Product Catalogue

BOME
TRIVITRON
speaking your language

Greetings from Turkey!

With over 30 years of experience in in vitro diagnostics (IVD), Bome Trivitron has a deep understanding of clinical laboratories requirements. We are dedicated to serving our clients by offering affordable, high-quality, and safe products. Our goal is not only to meet but also exceed our clients expectations and to provide them with a seamless experience throughout our cooperation.

What do we do?

Our company is a comprehensive solution provider for newborn screening (NBS) programs, offering end-to-end services ranging from sample collection, registration, to actual lab testing, data analysis, reporting and archiving. We pride ourselves in developing innovative newborn screening products and systems using fluorescent, photometric, molecular genetic and chromatographic methods and also provide a wide range of quality control materials for NBS testing.

In addition to our NBS offerings, we offer customized quality control materials for immunoassays, clinical chemistry, lipids, hormones, proteins, tumor markers, cardiac markers, diabetes and chromatographic applications.

Our validated products for clinical HPLC and LC-MS/MS are highly cost-effective and are supported by our experienced after-sales team.

Over the past decade, we have expanded into the molecular genetic market, providing products for infectious diseases, genetic screening and oncology. We have a dedicated in-house R&D center staffed with a highly trained multi-disciplinary team of scientists who work in collaboration with leading clinicians and thought leaders in the field.

We also have a high-capacity molecular assay production facility and have established collaborations with leading international R&D partners to leverage cutting-edge technologies in sample preparation, nucleic acid amplification and next-generation sequencing. Through these collaborations, we can combine our extensive experience in inherited genetic disorders and reliable CE marked products with the latest technology to bring innovative solutions to our customers.

www.bometrivitron.com.tr

How do we do what we do?

We prioritize the safety and regulatory compliance of our products throughout their entire life cycle. We adhere to ISO 13485:2016 standard, the 98/79/EC directive, and EU 2017/746 regulation to ensure the highest quality standards.

In addition to our commitment to quality, we also pride ourselves on our flexible approach to customer needs. We strive to meet both immediate and long-term requirements by introducing new and cost-effective ideas and solutions tailored to our customers unique circumstances. Close support and follow-up are key to our success at Bome Trivitron, and we have a dedicated and experienced after-sales team available for on-site and remote support.

We regularly participate in National and International External Quality Assessments and Proficiency Programs. We challenge ourselves through discussions, seminars and presentations, as well as through continuing technical education and collaborations with leading medical and academic institutions worldwide.

We look forward to collaborating with you!

CONTENTS

Immunoassay

Neonatal TSH EIA Kit

(Product Code: BR071200, Packaging Size: 960 Tests)

Neonatal TSH EIA Kit is a colorimetric enzymatic immunoassay kit that is developed to screen congenital hypothyroidism in neonates and quantifies Thyroid Stimulating Hormone (TSH) in dried blood spots.

- Calibrator and controls are traceable to certified reference material
- Minimal background
- Superior sensitivity and reproducibility
- Good agreement with EQA samples
- CE-IVD marked

Neonatal TSH FEIA Kit

(Product Code: BR071210, Packaging Size: 960 Tests)

Neonatal TSH FEIA Kit is a fluorometric enzymatic immunoassay kit that is developed to screen congenital hypothyroidism in neonates and quantifies Thyroid Stimulating Hormone (TSH) in dried blood spots.

- Calibrator and controls are traceable to certified reference material
- Minimal background
- Superior sensitivity and reproducibility
- Good agreement with EQA samples
- CE-IVD marked

Neonatal IRT FEIA Kit

(Product Code: BR071270, Packaging Size: 960 Tests)

Neonatal IRT FEIA Kit is a fluorometric enzymatic immunoassay kit that is developed to screen cystic fibrosis in neonates and quantifies Immunoreactive Trypsinogen (IRT) in dried blood spots.

- Superior reproducibility
- Minimal background
- Excellent sensitivity
- Good agreement with EQA samples
- CE-IVD marked

Colorimetry

Neonatal Biotinidase Reagent Kit

(Product Code: BR071191, Packaging Size: 960 Tests)

Neonatal Biotinidase Reagent Kit is a colorimetric enzymatic assay developed for neonatal biotinidase deficiency screening, through semi-quantitative analysis of biotinidase enzyme activity in dried blood spots.

- Easy to perform
- Good stability
- Good agreement with EQA samples
- CE-IVD marked

Fluorometry

Neonatal Phenylalanine Kit

(Product code: BR071231, Packaging Size: 960 Tests)

Neonatal Phenylalanine Kit is a fluorometric assay kit that is developed to quantitatively determine the phenylalanine concentration in dried blood spots; intended for neonatal screening of phenylketonuria (PKU).

- Calibrator and controls are traceable to certified reference material
- Superior analytical properties
- Easy to perform
- Good agreement with EQA samples
- CE-IVD marked

Neonatal Fluorometric Biotinidase Kit

(Product Code: BR071221, Packaging Size: 960 Tests)

Neonatal Fluorometric Biotinidase Kit is a fluorometric enzymatic assay kit developed for neonatal biotinidase deficiency screening, through semi-quantitative measurement of biotinidase enzyme activity in dried blood spots.

- Ready to use
- Good stability
- Good agreement with EQA samples
- CE-IVD marked

Chromatography

Congenital Adrenal Hyperplasia (CAH) LC-MS/MS Analysis Kit

(Product Code: BR130023, Packaging Size: 500 Tests)

Congenital Adrenal Hyperplasia (CAH) LC-MS/MS Analysis Kit allows the quantitative analysis of 17-hydroxyprogesterone, Androstenedione, Cortisol, 11-deoxycortisol and 21-deoxycortisol in dried blood samples.

- 9 minutes run time
- Deuterated internal standards
- Separation of 11-DOC and 21-DOC
- CE-IVD marked

Aromatic Amino Acids HPLC Analysis Kit

(Product Code: BR140010, Packaging Size: 200 Tests)

Aromatic Amino Acids HPLC Analysis Kit is developed for monitoring effectiveness of dietary therapy in patients with hyperphenylalaninemia. The kit allows quantitative measurement of phenylalanine, tyrosine and tryptophan levels in plasma samples during dietary therapy period.

The test requires an HPLC instrument with a UV detector.

- 8 minutes run time
- Single step sample preparation
- Suitable for serum and plasma samples
- CE-IVD marked

Quantitative Amino Acids LC-MS/MS Analysis Kit

(Product Code: BR130030, Packaging Size: 200 Tests)

Quantitative Amino Acids LC-MS/MS Analysis Kit enables the quantitative monitoring of free amino acid concentrations in plasma, urine and cerebrospinal fluid samples from patients treated for metabolic diseases. This kit can be used for monitoring effectiveness of dietary therapy in patients with hyperphenylalaninemia.

- High sensitivity by derivatization
- 20 minutes run time
- No evaporation steps
- Suitable for plasma, urine and CSF samples
- CE-IVD marked

Organic Acids GC-MS Analysis Kit

(Product Code: BR150001, Packaging Size: 200 Tests)

Organic Acids GC-MS Analysis Kit enables the screening and qualitative monitoring of organic acid concentrations in urine samples from patients treated for metabolic diseases. All the required reagents are provided with the kit.

- Well standardized reagents
- 60 minutes run time
- Suitable for urine samples
- CE-IVD marked

Very Long Chain Fatty Acids (VLCFA) GC-MS Analysis Kit

(Product Code: BR150010 Packaging Size: 200 Tests)

Very Long Chain Fatty Acids (VLCFA) GC-MS Analysis Kit is developed for the quantitative analysis of Phytanic acid, Pristanic acid, Phytanic Acid, Docosanoic acid (C22:0), Tetracosanoic acid (C24:0) and Hexacosanoic acid (C26:0) in serum or plasma samples. Testing the levels of VLCFA is typically one to aid in diagnosing a rare inherited condition known as adrenoleukodystrophy (ALD).

- 32 minutes run time
- Standardized reagents for sample preparation
- Deuterated IS for each analyte
- Suitable for serum and plasma samples
- CE-IVD marked

DNA Analysis

SMA qPCR Screening Kit

(Product Code: BR110020, Packaging Size: 96 Tests)

SMA qPCR Screening Kit is a multiplexed one-tube real-time PCR test capable of detecting deletions of *SMN1* gene exon 7 in human genomic DNA obtained from whole blood or dried blood spots.

- *SMN1* exon 7 copy number quantitation
- Good agreement with EQA samples
- Easy result interpretation
- Testing from DBS and whole blood
- CE-IVD marked

DBS DNA Extraction Kit

(Product Code: BR110072, Packaging Size: 96 Tests)

DBS DNA Extraction Kit is intended for extraction of DNA samples from dried blood spot specimens spotted and dried on filter paper.

- Compatible with SMA qPCR Screening kit
- Easy to perform
- High DNA yield from DBS
- Room temperature storage
- CE-IVD marked

Aminoacids and Metabolism

Quantitative Amino Acids LC-MS/MS Analysis Kit

(Product Code: BR130030, Packaging Size: 200 Tests)

Quantitative Amino Acids LC-MS/MS Analysis Kit enables the quantitative monitoring of free amino acid concentrations in plasma, urine and cerebrospinal fluid samples from patients treated for metabolic diseases. This kit can be used for monitoring effectiveness of dietary therapy in patients within hyperphenylalaninemia.

- High sensitivity by derivatization
- 20 minutes run time
- No evaporation steps
- Suitable for plasma, urine and CSF samples
- CE-IVD marked

Aromatic Amino Acids HPLC Analysis Kit

(Product Code: BR140010, Packaging Size: 200 Tests)

Aromatic Amino Acids HPLC Analysis Kit is developed for monitoring effectiveness of dietary therapy in patients with hyperphenylalaninemia. The kit allows quantitative measurement of phenylalanine, tyrosine and tryptophan levels in plasma samples during dietary therapy period.

The test requires an HPLC instrument with a UV detector.

- 8 minutes run time
- Single step sample preparation
- Suitable for serum and plasma samples
- CE-IVD marked

Organic Acids GC-MS Analysis Kit

(Product Code: BR150001, Packaging Size: 200 Tests)

Organic Acids GC-MS Analysis Kit enables the screening and qualitative monitoring of organic acid concentrations in urine samples from patients treated for metabolic diseases.

- Well standardized reagents
- 60 minutes run time
- Suitable for urine samples
- CE-IVD marked

Very Long Chain Fatty Acids (VLCFA) GC-MS Analysis Kit

(Product Code: BR150010 Packaging Size: 200 Tests)

Very Long Chain Fatty Acids (VLCFA) GC-MS Analysis Kit is developed for the quantitative analysis of Phytanic acid, Pristanic acid, Phytanic Acid, Docosanoic acid (C22:0), Tetracosanoic acid (C24:0) and Hexacosanoic acid (C26:0) in serum or plasma samples. Testing the levels of VLCFA is typically one to aid in diagnosing a rare inherited condition known as adrenoleukodystrophy (ALD).

- 32 minutes run time
- Standardized reagents for sample preparation
- Deuterated IS for each analyte
- Suitable for serum and plasma samples
- CE-IVD marked

Vitamin Status Analysis

25-hydroxyvitamin D3/D2 HPLC Analysis Kit

(Product Code: BR140003 Packaging Size: 1000 Tests)

25-hydroxyvitamin D3/D2 HPLC Analysis Kit is developed for quantitative analysis of 25-hydroxy metabolites of Vitamin D3 and Vitamin D2 in serum samples.

The test requires an HPLC instrument with a UV detector.

- 8 minutes run time
- Easy sample preparation
- Suitable for serum and plasma samples
- CE-IVD marked

Vitamin A/E HPLC Analysis Kit

(Product Code: BR140030, Packaging Size: 200 Tests)

Vitamin A/E HPLC Analysis Kit is developed quantitative analysis of Vitamin A and Vitamin E in serum samples.

The test requires an HPLC instrument with a UV detector.

- 6 minutes run time
- Easy sample preparation
- Suitable for serum and plasma samples
- CE-IVD marked

Therapeutic Drug Monitoring

Immunosuppressant Drugs Whole Blood LC-MS/MS Analysis Kit

(Product Code: BR130001 Packaging Size: 200 Tests)

Immunosuppressant Drugs Whole Blood LC-MS/MS Analysis Kit allows quantitative monitoring of the concentrations of four different Immunosuppressant drug molecules; Sirolimus, Tacrolimus, Everolimus and Cyclosporine in human whole blood samples.

The test requires an LC-MS/MS instrument with on-line SPE accessories.

- 5 minutes run time
- One step sample preparation
- Robust method with on-line SPE
- Deuterated IS for each analyte
- CE-IVD marked

Biogenic Amines

VMA, HVA, 5-HIAA Urine LC-MS/MS Analysis Kit

(Product code: BR130040, Packaging size: 200 Tests)

VMA, HVA, 5-HIAA Urine LC-MS/MS Analysis Kit enables the quantitative analysis of Vanilmandelic acid (VMA), Homovanillic acid (HVA) and 5-hydroxy-indole acetic acid (5-HIAA) in urine samples.

- 7 minutes run time
- Easy sample preparation
- Suitable for urine samples
- CE-IVD marked

Metanephrines Urine LC-MS/MS Analysis Kit

(Product code: BR130070, Packaging size: 200 Tests)

Metanephrines Urine LC-MS/MS Analysis Kit enables the quantitative analysis of Metanephrine, Normetanephrine and 3-methoxytyramine in urine samples.

- 10 minutes run time
- Easy sample preparation
- Suitable for urine samples
- Deuterated IS for each analyte
- CE-IVD marked

Catecholamines Urine LC-MS/MS Analysis Kit

(Product Code: BR130050, Packaging Size: 200 Tests)

Catecholamines Urine LC-MS/MS Analysis Kit enables the quantitative analysis of Epinephrine (Adrenaline), Norepinephrine (Noradrenaline) and Dopamine in urine samples.

- 16 minutes run time
- Quick derivatization steps
- Good sensitivity with derivatization
- Suitable for urine samples
- Deuterated IS for each analyte
- CE-IVD marked

Clinical Chemistry

Routine Clinical Chemistry Control

(For Level 1, Product Code: BRCNT20001, Packaging Size: 20x5 mL)

(For Level 2, Product Code :BRCNT20002, Packaging Size: 20x5 mL)

Clinical Chemistry Controls are lyophilized control materials prepared with human plasma, which are used in clinical laboratories to monitor the precision and accuracy of biochemistry kits and analyzers.

- Intended Use : Quality Control of analysis result of Biochemistry kits and analyzers
- Stable up to expiry date if stored unopened at +2/+8°C
- Stability after reconstitution:
  1 day at+15/+25 C
  7 days +2/+8 C
- CE-IVD marked

Routine Clinical Chemistry Plus Control

(For Level 1, Product Code: BRCNT20003, Packaging Size: 20x5 mL)

(For Level 2, Product Code: BRCNT20004, Packaging Size: 20x5 mL)

Clinical Chemistry Plus Controls are lyophilized control materials prepared with human plasma used in clinical laboratories in order to monitor the accuracy and precision of biochemistry kits and analyzers.

- Intended Use : Quality Control of analysis result of Biochemistry kits and analyzers
- Wide range of analytes
- Stable up to the expiry date if stored unopened at +2/+8°C
- Stability after reconstitution:
  1 day at+15/+25 C
  7 days +2/+8 C
- CE-IVD marked

Specific Proteins

Specific Protein Controls

(For Level 1, Product Code: BRCNT20012, Packaging Size: 6x2mL)

(For Level 2, Product Code: BRCNT20013, Packaging Size: 6x2 mL)

Specific Protein Controls are ready-to-use controls which are used in monitoring the accuracy and precision of test systems related to ASO, CRP, RF, IgA, IgG, IgM, Beta-2 Microglobulin parameters. They are control materials with assigned values and prepared with human plasma.

- Intended Use : Quality Control of analysis result of Biochemistry kits and analyzers
- Stable up to the expiry date if stored unopened at +2/+8°C
- Open vial stability
  1 day at +15/+25°C
  3 months at+2/+8°C
- CE-IVD marked

Lipid Controls

Lipid Controls

(For Level 1, Product Code: BRCNT20031, Packaging Size: 6x5 mL)
(For Level 2, Product Code: BRCNT20032, Packaging Size: 6x5 mL)

Lipid Controls are lyophilized control materials prepared with human plasma used in clinical laboratories in order to monitor the accuracy and precision of lipid test systems.

- Intended Use : Quality Control of analysis result of Biochemistry kits and analyzers
- Stable up to the expiry date if stored unopened at +2/+8°C
- Stability after reconstitution:
  1 day at +15/+25°C
  1 week at +2/+8°C
- CE-IVD marked

Diabetes

HbA1c Controls

(For Level 1, Product Code: BRCNT20009, Packaging Size: 6x0.5 mL)
(For Level 2, Product Code: BRCNT20010, Packaging Size: 6x0.5 mL)

HbA1c Controls are lyophilized control materials prepared with human blood used in clinical laboratories to monitor the precision and accuracy of HbA1c kits and analyzers.

- Intended Use : Quality Control of analysis result of Biochemistry kits and analyzers
- Stable up to expiry date if stored unopened at +2/+8°C
- Stability after reconstitution:
  1 day at +15/+25°C
  1 week at +2/+8°C
- CE-IVD marked

Urine

Dipstick Urine Controls

(For Level 1, Product Code: BRCNT20038, Packaging Size: 12x12 mL)
(For Level 2, Product Code: BRCNT20039, Packaging Size: 12x12 mL)

Dipstick Urine Controls are liquid control materials prepared with human urine, which are used to monitor the accuracy of urine analyzers and urine strips used in clinical laboratories.

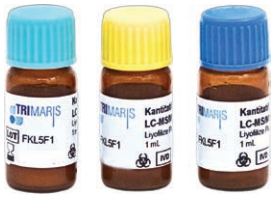
- Intended Use : Quality control of urine test strips and urine analyzers
- Stable up to expiry date if stored unopened at +2/+8°C
- Parameters: Bilirubin, Glucose, Specific Gravity, Blood, Ketone, Leukocytes, Nitrite, pH, Protein, Urobilinogen
- Product Type: Liquid urine
- CE-IVD marked

Newborn Screening

Quantitative Amino Acids Calibrator Set

(Product Code: BR130030CS, Packaging Size: Calibrator 1: 1x1 mL, Calibrator 2: 1x1 mL, Calibrator 3: 1x1 mL)

Quantitative Amino Acids Calibrator Set is a traceable material produced from human plasma and its value has been certified by using reference materials.



- Intended Use: Calibration of the LC-MS/MS methods which are used for Amino Acid analysis
- Parameters: 44 Amino Acids
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Quantitative Amino Acids Control Set

(Product Code: BR130030KS, Packaging Size: L1 1x1 mL, L2 1x1 mL)

Quantitative Amino Acid controls are produced from human plasma.

- Intended Use: Verification of the LC-MS/MS methods which are used for Amino Acids analysis
- Parameters: 44 Amino Acids
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Aromatic Amino Acids Calibrator

(Product Code: BR140010K1, Packaging Size: 1x1 mL)

Aromatic Amino Acids calibrator is a traceable material produced from human plasma and its value has been certified by using reference materials.

- Intended Use : Calibration of the HPLC and LC-MS/MS methods which are used for Phenylalanine, Tyrosine and Tryptophan analysis
- Parameters: Phenylalanine, Tyrosine, Tryptophan
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C.
- CE-IVD marked

QUALITY CONTROLS MATERIALS

Aromatic Amino Acids Control Set

(Product Code: BR140010KS, Packaging Size: L1 1x1 mL, L2 1x1 ml)

Aromatic Amino Acids controls are produced from human plasma.

- Intended Use : Quality Control of the HPLC and LC-MS/MS methods which are used for Phenylalanine, Tyrosine and Tryptophan analysis
- Parameters: Phenylalanine, Tyrosine, Tryptophan
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Biotinidase Calibrator and Control Set

(Product Code: BR071220KS, Packaging Size: 5 sets)

Biotinidase calibrator & control sets are developed for biotinidase deficiency screening and confirmation in newborns. Biotinidase calibrators and controls hematocrit level adjusted to represent neonatal blood samples, and contain biotinidase enzyme.

- Intended Use : Quality Control of biotinidase enzyme deficiency screening methods.
- Parameters: Biotinidase enzyme
- Product Type: Dried Blood Spot
- Stable up to the expiry date if stored unopened at +2/+8°C
- CE-IVD marked

IRT Calibrator and Control Set

(Product Code: BR071271KS, Packaging Size: 5 sets)

IRT (immunoreactive trypsinogen) calibrators & controls sets are developed for cystic fibrosis screening and confirmation in newborns. IRT calibrators and controls hematocrit level adjusted to represent neonatal blood samples, and contain stabilized immunoreactive trypsinogen antigen.

- Intended Use : Quality Control of cystic fibrosis screening methods
- Parameters: immunreactive trypsinogen antigen
- Product Type: Dried Blood Spot
- Stable up to the expiry date if stored unopened at +2/+8°C
- CE-IVD marked

Congenital Adrenal Hyperplasia Calibrator and Control Set

(Product Code:BR130023KS, Packaging Size: 5 sets)

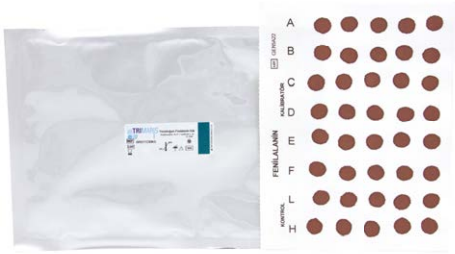
Congenital Adrenal Hyperplasia calibrator & control sets are a traceable material produced from human blood and its value has been certified by using reference materials. Hematocrit levels of the material adjusted to represent newborn blood samples.

- Intended Use: Calibration and verification of the LC-MS/MS methods which are used for Congenital Adrenal Hyperplasia screening and confirmation
- Parameters: 17-hydroxyprogesterone, Androstenedione, Cortisol, 11-deoxycortisol, 21-deoxycortisol
- Product Type: Dried Blood Spot
- Stable up to the expiry date if stored unopened at +2/+8°C
- CE-IVD marked

Phenylalanine Calibrator and Control Set

(Product Code:BR071230KS, Packaging Size: 5 sets)

Phenylalanine calibrator & control sets are developed to determine the accuracy of chemical, enzymatic and chromatography based phenylketonuria screening and confirmation methods. Phenylalanine calibrators and controls are traceable and hematocrit levels adjusted to represent neonatal blood samples.



- Intended Use : Quality Control of phenylketonuria screening methods
- Parameters: Phenylalanine
- Product Type: Dried Blood Spot
- Stable up to the expiry date if stored unopened at +2/+8°C
- CE-IVD marked

TSH Calibrator and Control Set

(Product Code: BR071211KS, Packaging Size: 5 sets)

TSH (Thyroid Stimulating Hormone) control & calibrator sets are developed for congenital hypothyroidism screening and confirmation. TSH calibrators and controls are traceable and hematocrit levels adjusted to represent neonatal blood samples.

- Intended Use : Quality Control of congenital hypothyroidism screening methods
- Parameters: Thyroid Stimulating Hormone
- Product Type: Dried Blood Spot
- Stable up to the expiry date if stored unopened at +2/+8°C
- CE-IVD marked

Chromatography

Vitamin A/E Calibrator

(Product Code: BR140030K1, Packaging Size: 1x1 mL)

Vitamin A/E calibrator is a traceable material produced from human plasma and its value has been certified by using reference materials.

- Intended Use: Calibration of the HPLC and LC-MS/MS methods which are used for Vitamin A/E analysis
- Parameters: Alpha-tocopherol and Retinol
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Vitamin A/E Control Set

(Product Code: BR140030KS, Packaging Size: L1 1x1 mL, L2 1x1 mL)

Vitamin A/E controls are produced from human plasma.

- Intended Use: Verification of the HPLC and LC-MS/MS methods which are used for Vitamin A/E analysis
- Parameters: Alpha-tocopherol and Retinol
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Vitamin D2/D3 Calibrator

(Product Code: BR140003K1, Packaging Size: 5x2.5 mL)

Vitamin D2/D3 calibrator is a traceable material produced from human plasma and its value has been certified by using reference materials.

- Intended Use: Calibration of the HPLC and LC-MS/MS methods which are used for Vitamin D2/D3 analysis
- Parameters: 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Vitamin D2/D3 Control Set

(Product Code: BR140003KS, Packaging Size: L1 5x2.5 mL, L2 5x2.5 mL)

Vitamin D2/D3 controls are produced from human plasma.

- Intended Use: Verification of the HPLC and LC-MS/MS methods which are used for Vitamin D2/D3 analysis
- Parameters: 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3
- Product Type: Lyophilized Plasma
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Immunosuppressant Drugs Calibrator Set

(Product Code: BR130001CS, Packaging Size: Calibrator 0: 1x1 mL, Calibrator 1: 1x1 mL, Calibrator 2: 1x1 mL, Calibrator 3: 1x1 mL, Calibrator 4: 1x1 mL)

Immunosuppressant Drugs calibrator set is a traceable material produced from human whole blood and its value has been certified by using reference materials.

- Intended Use: Calibration of the LC-MS/MS methods which are used for immunosuppressant drug analysis
- Parameters: Sirolimus, Tacrolimus,Everolimus and Cyclosporine
- Product Type: Lyophilized Whole Blood
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Immunosuppressant Drugs Control Set

(Product Code: BR130001KS, Packaging Size: L1 1x1 mL, L2 1x1 mL, L3 1x1 mL)

Immunosuppressant Drug controls are produced from human whole blood.

- Intended Use: Verification of the LC-MS/MS methods which are used for immunosuppressant drug analysis
- Parameters: Sirolimus, Tacrolimus,Everolimus and Cyclosporine
- Product Type: Lyophilized Whole Blood
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

VMA, HVA, 5-HIAA Calibrator

(Product Code:BR130040K1, Packaging Size: 1x2 mL)

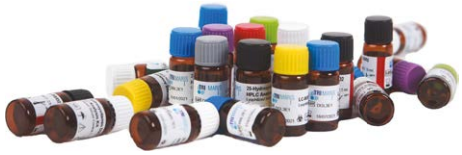
VMA, HVA, 5-HIAA calibrator is a traceable material produced from human urine and its value has been certified by using reference materials.

- Intended Use: Calibration of the HPLC and LC-MS/MS methods which are used for Vanilmandelic acid (VMA),Homovanillic acid (HVA) and 5-Hydroxy-indole acetic acid (5-HIAA) analysis
- Parameters: VMA, HVA and 5-HIAA
- Product Type: Lyophilized Urine
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

VMA, HVA, 5-HIAA Control Set

(Product Code: BR130040KS, Packaging Size: L1 1x2 mL, L2 1x2 mL)

Immunosuppressant Drugs controls are produced from human urine.



- Intended Use: Verification of the HPLC and LC-MS/MS methods which are used for Vanillymandelic acid (VMA), Homovanillic acid (HVA) and 5-Hydroxyindoleacetic acid (5-HIAA) analysis
- Parameters: VMA, HVA and 5-HIAA
- Product Type: Lyophilized Urine
- Stable up to the expiry date if stored unopened at -20°C
- CE-IVD marked

Infectious Diseases

SARS-CoV-2 RT-qPCR Kit

(Product Code: BR110030, Packaging Size: 100 Tests)

SARS-CoV-2 RT-qPCR Kit determines the presence of SARS-CoV-2 nucleic acids from respiratory tract samples. Three independent SARS-CoV-2 specific targets are multiplexed into a single channel in a single tube. Proprietary rapid (3 minutes) single-step sample preparation reagent is included.

- Easy result interpretation
- Wide instrument compatibility
- Resilience to evolving mutations
- CE-IVD marked

SARS-CoV-2 Express RT-qPCR Kit

(Product Code: BR110051, Packaging Size: 100 Tests)

SARS-CoV-2 Express RT-qPCR Kit determines the presence of SARS-CoV-2 nucleic acids from respiratory tract samples. Three independent SARS-CoV-2 specific targets are multiplexed into a single channel in a single tube. Proprietary rapid (3 minutes) single-step sample preparation reagent is included. Running time is 35 minutes.

- Express sample preparation and thermocycling
- Easy result interpretation
- Wide instrument compatibility
- Resilience to evolving mutations
- CE-IVD marked

CoviFlu v2.1 RT-qPCR Test Kit

(Product Code: GPDX-CFU-22-100 Packaging Size: 100 Tests)

CoviFlu v2.1 RT-qPCR Test Kit is a single-tube multiplexed real time reverse transcription polymerase chain reaction (RT-qPCR) assay for the detection of nucleic acids from SARS-CoV-2, Influenza A and Influenza B. This assay will detect all known variants of SARS-CoV-2 and all subtypes and lineages of Influenza A and Influenza B but will not distinguish between these variants and subtypes.

- Highly sensitive and specific single-tube assay
- Compatible with most 4-color detection cyclers
- Easy result interpretation
- CE-IVD marked

Inherited Diseases

SMA qPCR Screening Kit

(Product Code: BR110020, Packaging Size: 96 Tests)

SMA qPCR Screening Kit is a multiplexed one-tube real-time PCR test capable of detecting deletions of *SMN1* gene exon 7 in human genomic DNA obtained from whole blood or dried blood spots.

- *SMN1* exon 7 copy number quantitation
- Good agreement with EQA samples
- Easy result interpretation
- Testing from DBS and whole blood
- CE-IVD marked

SMA qPCR v2.0 Screening Kit

(Product Code: BR110120, Packaging Size: 96 Tests)

SMA qPCR v2.0 Screening Kit is a multiplexed one-tube real-time PCR test capable of detecting deletions of *SMN1* gene exon 7 in human genomic DNA obtained from whole blood. This kit detects normal and carrier individuals for SMA by detecting exon 7 deletions and c.840C>T in the *SMN1* gene.

- *SMN1* exon 7 copy number quantitation
- High accuracy carrier detection
- Easy result interpretation
- CE-IVD marked

SMA (Q) dPCR Kit

(Product Code: BR110130, Packaging Size: 96 Tests)

SMA (Q) dPCR Kit is a digital PCR kit intended for quantitation of exon 7 copy numbers of *SMN1* and *SMN2* genes in human genomic DNA samples.

- Compatibility with DNA obtained from whole blood and DBS samples
- Copy number determination through absolute quantitation
- Easy result interpretation
- Excellent agreement with MLPA
- CE-IVD marked

Hemato-Oncology

JAK2 v2 Real Time qPCR Test Kit

(Product Code: GPDX-JK-01-096, Packaging Size: 96 Tests)

JAK2 v2 Real Time qPCR kit is intended for detection of *JAK2* V617F mutation [JAK2:c.G1849T (p.V617F)] in genomic DNA extracted from either EDTA peripheral blood or bone marrow samples.

- One tube multiplexed reaction
- Broad instrument compatibility
- Standards help calculate percent relative MAF
- CE-IVD marked

BCR-ABL IS v1 RQ-PCR Test Kit

(Product Code: GPDX-BCR-01-096, Packaging Size: 96 Tests)

BCR-ABL IS v1 RQ-PCR test kit is intended for quantification of the Major *BCR-ABL* [t(9;22)(q34;q11)] fusion transcripts (e13/e14-a2 or b2b3-a2) in peripheral blood or bone marrow samples of patients with Chronic Myeloid Leukemia (CML) using real time PCR systems.

- One tube multiplexed RT-qPCR reaction
- Broad instrument compatibility
- Easy result interpretation
- MRD determination
- Results reported on the IS scale
- CE-IVD marked

QUALITY CERTIFICATIONS

eurofins

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

Bome Trivitron Sanayi Ürünleri Dış Ticaret A.Ş.

Ostim OSB Mahallesi, 1250. Cadde, No:1, Yenimahalle, Ankara
Turkey

Eurofins Electric & Electronics Finland Oy has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016.
This certificate covers the following functions/services:

Design, manufacturing, import, distribution, marketing, sales and after sales services of in vitro diagnostic devices, reagent kits, controls and calibrators for newborn screening, inherited genetic disorders, hematology, metabolic diseases, endocrinology and infectious diseases.

Valid from:
29 April, 2023

Valid until:
29 April, 2026

First issued:
29 April, 2020

Aliisa Siljander
Decision Maker

Riikka Kylväjä
Lead Auditor

FINAS
Finnish Accreditation Service
5021 (EN ISO/IEC 17021-1)

Certificate nr.
EUFI29-23000021-S

IAF

Certification body:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

v. 1.3 / 1.4.2022

eurofins

FINAS
Finnish Accreditation Service
5021 (EN ISO/IEC 17021-1)

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Bome Trivitron Sanayi Ürünleri Diş Ticaret A.Ş.
Ostim OSB Mahallesi, 1250.
Cadde, No:1, Yenimahalle, Ankara
TURKEY

Coverage of Certificate: Design, manufacture and final inspection

Product category: Reagents and reagent products for diagnosing phenylketonuria

Valid until: 29 April 2025

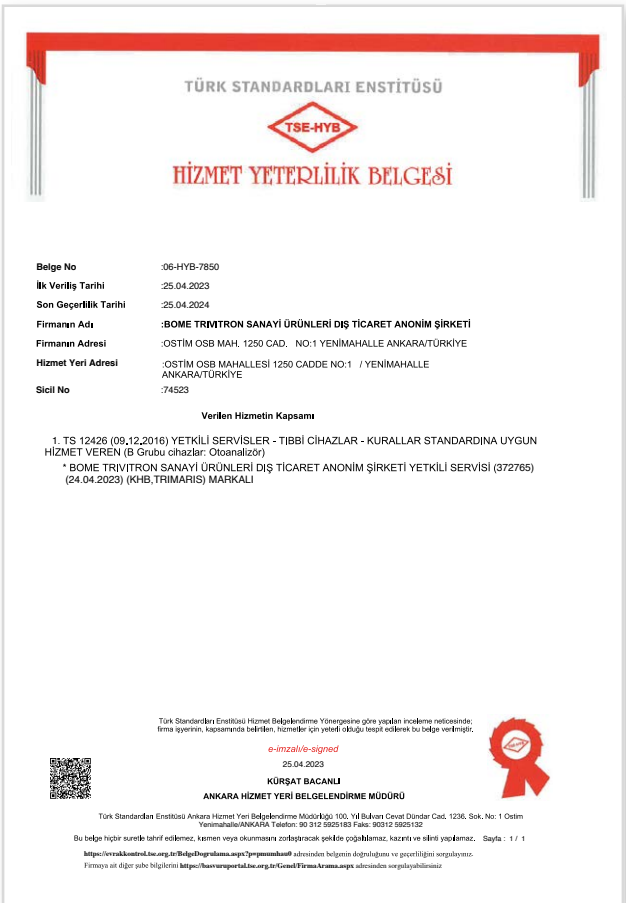
The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Valid from: 25 May 2022

Aliisa Siljander
Certificate no.
C-02-1208-798-22

Riikka Kylväjä
Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

v. 1.2 / 1.4.2022



TÜRK STANDARDLARI ENSTİTÜSÜ

TSE-HYB

HİZMET YETERLİLİK BELGESİ

Belge No	:06-HYB-7850
İlk Veriliş Tarihi	:25.04.2023
Son Geçerlilik Tarihi	:25.04.2024
Firmanın Adı	**:BOME TRIVITRON SANAYİ ÜRÜNLERİ DIŞ TİCARET ANONİM ŞİRKETİ**
Firmanın Adresi	:OSTİM OSB MAH. 1250 CAD. NO:1 YENİMAHALLE ANKARA/TÜRKİYE
Hizmet Yeri Adresi	:OSTİM OSB MAHALLESİ 1250 CADDE NO:1 / YENİMAHALLE ANKARA/TÜRKİYE
Sicil No	:74523

Verilen Hizmetin Kapsamı

1. TS 12426 (09.12.2016) YETKİLİ SERVİSLER - TIBBİ CİHAZLAR - KURALLAR STANDARDINA UYGUN HİZMET VEREN (B Grubu cihazlar: Otoanalizör)
* BOME TRIVITRON SANAYİ ÜRÜNLERİ DIŞ TİCARET ANONİM ŞİRKETİ YETKİLİ SERVİSİ (372765) (24.04.2023) (KHB,TRIMARIS) MARKALI

Türk Standardları Enstitüsü Hizmet Belgelendirme Yönergesine göre yapılan inceleme neticesinde; firma işyerinin, kapsamında belirtilen, hizmetler için yeterli olduğu tespit edilerek bu belge verilmiştir.

e-imzalı/e-signed

25.04.2023

KÜRŞAT BACANLI

ANKARA HİZMET YERİ BELGELENDİRME MÜDÜRÜ

Türk Standardları Enstitüsü Ankara Hizmet Yeri Belgelendirme Müdürlüğü 100. Yıl Bulvarı Cevat Dündar Cad. 1236. Sok. No: 1 Ostim Yenimahalle/ANKARA Telefon: 90 312 5925183 Faks: 90312 5925132

Bu belge hiçbir surette tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz. Sayfa : 1 / 1

https://sreraklkontrol.tse.org.tr/BelgeDogrulama.aspx?prpnumuhaet9 adresinden belgenin doğruluğunu ve geçerliliğini sorgulayınız.
Firmaya ait diğer şube bilgilerini https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx adresinden sorgulayabilirsiniz

Product Catalogue

BOME
TRIVITRON
speaking your language

Ostim OSB Mahallesi, 1250. Cadde No:1
Yenimahalle, Ankara, Türkiye

www.bometrivitron.com.tr
info@bometrivitron.com.tr

KAT.014.1 / 18.09.2023 / Rev0