ONE STOP
COMPREHENSIVE
**NEWBORN SCREENING**
SOLUTIONS FROM
THE **PIONEER**

**LABSYSTEMS**
**D I A G N O S T I C S**

*speaking your language*

## Labsystems Diagnostics - Leadership is about being first in setting trends

### Evolution

Labsystems Diagnostics Oy has been a forerunner in innovative diagnostic research and development for the last 30 years. The company develops, manufactures and markets high quality enzyme immunoassays, molecular assays and Point of Care tests. Labsystems Diagnostics has been a pioneer in the field of In Vitro Diagnostics bringing unique and relevant products and assays addressing a wide array of medical conditions.

### Breakthroughs in Newborn Screening (NBS)

- The first company in the world to introduce fluorometric microplate based assay for phenylalanine for diagnosing phenylketonuria (PKU) in newborns
- Pioneered Newborn Screening products and systems based on fluorescence and photometric detection
- The first and only company in the world to have an assay for the diagnosis of neonatal Toxoplasmosis
- Fully integrated robotic platforms NS2400 with the most comprehensive menu of NBS assays helping screen millions of babies for inborn errors of metabolism and congenital problems
- Neonatal PKU, hTSH, **T4**, 17-OH-Progesterone, IRT, G6PD, TGAL, **GALT**, Biotinidase, Toxoplasma gondii IgM kits
- NeoMass AAAC Plus, expanded newborn screening panel for the quantitantive detection of amino acids (AA), acylcarnitines (AC), argininosuccinic acid (ASA) and succinylacetone (SUAC) on MS/MS platform.
- NS 496 Plus Puncher, NS Incubator/ Shaker, NS Disc Remover, NS Washer, NS/NS200 reader.
- The first and only company in the world to have an assay for the diagnosis of severe combined immunodeficiency (SCID) and spinal muscular atrophy (SMA), simultaneously.

## Newborn Screening

Newborn Screening or Neonatal Screening is a preventive pediatric screening service performed to diagnose congenital or inborn errors of metabolism in order to identify patients and administrate treatment starting from the first weeks of life to reverse the prognosis. Early diagnosis and treatment correlates with significant reduction in mortality and morbidity associated disabilities for those affected.

Complete
# Newborn Screening System
with fully automated **NS2400** fluorescence platform

## FLEXIBILITY OF USE

All reagent kits can be used manually in modular or in fully automated systems.
All our reagents and instruments are CE marked.

CE

## REVOLUTIONARY NS2400
## NEWBORN SCREENING AUTOMATE

Fully integrated robotic high throughput system
25 plates per run (NS2400)
Performs all assays (TSH, T4, PKU, 17OHP, G6PD, TGAL, GALT, IRT, Biotinidase & Toxo IgM)
Reduced running costs (no disposable tips)
Integrated disc remover
High sensitive fluorometric detection
Patient management software

## NEWBORN SCREENING MODULAR DEVICES

**Reliable Newborn Screening devices provided by
Labsystems Diagnostics**

| |
| --- |
| NS 496 Plus DBS Puncher |
| NS Incubator / Shaker |
| NS 96 Disc Remover |
| NS/NS200 Reader |
| NS Washer |
| Sample Cards |

The use of reliable and fast equipment in the screening process is important to ensure the care that the little patients and their families deserve.

## AUTOMATIC NEONATAL DBS PUNCHER *

NEW PRODUCT

**Accurate disc punching of dried blood spot samples**

NS496 Plus DBS puncher is designed for automated punching of 3.2mm (1/8 inch) discs from dried blood spot samples. Up to 4 plates can be handled at the same time.

* Air humidification system to overcome static
* Unique disc sensor to ensure discs are falling into the plate
* Punch cleaning function
* Multiple assay punch
* Three mode punching

## NS96 DISC REMOVER

Stand-alone NS96 Disc Remover automatically removes the sample discs and reagents from 96-well microtitre plate in less than a minute.

## NEONATAL PHENYLALANINE

**Quantitative fluorometric screening kit for PKU**

A chemical method intended for the quantitative determination of phenylalanine from dried blood spots.

Extensive experiences from worldwide customers
Calibrated against the latest international references

## NEONATAL hTSH FEIA PLUS

**Fluorometric enzyme immunoassay for the quantitative determination of human thyrotropin from dried blood spots.**

Minimal background
Good agreement with CDC samples

## NEONATAL T4 FEIA ⭐ NEW PRODUCT

**Fluorometric enzyme immunoassay for the quantitative determination of human thyroxine from dried blood spots.**

Single kit for both manual and automated procedures
Less processing time

## NEONATAL 17-OH-PROGESTERONE FEIA

**Easy and reliable screening for CAH from dried blood spots**

Fluorometric enzyme immunoassay for the quantitative determination of human 17-OH-progesterone from dried blood spots.

Excellent reproducibility
High sensitivity with high signal/background ratio.

## NEONATAL IRT FEIA

**Fluorometric enzyme immunoassay for the quantitative determination of human Immunoreactive Trypsinogen (IRT) from dried blood spots for cystic fibrosis (CF).**

Easy to perform, similar procedure as other kits (TSH, 17OHP)
Stable reagents

## NEONATAL GLUCOSE-6-PHOSPHATE DEHYDROGENASE (NEONATAL G6PD)

Enzymatic method for the quantitative determination of glucose-6-phosphate dehydrogenase activity from dried blood spots, with fluorometric detection.

Superior agreement with external quality samples
Good stability

## NEONATAL GALACTOSE

**Combined fluorometric determination of free galactose and galactose-1-phosphate**

Excellent reproducibility
Excellent analytical sensitivity

## NEONATAL GALT ⭐ NEW PRODUCT

**Fluorometric enzyme immunoassay for the quantitative determination of galactose-1-phosphate uridyltransferase**

No false positives caused by G6PD deficiency
Single kit for both manual and automated procedures

## NEONATAL BIOTINIDASE

**Enzymatic method for the quantitative determination of biotinidase enzyme activity in dried blood spots, with fluorometric detection.**

Easy to perform
No centrifuge or filtration step needed

## NEONATAL TOXOPLASMA GONDII IgM FEIA

Fluorometric enzyme immunoassay for the determination of IgM antibodies to Toxoplasma gondii from dried blood spots.

First Neonatal Toxoplasma screening test in the world
High sensitive μ-capture test

# NEOMASS AAAC PLUS

NeoMass AAAC Plus is used to detect concentrations of 15 amino acid, 13 (acyl) carnitine, succinylacetone (SUAC) and argininosuccinic acid (ASA) from a **single injection/single run**

Detects more than 50 disorders.

Sample extraction without derivatization

**Use of non-toxic/non-carcinogenic compounds (methanol & formic acid) for extraction**

Enables detection of complete Urea cycle disorders (includes both proximal and distal urea cycle defects)

**3 levels of dried blood spot controls** framing the decisional cut-off area for each of the matching internal standards
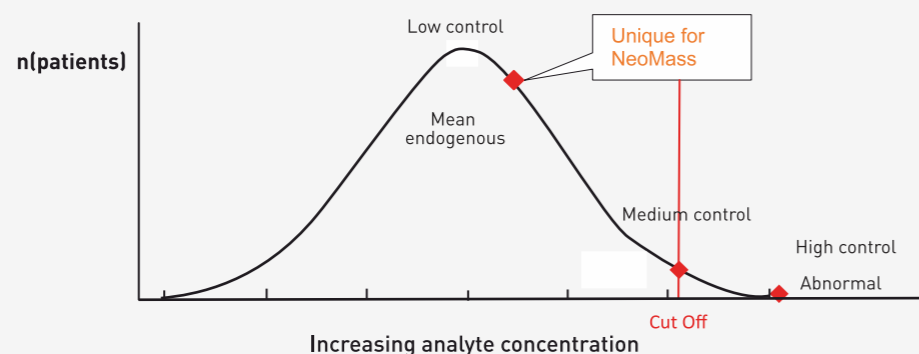


## Provided Isotope – labelled internal standards and analaytes spiked in controls

| ISTD | Control | ISTD | Control |
|------|---------|------|---------|
| $^2H_4$-Alanine | Alanine(Ala) | $^2H_9$-Carnitine | Carnitine(C0) |
| $^2H_4$- $^{13}C$ Arginine | Arginine(Arg) | $^2H_3$-Acetylcarnitine | Acetylcarnitine(C2) |
| $^2H_3$- Aspartate | Aspartate(Asp) | $^2H_3$-Propionylcarnitine | Propionylcarnitine(C3) |
| $^2H_2$- Citrulline | Citrulline(Cit) | $^2H_3$-Butyrylcarnitine | Butyrylcarnitine(C4) |
| $^2H_3$- Glutamate | Glutamate(Glu) | $^2H_9$-Isovalerylcarnitine | Isovalerylcarnitine(C5) |
| $^{15}N$-$^{13}C$- Glycine | Glycine(Gly) | $^2H_3$-Glutarylcarnitine | Glutarylcarnitine(C5DC) |
| $^2H_3$- Leucine | Leucine(Leu) | $^2H_3$-Hexanoylcarnitine | Hexanoylcarnitine(C6) |
| $^{13}C_6$-$^{15}N_2$- Lysine | Lysine(Lys) | $^2H_3$-Octanoylcarnitine | Octanoylcarnitine(C8) |
| $^2H_3$- Methionine | Methionine(Met) | $^2H_3$-Decanoylcarnitine | Decanoylcarnitine(C10) |
| $^2H_6$- Ornithine | Ornithine(Orn) | $^2H_3$-Dodecanoylcarnitine | Dodecanoylcarnitine(C12) |
| $^{13}C_6$- Phenylalanine | Phenylalanine(Phe) | $^2H_9$-Myristoylcarnitine | Myristoylcarnitine(C14) |
| $^2H_5$- Proline | Proline(Pro) | $^2H_3$-Palmitoylcarnitine | Palmitoylcarnitine(C16) |
| $^{13}C_3$- Serine | Serine(Ser) | $^2H_3$-Stearoylcarnitine | Stearoylcarnitine(C18) |
| $^{13}C_6$- Tyrosine | Tyrosine(Tyr) | $^{13}C_5$-Succinylacetone | Succinylacetone(SUAC) |
| $^2H_8$- Valine | Valine(Val) | $^{15}N_4$-$^{13}C_6$Argininosuccinic acid | Argininosuccinic acid (ASA) |

## Patented innovation by Labsystems Diagnostics

### Unique Properties of NeoMass AAAC Plus kit – detection of OTC, CPS1 and NAGS deficiencies

Deficiencies of enzymes in the proximal part of the urea cycle have been challenging to detect in the past but the patented innovation in the new NeoMass AAAC Plus kit changes this. As a first in the world achievement, Labsystems Diagnostics has established a methodology to measure OTC, CPS1 and NAGS deficiencies on dried blood spots along with the traditional detection of ASS, ASL and ARG1 enzyme deficiencies. NeoMass AAAC Plus for tandem MS will therefore enable detection of all urea cycle abnormalities.
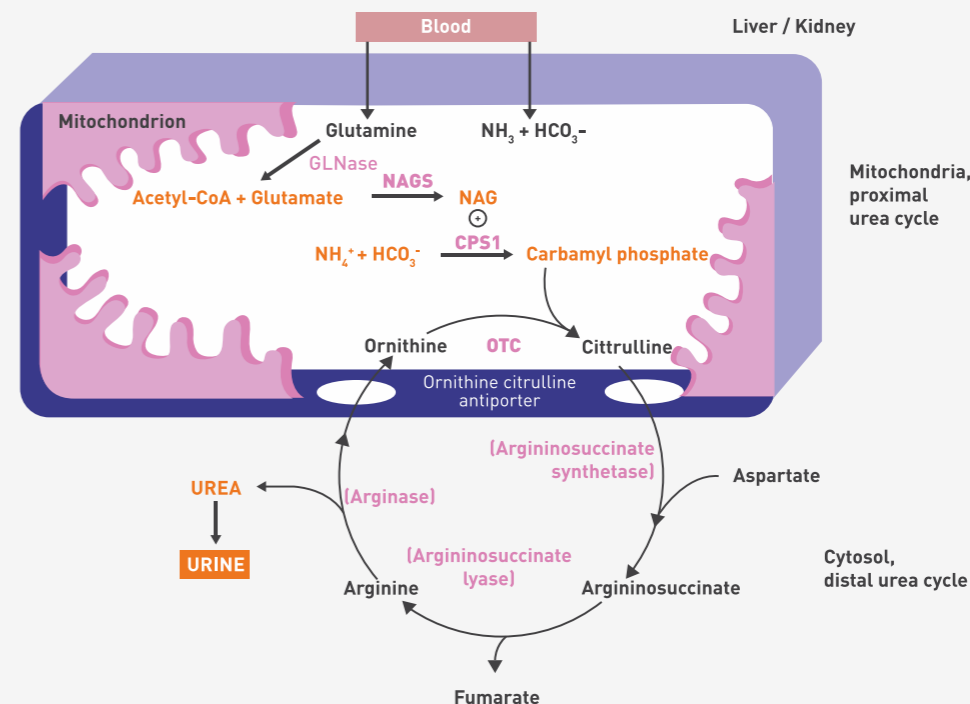


### New Proximal urea cycle deficiencies

- N-Acetylglutamate Synthase **(NAGS)** Deficiency
- Carbamyl Phosphate Synthetase **(CPS)** Deficiency
- Ornithine Transcarbamylase **(OTC)** Deficiency
- Ornithine Translocase Deficiency **(HHH)** Syndrome

### Traditional – distal urea cycle deficiences

- Argininosuccinate Synthetase **(ASS)** Deficiency (Citrullinemia **I**)
- Citrin Deficiency (Citrullinemia **II**)
- Argininosuccinate Lyase **(ASL)** Deficiency(Argininosuccinic Aciduria)
- Arginase Deficiency **(ARG1)** (Hyperargininemia)

## CAH – Steroid Profiling

The CAH-Kit is designed for accurate and sensitive quantitation of 17-hydroxyprogesterone, androstenedione, cortisol, 11-deoxycortisol and 21-deoxycortisol in **dried blood spot** samples using LC-MS/MS.

Can be used as a **2nd tier confirmatory tests** for congenital adrenal hyperplasia

Congenital adrenal hyperplasia (CAH) refers to a group of autosomal recessive disorders that impair cortisol biosynthesis. CAH represents a continuous phenotypic spectrum with over 95% of all cases caused by 21-hydroxylase deficiency.

### LC-MS/MS Parameters

| System | Shimadzu 8050 or higher MS/MS with UHPLC System |
|---|---|
| Ionization | ESI Positive |
| Flow | 0.4 mL/min, gradient |
| Column Oven | 40°C |
| Injection Volume | 20 µL |
| Run Time | 12 Minutes |
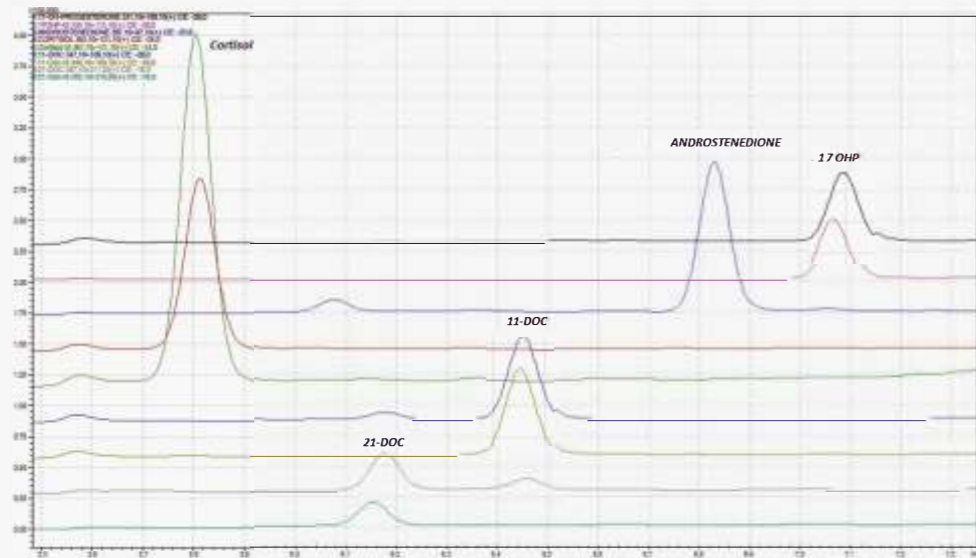
## SCID-SMA MULTIPLEX REAL TIME - PCR

Intended for the rapid and simultaneous detection of severe combined immunodeficiency (SCID) syndrome and spinal muscular atrophy (SMA) in newborns by using DNA samples either from **whole blood or dried blood spots** (after DNA extraction).

**First in the world** to detect SCID and SMA simultaneously.

Simultaneously detects the absence of T cell Receptor Excision Circles (TRECs) and Kappa – deleting recombination Excision Circles (KRECs) for screening SCID.

**SMA detection is done by detecting mutation in *SMN* gene**

Provided with three levels of controls.

# Newborn Screening Reagents

| Cat. No | Product name | Plate type/Format | Detection Method | Pack Size |
|---|---|---|---|---|
| 7100100 | Neomass AAAC | Solid | MS/MS | 960 |
| 7100110 | Neomass AAAC Plus★ | Solid | MS/MS | 960 |
| BR 130022 | CAH-Kit★ | Vial | LC-MS | 100 |
| BR 130023 | CAH-Kit★ | Vial | LC-MS | 500 |
| 6199821 | Neonatal Biotinidase | Solid | Fluorescence | 960 |
| 6199831 | Neonatal IRT FEIA | Solid | Fluorescence | 960 |
| 6199850 | Neonatal Galactose | Solid | Fluorescence | 960 |
| 6199810 | Neonatal GALT★ | Solid | Fluorescence | 960 |
| 6199860 | Neonatal G6PD | Solid | Fluorescence | 960 |
| 6199870 | Neonatal 17-OH-Progesterone FEIA | Strip | Fluorescence | 480 |
| 6199871 | Neonatal 17-OH-Progesterone FEIA | Solid | Fluorescence | 960 |
| 6199872 | Neonatal 17-OH-Progesterone FEIA | Strip | Fluorescence | 960 |
| 6199880 | Neonatal hTSH FEIA Plus | Solid | Fluorescence | 960 |
| 6199882 | Neonatal hTSH FEIA Plus | Strip | Fluorescence | 480 |
| 6199883 | Neonatal hTSH FEIA Plus | Strip | Fluorescence | 960 |
| 6199890 | Neonatal T4 FEIA★ | Strip | Fluorescence | 480 |
| 6199891 | Neonatal hTSH EIA | Strip | Photometric | 480 |
| 6199896 | Neonatal Phenylalanine (PKU) | Solid | Fluorescence | 960 |
| 6199802 | Neonatal Toxoplasma gondii IgM FEIA★ | Strip | Fluorescence | 480 |
| 8100400 | SCID-SMA Multiplex PCR★ | NA | qPCR | 25 |

# Newborn Screening Instruments

| Cat. No | Product name | Type | Unit |
|---|---|---|---|
| 5400200 | Newborn Screening Automate NS2400 | Instrument | 1 |
| 5450300 | Neonatal NS496 Plus DBS Puncher★ | Instrument | 1 |
| 5550400 | Neonatal Disc Remover NS96 (110 V) | Instrument | 1 |
| 5550300 | Neonatal Disc Remover NS96 (220 V) | Instrument | 1 |
| 5420211 | NS Microplate Washer | Instrument | 1 |
| 5450500 | NS Microplate Incubator Shaker | Instrument | 1 |
| 5410211 | NS Microplate Fluorometric Reader | Instrument | 1 |
| 5410300 | NS 200 Multimode Reader | Instrument | 1 |

For more information, please contact sales@labsystemsdx.com, logistics@labsystemsdx.com

★ Please check for the availability

# LABSYSTEMS
## D I A G N O S T I C S
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