



Newborn Screening Solutions

One Stop Comprehensive

Greetings from Finland



Dear customers,

Labsystems Diagnostics Oy, Finland has been developing, manufacturing and distributing innovative products for newborn screening for over 3 decades. We cover the entire range of methods for newborn screening and also offer complete solutions including automation and software options. We distribute our products to over 70 countries worldwide and all our processes and products are CE IVD certified compliant to the ISO 13485 standards. The high quality of our products is confirmed by regular participation in international proficiency programmes. Cooperation and studies in customer laboratories enable us to independently test our products under real conditions. Our goal for future is to develop new innovative products for the detection of inborn errors of metabolism and to get better every day. We are confident that our products meet the requirements of all customers globally.

Newborn Screening Kits & Equipment

Fluorescence Immunoassays

Neonatal TSH
Neonatal 17-OHP
Neonatal IRT
Neonatal T4
Neonatal Toxoplasma gondii IgM

Fluorescence Immunoassays – Biochemical & Enzymatic

Neonatal Phenylalanine
Neonatal G6PD
Neonatal Total Galactose (TGAL)
Neonatal Galactose Transferase (GALT)
Neonatal Biotinidase

Newborn Screening by Real Time PCR

NeoNat SCID-SMA

Expanded Newborn Screening by LC-MS/MS

NeoMass AAAC Plus
NeoMass AAAC 3.0

Confirmatory Test for CAH by LC-MS/MS (Steroid Profiling)

NeoMass CAH

Newborn Screening Equipment

Newborn Screening Automate NS2400
NS496 Plus DBS Puncher
NS Reader
NS Washer
NS Incubator / Shaker
NS96 Disc Remover

Fluorescence Immunoassays



Neonatal TSH

(Product Code: 6199880)

Fluorometric determination of Thyroid Stimulating Hormone (TSH) in Dried Blood Spot (DBS) specimens for the Screening of Congenital Hypothyroidism (CH).

- ◆ Based on direct sandwich technique, and fluorescence signals are directly proportional to analyte concentrations in the samples
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal 17-OHP

(Product Code: 6199871)

Fluorometric determination of 17 α -Hydroxy-Pro-gesterone in Dried Blood Spot (DBS) specimens for the Screening of Congenital Adrenal Hyperplasia (CAH).

- ◆ Based on competitive binding, and fluorescence signals are inversely proportional to analyte concentrations in the samples
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal IRT

(Product Code: 6199831)

Fluorometric determination of Immunoreactive Trypsinogen (IRT) in Dried Blood Spot (DBS) specimens for the Screening of Cystic Fibrosis (CF).

- ◆ Based on direct sandwich technique, and fluorescence signals are directly proportional to analyte concentrations in the samples
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal T4

(Product Code: 6199890)

Fluorometric determination of Thyroxine T4 in Dried Blood Spot (DBS) specimens for the Screening of Congenital Hypothyroidism (CH).

- ◆ Based on competitive binding, and fluorescence signals are inversely proportional to analyte concentrations in the samples
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in strip plate format of 480 assays



Neonatal Toxoplasma gondii IgM

(Product Code: 6199802)

Fluorometric determination of IgM-class antibodies to Toxoplasma gondii in Dried Blood Spot (DBS) specimens.

- ◆ Available in Strip plate format of 480 tests

Fluorescence Immunoassays – Biochemical & Enzymatic

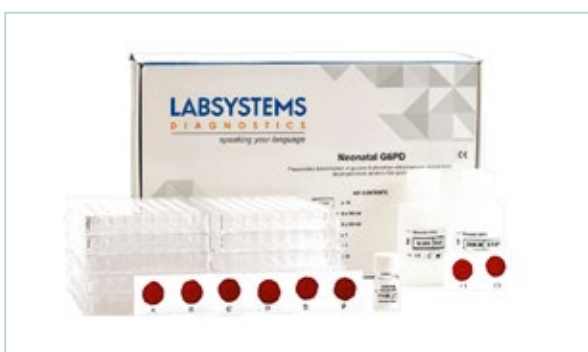


Neonatal Phenylalanine

(Product Code: 6199896)

Fluorometric determination of Phenylalanine in Dried Blood Spot (DBS) specimens for the Screening of Phenylketonuria (PKU).

- ◆ Based on the fluorescent ninhydrin reaction technology
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal G6PD

(Product Code: 6199860)

Fluorometric determination of Glucose-6-Phosphate Dehydrogenase enzyme activity in Dried Blood Spot (DBS) specimens for the Screening of G6PD deficiency.

- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal Total Galactose (TGAL)

(Product Code: 6199850)

Fluorometric determination of total Galactose (TGAL) in Dried Blood Spot (DBS) specimens for the Screening of classical Galactosemia.

- ◆ Combined determination of free and released Galactose from the cleavage of Galactose-1-Phosphate
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls, except absolute ethyl alcohol
- ◆ Available in solid plate format of 960 assays



Neonatal Galactose Transferase (GALT)

(Product Code: 6199810)

Fluorometric determination of Galactose-1-Phosphate Uridyl Transferase (GALT) enzyme activity in Dried Blood Spot (DBS) specimens for the Screening of classical Galactosemia.

- ◆ Based on the fluorescent signal of NADPH, which is formed during the enzymatic reaction
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays



Neonatal Biotinidase

(Product Code: 6199821)

Fluorometric determination of Biotinidase enzyme activity in Dried Blood Spot (DBS) specimens for the Screening of Biotinidase deficiency.

- ◆ Based on the fluorescent signal of 6-Amino-quinoline (6-AQ) product, which is formed during the enzymatic reaction
- ◆ No centrifugation or filtration steps needed
- ◆ Kit includes all reagents required for sample processing including DBS calibrators and controls
- ◆ Available in solid plate format of 960 assays

Newborn Screening by Real Time PCR



NeoNat SCID-SMA

Screening for Severe Combined Immuno-deficiency (SCID) and Spinal Muscular Atrophy (SMA) by Real Time PCR.

- ◆ Genes targeted are T-Cell Receptor Excision Circle (TREC) as well as Kappa Deleting Recombination Excision Circle (KREC) for SCID, and Survival Motor Neurons 1 & 2 (SMN1, SMN2) for SMA, along with internal controls
- ◆ Kit includes all reagents required for sample processing including DNA extraction components to screen SCID and SMA from Dried Blood Spot (DBS) specimens
- ◆ Automated solution available
- ◆ Three variants available
SCID-SMA Multiplex (8100411, 8100412, 8100413)
SCID (8100441, 8100442, 8100443)
SMA (8100461, 8100462, 8100463)
- ◆ All three variants available in three different pack sizes (96, 192 and 480)

Expanded Newborn Screening by LC-MS/MS



NeoMass AAAC Plus

(Product Code: 7100110)

A non-derivatized LC-MS/MS kit for the screening of 15 Amino Acids (AA), 13 Acylcarnitines (AC), Succinylacetone (SUAC) and Argininosuccinic Acid (ASA) from Dried Blood Spot (DBS) samples within a single LC-MS/MS run.

- ◆ Simple and time saving sample extraction protocol within 1 h for all analytes including SUAC without the use of any carcinogenic derivatization compound
- ◆ Automated sample preparation available
- ◆ Suitable for most mid- and high-sensitive LC-MS/MS instruments and with analysis times of approximately 3 hrs / plate (96 wells)
- ◆ All components are also available individually
- ◆ Ready-to-use Kit for 960 analyses



NeoMass AAAC 3.0

(Product Code: 7100120)

An update of the non-derivatized NeoMass AAAC Plus kit for the screening of inborn errors of metabolism. This expanded panel includes the additional detection of X-linked Adrenoleukodystrophy (X-ALD) and Adenosine Deaminase (ADA) disorders.

- ◆ Simple and time saving sample extraction protocol within 1 h for all analytes including 15 Amino Acids (AA), 14 Acylcarnitines (AC), Succinylacetone (SUAC), Argininosuccinic Acid (ASA), C26:0-Lysophosphatidylcholine (C26:0-LPC) and Adenosine (ADO) without the use of any carcinogenic derivatization compound
- ◆ Automated sample preparation available
- ◆ Suitable for most mid- and high-sensitive LC-MS/MS instruments and with analysis times of approximately 3 hrs / plate (96 wells)
- ◆ Ready-to-use Kit for 960 analyses

List of Analytes

Analyte	ISTD	Analyte	ISTD	Analyte	ISTD	Analyte	ISTD
Ala	$^2\text{H}_4\text{-Ala}$	Met	$^2\text{H}_3\text{-Met}$	C0	$^2\text{H}_9\text{-C0}$	C12	$^2\text{H}_3\text{-C12}$
Arg	$^2\text{H}_4\text{-}^{13}\text{C-Arg}$	Orn	$^2\text{H}_6\text{-Orn}$	C2	$^2\text{H}_3\text{-C2}$	C14	$^2\text{H}_9\text{-C14}$
Asp	$^2\text{H}_3\text{-Asp}$	Phe	$^{13}\text{C}_6\text{-Phe}$	C3	$^2\text{H}_3\text{-C3}$	C16	$^2\text{H}_3\text{-C16}$
Cit	$^2\text{H}_2\text{-Cit}$	Pro	$^2\text{H}_5\text{-Pro}$	C4	$^2\text{H}_3\text{-C4}$	C18	$^2\text{H}_3\text{-C18}$
Glu	$^2\text{H}_3\text{-Glu}$	Ser	$^{13}\text{C}_6\text{-Ser}$	C5	$^2\text{H}_9\text{-C5}$	C26	$^2\text{H}_3\text{-C26}$
Gly	$^{15}\text{N-}^{13}\text{C-Gly}$	Tyr	$^{13}\text{C}_6\text{-Tyr}$	C5DC	$^2\text{H}_3\text{-C5DC}$	SUAC	$^{13}\text{C}_5\text{-SUAC}$
Leu	$^2\text{H}_3\text{-Leu}$	Val	$^2\text{H}_8\text{-Val}$	C6	$^2\text{H}_3\text{-C6}$	ASA	$^{15}\text{N}_4\text{-}^{13}\text{C}_6\text{-ASA}$
Lys	$^{13}\text{C}_6\text{-}^{15}\text{N}_2\text{-Lys}$			C8	$^2\text{H}_3\text{-C8}$	C26:0 LPC	$^2\text{H}_4\text{-C26:0-LPC}$
				C10	$^2\text{H}_3\text{-C10}$	ADO	$^{13}\text{C}_5\text{-ADO}$

Features of NeoMass AAAC Plus & 3.0

- ◆ Both kits include three level of controls covering the wide range from endogenous to abnormal high concentrations of analytes.
- ◆ Both kits cover the complete Urea Cycle Disorders (UCDs). Deficiencies of enzymes in the proximal part of the urea cycle have been challenging to detect in the past but is now possible with the patented innovation of the LabSystems Diagnostics NeoMass AAAC Plus and NeoMass AAAC 3.0 kits. LabSystems Diagnostics has

established a methodology to measure Ornithin Transcarbamylase (OTC), Carbamyl Phosphate Synthetase 1 (CPS1) and N-Acetylglutamate Synthase (NAGS) deficiencies from Dried Blood Spot (DBS) samples along with the traditional detection of Argininosuccinate Synthetase (ASS), Argininosuccinate Lyase (ASL) and Arginase 1 (ARG1) enzyme deficiencies. Both the NeoMass kits for the LC-MS/MS will therefore enable detection of all urea cycle abnormalities.

Confirmatory Test for CAH (Steroid Profiling)

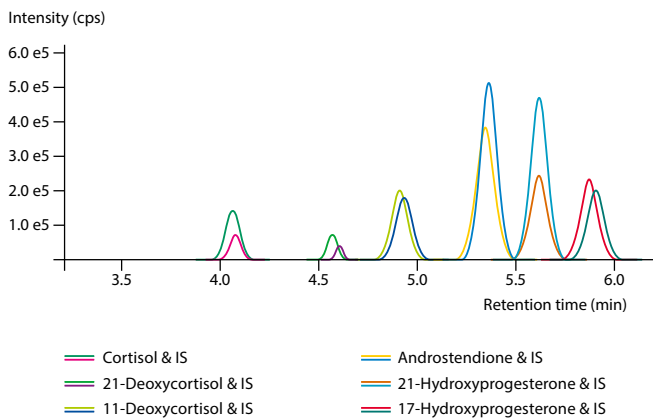


NeoMass CAH

(Product Code: 7150022)

Second Tier LC-MS/MS Kit for Confirmation of Congenital Adrenal Hyperplasia (CAH) from Dried Blood Spots.

- ◆ Quantitative and simultaneous determination of most clinically relevant steroids to diagnose or confirm Congenital Adrenal Hyperplasia from Dried Blood Spot (DBS) samples using LC-MS/MS
- ◆ Isotopically labelled internal standards for all analytes
- ◆ Sample preparation protocol, either using reaction vials or 96-well plates, from a single 3.2 mm DBS disc in less than 45 min
- ◆ Proven eight level DBS-calibrators and three level DBS controls prepared according to CLSI guidelines
- ◆ Clear and reliable 10 min-chromatographic separation including isobaric compounds
- ◆ HPLC or UHPLC columns are available separately (throughput of more than 1000 tests per column)
- ◆ Suitable for most mid- and high-sensitive LC-MS/MS instruments
- ◆ All kit components are also available individually
- ◆ Available in a pack size of 200 assays



Newborn Screening Equipment

Newborn Screening Automate NS2400

(Product Code: 5400200)



- ◆ Fully integrated high throughput fluorescence based robotic system for up to 25 plates (96 wells) per run
- ◆ Fixed standard tips with Liquid Level Detection (LLD) feature
- ◆ Real time monitoring of workflow
- ◆ Windows based operation software with high flexibility and ability to connect to any Laboratory Information System (LIS)



NS496 Plus DBS Puncher

(Product Code: 5450300)

- ◆ Automatic puncher for processing of up to 4 plates at the same time with punch cleaning function
- ◆ Punch size of 3,2 mm discs from Dried Blood Spot (DBS) samples
- ◆ Air humidification system to overcome static charging
- ◆ Disc detection system sensors ensure that discs are falling into the plate



NS Reader

(Product Code: 5420100)

- ◆ Direct / Prompt fluorescence based
- ◆ Windows-based, versatile software for easy data processing and compatibility with the NS2400
- ◆ Capable to export and import various file formats



NS Washer

(Product Code: 5410100)

- ◆ High quality washing with very low residual volume
- ◆ Multiple aspiration points for flat bottoms
- ◆ Compatible with the NS2400
- ◆ Advanced option for process control



NS Incubator / Shaker

(Product Code: 5450500/5450501)

- ◆ Available as instrument with two & four plate capacity
- ◆ Rotation speed regulation
- ◆ Temperature range control



NS96 Disc Remover

(Product Code: 5550300/5550400)

- ◆ Automatic removal of 3.2 mm discs
- ◆ Plug and one push button for operation
- ◆ Compatible with the NS2400
- ◆ Available in 220V and 110V variants



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