

A close-up photograph of a woman with dark hair tied back, wearing a white top, looking down at a baby she is holding. The baby is also wearing a white top and has its hands clasped near its feet. The background is a soft, out-of-focus light blue.

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



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 quantitative 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. **CE**
 All our reagents and instruments are CE marked.



**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** ★



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

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, 170HP)
- 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

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

- 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**

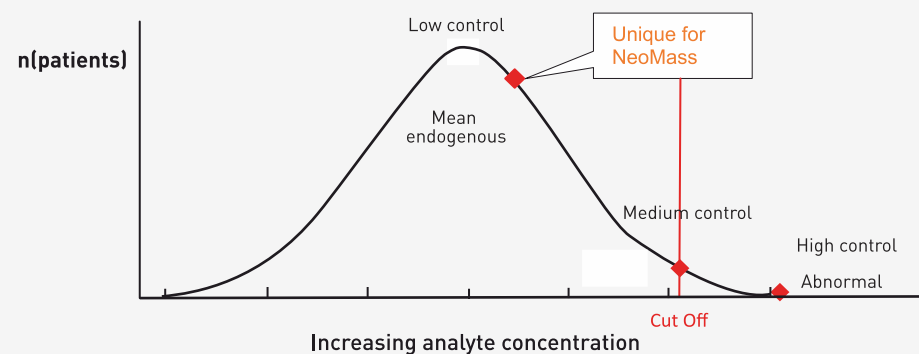
Detects more than 50 disorders.

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



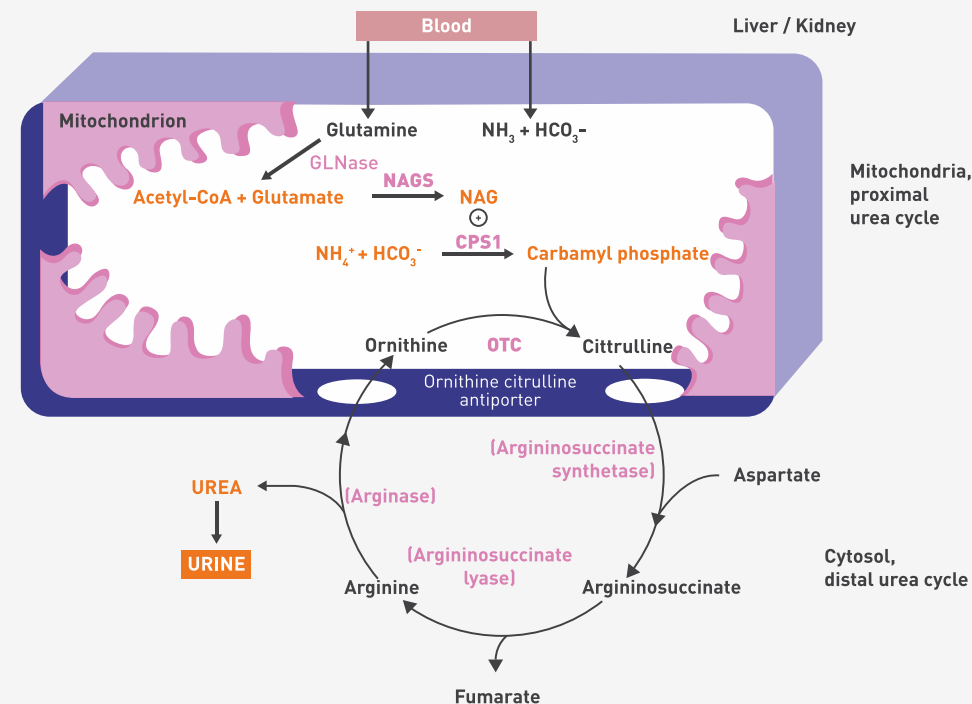
Provided Isotope - labelled internal standards and analytes spiked in controls

ISTD	Control	ISTD	Control
² H ₄ -Alanine	Alanine(Ala)	² H ₉ -Carnitine	Carnitine(C0)
² H ₄ - ¹³ C Arginine	Arginine(Arg)	² H ₃ -Acetylcarnitine	Acetylcarnitine(C2)
² H ₃ -Aspartate	Aspartate(Asp)	² H ₃ -Propionylcarnitine	Propionylcarnitine(C3)
² H ₂ -Citrulline	Citrulline(Cit)	² H ₃ -Butyrylcarnitine	Butyrylcarnitine(C4)
² H ₃ -Glutamate	Glutamate(Glu)	² H ₉ -Isovalerylcarnitine	Isovalerylcarnitine(C5)
¹⁵ N- ¹³ C- Glycine	Glycine(Gly)	² H ₃ -Glutaryl carnitine	Glutaryl carnitine(C5DC)
² H ₃ -Leucine	Leucine(Leu)	² H ₃ -Hexanoylcarnitine	Hexanoylcarnitine(C6)
¹³ C ₆ - ¹⁵ N ₂ -Lysine	Lysine(Lys)	² H ₃ -Octanoylcarnitine	Octanoylcarnitine(C8)
² H ₃ -Methionine	Methionine(Met)	² H ₃ -Decanoylcarnitine	Decanoylcarnitine(C10)
² H ₆ -Ornithine	Ornithine(Orn)	² H ₃ -Dodecanoylcarnitine	Dodecanoylcarnitine(C12)
¹³ C ₆ -Phenylalanine	Phenylalanine(Phe)	² H ₉ -Myristoylcarnitine	Myristoylcarnitine(C14)
² H ₅ -Proline	Proline(Pro)	² H ₃ -Palmitoylcarnitine	Palmitoylcarnitine(C16)
¹³ C ₃ -Serine	Serine(Ser)	² H ₃ -Stearoylcarnitine	Stearoylcarnitine(C18)
¹³ C ₆ -Tyrosine	Tyrosine(Tyr)	¹³ C ₅ -Succinylacetone	Succinylacetone(SUAC)
² H 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 deficiencies

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



CAH - Steroid Profiling



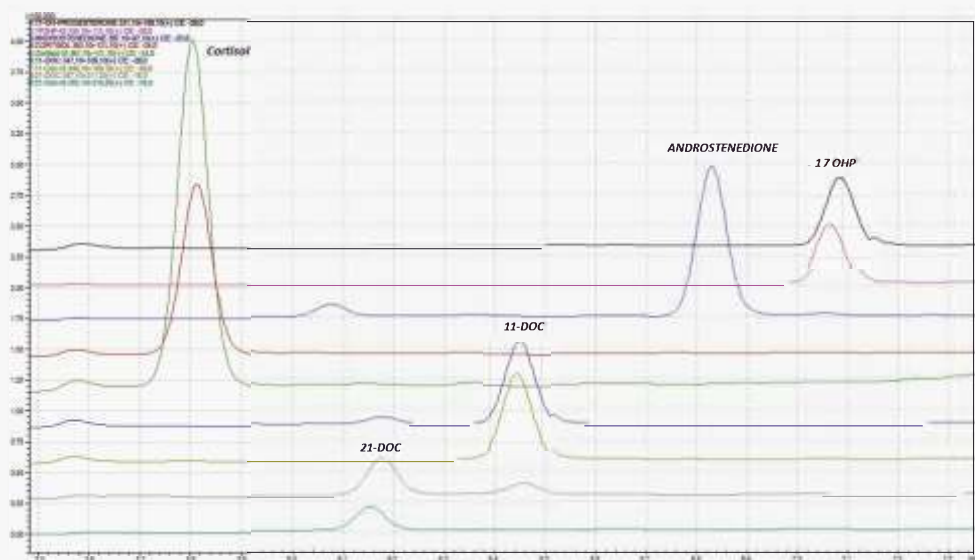
The CAH-Kit is designed for accurate and sensitive quantitation of 17-hydroxyprogesterone, androstenedione, cortisol, 11-deoxycortisol and 21-deoxycortisol in **dried blood spot** samples using LC-MS/MS.

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 REAL TIME PCR KIT



Intended for the rapid 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

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
8100401	SCID-SMA Real time PCR Kit	NA	qPCR	96
8100402	SCID-SMA Real time PCR Kit	NA	qPCR	192
8100403	SCID-SMA Real time PCR Kit	NA	qPCR	480

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