prompt fluorescence (PKU, GALT, TGAL, BTD, G6PD)
- MultiCalc software included for result calculation, QC control and communication with LIMS

## PERKINELMER 226 SAMPLE COLLECTION DEVICE

- 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 specialized newborn screening requirements

## DBS PUNCHER® INSTRUMENT

- Semi-automatic device for punching dried-blood spot samples into microtitration plates
- The 2-plate capacity puncher is easy-to-use
- Robust option for lower capacity screening
- Alternatively Panthera-Puncher™ 9

## DELFIA® PLATE DISPENSE

- Automatic and precise addition of Enhancement solution
- Optimized for DELFIA reagents
- As an option DELFIA Dispense Unit can be ADDED allowing automatic dispensing e.g. buffer or tracer solution

## DELFIA® WASHER-DISKREMOVE

- Automatically removes the eluated filter paper disks from the wells
- Performs all needed wash stages as specified in the assay protocol
- Overfilling of wells is avoided
- Up to 100 protocols can be stored
- Optimized for use with DELFIA neonatal assays

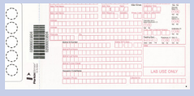
## TRINEST™ INCUBATOR SHAKER

- A high quality, easy to use device for processing standard-height microplates
- Accurate and uniform temperature assures highly repeatable results
- Capacity for 3 plates
- Up to 20 incubating and shaking programs can be stored

## DELFIA® PLATESHAKE

- Two preset shaking speeds optimized for DELFIA assays
- Fully adjustable shaking speed between 100-1350 rpm for general use
- With non-slip surface easy to load and easy to use
- Electronic feedback circuit ensures that shaking speeds remain constant

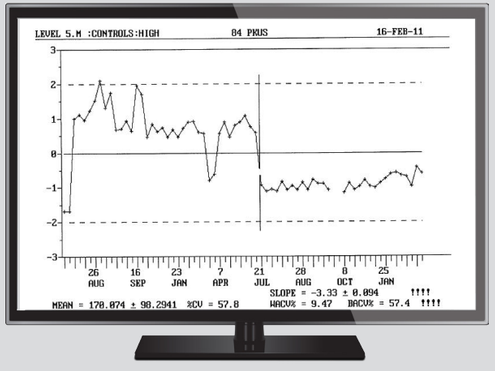
## THE SEMI-AUTOMATED SYSTEM FOR YOUR SCREENING PROGRAM



| SAMPLE COLLECTION | SAMPLE PREPARATION | SAMPLE PROCESSING | MEASURING | DATA PROCESSING & REPORTING |
|---|---|---|---|---|
| **Sample collection device**<br>PerkinElmer 226 sample collection device | **Puncher**<br>Panthera-Puncher™ 9 or DBS Puncher (or Puncher from another supplier) | **Sample preparation**<br>TriNEST™ incubator shaker<br>DELFIA® Plate dispenser<br>DELFIA® Platewash<br>DELFIA® Plateshake<br>Reagents | **Measuring device**<br>VICTOR™2D fluorometer | **Software**<br>MultiCalc |

## MULTICALC SOFTWARE

For data evaluation and quality control




- ☑ Included with Victor™ 2D
- ☑ Can be connected to LIMS
- ☑ Automatic QC follow-up of assays
- ☑ Software includes all the protocols for PerkinElmer neonatal assays as default
- ☑ Results directly ready from the software

# COMPLETE RANGE. BETTER SCREENING.

## BENEFITS OF THE ASSAYS

- PerkinElmer offers reagents, instruments, software, training and support
- The widest test panel - easy and cost-efficient to expand the analyte menu
  - Low repeat testing rate due to high accuracy
  - Low lot-to-lot variation - no need to constantly reset cut-offs
- Long-standing provider and market leader in NBS - proof of our reliability and customer satisfaction
- Calibrators and controls in DBS, lot-specific format
- The unique fluorescent properties of lanthanide chelates of DELFIA technology are the basis for high sensitivity and low assay variation
- All assays can be run either separately or together

**THE MANUAL SYSTEM FOR PRENATAL SCREENING**

VICTOR 2D can also be used for 1st and 2nd trimester prenatal screening*

* The reagent products for prenatal screening using manual system are not available in Japan, Singapore and some other Asian or Latin-America countries. Products may not be licenced in accordance with Canadian law.

| | DBS® Puncher | DELFIA® Plateshake | TriNEST™ Incubator shaker | DELFIA® Washer Diskremove | DELFIA® Plate Dispenser | Victor™2D |
|---|---|---|---|---|---|---|
| TSH | x | x | | x | (x) | x |
| T4 | x | x | | x | (x) | x |
| 17-OHP | x | x | | x | (x) | x |
| IRT | x | x | | x | (x) | x |
| PKU | x | | x | | | x |
| TGAL | x | | | | | x |
| GALT | x | | x | | | x |
| BTD | x | | x | | | x |
| G6PD | x | x | | | | x |

(x) = Alternatively manual pipeting

# INSTRUMENT SPECIFICATIONS

## DBS® PUNCHER INSTRUMENT

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 305 mm
Width: 420 mm
Depth: 480 mm
Weight: 20 kg

**Power requirements**
Voltage/Frequency: 110 -120 V/ 220 - 240 V, 50/60 Hz

**Environmental conditions**
Temperature: 15-35 °C
Relative humidity: 20-80 %

Punch diameter: 1.5 mm (1/16")
3.2 mm (1/8")
4.7 mm (3/16")
6 mm

Plate height: 15 -41mm (suits standard and deep well plates

Operational control: 4 selection button for:
- operation mode selection
- plate movement
- barcode display
- operation guidance
- protocol editing

## VICTOR™ 2D INSTRUMENT

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 383 mm (510 mm with stackers)
Width: 485 mm
Depth: 590 mm
Weight: 49 kg (stacker model 60 kg)

**Power requirements**
Power consumption max: 400 VA
Voltage/Frequency: 110 -120 V/ 220 - 240 V, 50/60 Hz

**Environmental conditions**
Temperature: 15-35 °C
Relative humidity: 10-85 %

Measurement time: 1 s / sample, 3 min / plate
Noise of the device in function: max 70 dB

**Light sources**
Continuous light source for fluorometric measurements:
1. Tungsten-halogen lamp, 75W, lifetime > 300h, Spectral range 340 - 700 nm.
2. Rotatable filter wheel A, provided with 8 filter positions (Ø 15 mm). Standard high quality interference filters 340 nm, 355 nm, 390 nm, 485 nm, 544 nm. Changeable rotatable filter wheel B, provided with 4 filter positions (Ø 25.4 mm)
Flash light source for TR-fluorometric measurements:
1. UV xenon flash tube, L4642 or equivalent, spectral range 280 - 400 nm.
2. Filter slide, provided with 3 filter positions (Ø 22.4mm). Filters 340 nm and 320 nm are fitted.

**Detection units**
Fluorometry and TR-fluorometry:
1. Photomultiplier tube, R 1527
2. Emission filter slide A, provided with 8 filter positions (Ø 25.4mm) with the following filters: 405, 460, 486, 535, 590, 615 and 642 nm
Changeable emission filter slide B, provided with 8 filter positions (Ø25.4mm)

## TRINEST™ INCUBATOR SHAKER

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 223 mm
Width: 388 mm (plate carrier out)
Depth: 310 mm
Weight: 15 kg

**Power requirements**
Power consumption max: 160VA
Voltage/Frequency: 100-120 V or 220-240 V, 50/60 Hz

**Environmental conditions**
Operating: 15°C to +35°C, RH 10-75%

### PERFORMANCE SPECIFICATIONS

**General**
Capacity: 3 plates per unit, 3 units stackable
96-well and 384-well plates
Programmable: up to 20 programs
LCD graphics display
The 3 plates are processed with the same program but can be loaded at different times
Buzzer and LED lights indicate when incubation is complete

**Incubation**
Temperature range: from 3°C above ambient to 70°C in 1°C increments
Precision: ± 0.5°C
Variation across plate: < 0.6°C
Warming speed: less than 15 min from +24°C to +70°C
Incubation time: 0-48h in increments of 1 min
Preheat function assuring incubation starts at precisely the specified temperature

**Shaking**
Shaking frequency: 400-1200 rpm (or 0 rpm) in 100 rpm increments
Precision: ± 2%
Orbit: ~2 mm
Time: 0-48h in increments of 1 min
Interval shaking: interval up to 60 min in increments of 1s or 1 min

## DELFIA® WASHER-DISKREMOVE

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 483 mm
Width: 530 mm (plate carrier out)
Depth: 310 mm
Weight: 16.0 kg

**Power requirements**
Power consumption max: 100 VA
Voltage/Frequency: 240/100 VAC, 50/60 Hz
Power cord: on CEI socket

**Environmental conditions**
Temperature: 15-33 °C
Relative humidity: 15-85 %

### PERFORMANCE SPECIFICATIONS

**Hardware specifications**
Manifold: 12 channels, 8 channels available on request
Vacuum: separate vacuum unit
Volumes of bottles: Waste 8L, Wash 5L, Rinse 2L

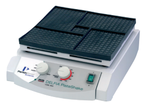
**Software specifications**
Protocols: Up to 100 washing protocols, up to 75 freely programmable.
Wash modes: Strip or Plate

### VACUUM UNIT

**Physical dimensions**
Height: 370 mm
Width: 140 mm
Depth: 400 mm
Weight: 13.0 kg (approx.)

**Power requirements**
Power consumption max: 230VA
Voltage/Frequency: 200-230/100-115 VAC, 50/60 Hz

**Environmental conditions**
Temperature: 15-30 °C
Relative humidity: 15-85 %



## DELFIA® PLATESHAKE

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 128 mm
Width: 245 mm
Depth: 310 mm
Weight: 5.5 kg

**Power requirements**
Power input: 15 W
Voltage/Frequency:
1296-003: 220/240V, 50/60 Hz
1296-004: 110/240V, 50/60 Hz

**Environmental conditions**
Temperature: 0-50 °C
Relative humidity max: 80 %
Suitable for use in gassing and incubating cabinets

### PERFORMANCE SPECIFICATIONS

Shaking frequency: 100 - 1350 cycles/min
Total stroke/orbit: 1.5 mm
The platform has a non-slip, removable moulded rubber pad for accommodating the microtitration plates.
Shaking modes: Fast, Slow or Variable

## DELFIA® PLATE DISPENSE

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 268 mm
Width: 290 mm (plate carrier out)
Depth: 300 mm
Weight: 10.3 kg

**Power requirements**
Power consumption max: 35 VA
Voltage/Frequency: 220/240 V 50/60 Hz or 100/120 V 40/60 Hz

**Environmental conditions**
Temperature: +15 – 35 °C
Relative humidity: max 85 %

### PERFORMANCE SPECIFICATIONS

Speed 3 min 20 sec / plate
Volume dispensed 200 µl per well (preadjusted)
Accuracy better than 1 % at 200 µl
Precision better than 3 % at 200 µl

## DELFIA® DISPENSE UNIT

### INSTRUMENT SPECIFICATIONS

**Physical dimensions**
Height: 85 mm
Width: 150 mm (+65 mm for the bottle holder)
Depth: 135 mm
Weight: 2 kg

### PERFORMANCE SPECIFICATIONS

Speed 2 min 20 sec for one plate
Volume dispensed 50 or 100 µl per stroke (user adjustable)
Accuracy better than 1 % at 200 µl
Precision better than 3 % at 200 µl

# HIGH QUALITY ASSAYS FOR OPTIMIZED SCREENING

## DELFIA NEONATAL HTSH KIT

- Based on DELFIA technology
- The intended use is for the quantitative determination of human thyroid stimulating hormone (hTSH) in blood specimens dried on filter paper as an aid in screening newborns for congenital hypothyroidism
- Kit reagents for 10 plates (960 assays)

## DELFIA NEONATAL THYROXINE (T4) KIT

- Based on DELFIA technology
- The intended use is for the quantitative determination of human thyroxine (T4) in blood specimens dried on filter paper as an aid in screening newborns for congenital hypothyroidism
- Kit reagents for 10 plates (960 assays)

## DELFIA NEONATAL 17α-OH-PROGESTERONE KIT

- Based on DELFIA technology
- The intended use is 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
- Two package sizes available: 4 plates (A024-104) and 10 plates (A024-110)

## DELFIA NEONATAL IRT KIT

- Based on DELFIA technology
- The intended use is for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis
- Two package sizes available: 4 plates (A005-204) and 10 plates (A005-210)

## NEONATAL PHENYLALANINE KIT*

- The kit makes use of a fluorescent ninhydrin method
- The intended use is for the quantitative determination of phenylalanine in blood specimens dried on filter paper as an aid in screening newborns for elevated levels phenylalanine in the blood
- Two packages sizes available: 10 plates (NP-1000*) and 50 plates (NP-4000*)

## NEONATAL G6PD KIT*

- The assay involves the oxidation of G-6-P substrate to 6-PG by the G6PD enzyme present in the sample
- The intended use is for the quantitative determination of glucose-6-phosphate concentrations in blood specimens dried on filter paper as an aid in screening newborns for G6PD deficiency
- Kit reagents for 10 plates (960 assays)

## NEONATAL TOTAL GALACTOSE KIT

- Controls in DBS including both Gal and Gal-1-P
- The kit makes use of a fluorescent galactose oxidase method
- The intended use is 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
- Kit reagents for 10 plates (960 assays)

## NEONATAL GALT KIT

- The assay is an adaptation of the semi-quantitative enzymatic assay of Beutler and Baluda
- The intended use is for the (semi-quantitative) determination of galactose-1-phosphate uridyl transferase (GALT) concentrations in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency
- Two packages sizes available: 10 plates (NG-1100) and 50 plates (NG-4100)

## NEONATAL BIOTINIDASE KIT

- The assay is based on a semi-quantitative fluorometric assay
- The intended use is for the semi-quantitative determination of biotinidase activity in blood specimens dried on filter paper as an aid in screening newborns for biotinidase deficiency
- Two packages sizes available: 10 plates (3018-0010) and 50 plates (3018-001B)

## ORDERING INFORMATION

**Instruments**

| | | |
|---|---|---|
| • | 1296-071 | DBS® Puncher |
| • | 1296-0050 | TriNEST™ Incubator Shaker |
| • | 1296-003 | DELFIA® Plateshake (220/240V) |
| • | 1296-004 | DELFIA®Plateshake (110/240V) |
| • | 1296-0010 | DELFIA® Washer-Diskremove |
| • | 1296-041 | DELFIA® Plate Dispense |
| • | 1420-020 | Victor™2D fluorometer, manual loading |
| • | 1420-021 | Victor™2D fluorometer, stacker model<br>- Victor™2D including PC, monitor, necessary filters, instrument software and MultiCalc |

**Kits**

| | | |
|---|---|---|
| • | A032-310 | DELFIA® Neonatal hTSH kit (10 plate) |
| • | A065-110 | DELFIA® Neonatal Thyroxine (T4) kit (10 plate) |
| • | A024-104 | DELFIA® Neonatal 17α-OH-progesterone kit (4 plate) |
| • | A024-110 | DELFIA® Neonatal 17α-OH-progesterone kit (10 plate) |
| • | A005-204 | DELFIA® Neonatal IRT kit (4 plate) |
| • | A005-210 | DELFIA® Neonatal IRT kit (10 plate) |
| • | NP-1000 | Neonatal Phenylalanine kit (10 plate) |
| • | NP-4000 | Neonatal Phenylalanine kit (50 plate) |
| • | ND-1000 | Neonatal G6PD kit (10 plate)* |
| • | 3029-0010 | Neonatal Total Galactose kit (10 plate) |
| • | NG-1100 | Neonatal GALT kit (10 plate) |
| • | NG-4100 | Neonatal GALT kit (50 plate) |
| • | 3018-0010 | Neonatal Biotinidase kit (10 plate) |
| • | 3018-001B | Neonatal Biotinidase kit (50 plate) |

**Options (sold separately)**

| | | |
|---|---|---|
| • | 1420-221D | Barcode reader |
| • | 2011-0010 | Laboratory laser printer (230 V) |
| • | 2011-0040 | Laboratory laser printer (115 V) |
| • | 1296-043 | DELFIA® Dispense Unit |

**Consumables (sold separately)**

| | | |
|---|---|---|
| • | 3033-0010 | Clear, V-bottomed microplates (for Neonatal Phenylalanine kit)<br>Bulk package of 100 plates |
| • | 4090-0100 | 96-well plate covers |
| • | 1420-450 | ID-labels for 1-99, 10 sheets |

Products for neonatal screening may not be available in Japan, Singapore and some other Asian or Latin-America countries. Products may not be licenced in accordance with Canadian law. Confirm availability with your PerkinElmer representative

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

PerkinElmer, Inc.
Wallac Oy
PO Box 10
20101 Turku, Finland
Phone: + 358 2 2678 111
Fax: + 358 2 2678 357

ISO 13485
ISO 9001
CMDCAS
ISO 14001
OHSAS 18001

PerkinElmer®

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



1599-9806 BRO The semi-automated Victor2D system (ROW), April 2016 PerkinElmer