nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Plus Analyzer System including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (Two Pages)
Classification:	Other/General
Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2:101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/24/2020

Digitally signed by Ceaicovschi Tudor
Date: 2026.02.27 18:03:34 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57400	Stat Profile Prime Plus® Analyzer	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
59508	Stat Profile Prime Plus® Analyzer (Remanufactured)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57820	Stat Profile Prime Plus MicroSensor Card™ with COOX	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57821	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57822	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57823	Stat Profile Prime Plus Reference Cartridge	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57845	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
58379	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58642	Stat Profile Prime Plus MicroSensor Card™	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58643	Stat Profile Prime Plus MicroSensor Card™ (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
55229	Nova Linearity Level 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
56198	Linearity Standard Set G Multipack	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00
61656	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Holder of Certificate: **Nova Biomedical Corporation**
200 Prospect Street
Waltham MA 02454
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; and Distribution of Lancets.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 02

Report No.: 72198686

Valid from: 2024-10-25
Valid until: 2027-10-24

Date, 2024-10-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments
.

Nova Biomedical Corporation
4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Analyzer System Family including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (two pages)
Classification:	Other/General
Near Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	**Medical devices. Quality management systems. Requirements for regulatory purposes**
EN ISO 14971:2012	**Medical devices – Application of risk management to medical devices**
EN 61010-1:2010	**Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements**
EN 61010-2:101:2015	**Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/22/2020

List of Catalog items covered:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
14631	Power Cord Int 230V	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38846	Nova Biomedical Capillary Tube Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38883	Stat Profile Critical Care Xpress Syringe Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42032	Prime Sensor Card CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42033	Prime Sensor Card CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42043	Prime Reference Cartridge	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52484	Prime Pump Harness	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52582	Prime Probe S Line 100 ul	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52616	Prime Tubing L1 L2 L3	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52617	Prime Tubing Harness ABG/CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52669	Prime Safety Sample Port 5 Pk	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52703	Prime Acc Pack	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52856	Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52857	Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53418	Remanufactured Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53420	Remanufactured Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53656	Prime CCS w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53657	Prime CCS Comp w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53666	Remanufactured Prime CCS w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53667	Remanufactured Prime CCS Comp w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55263	Prime Sensor Card CCS (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55264	Prime Sensor Card CCS Comp (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42031	Prime Sensor Card ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
52855	Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53421	Remanufactured Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53655	Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53665	Remanufactured Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
55262	Prime Sensor Card ABG (High Volume)	56671	Point-of-Care blood gas analyzer IVD	21-02-02
25217	Linearity Standard Set A Levels 1,2,3,4 Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
55229	Nova Linearity Level 1,2,3,4	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
56198	Linearity Standard Set G Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-90-00

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
45150	Prime Auto QC Cartridge CCS 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52714	Prime Ampuled Control ABG/CCS	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52864	Prime Auto QC Cartridge CCS 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53107	Prime Auto QC Cartridge ABG 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53108	Prime Auto QC Cartridge ABG 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53455	Prime Auto QC Cartridge CCS 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53456	Prime Auto QC Cartridge ABG 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52427	Prime Calibrator Cartridge CCS Comp 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52861	Prime Calibrator Cartridge CCS Comp 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52862	Prime Calibrator Cartridge CCS 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52863	Prime Calibrator Cartridge CCS 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53104	Prime Calibrator Cartridge ABG 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53105	Prime Calibrator Cartridge CCS Comp 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53359	Prime Calibrator Cartridge ABG 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53360	Prime Calibrator Cartridge ABG 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53364	Prime Calibrator Cartridge CCS 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53365	Prime Calibrator Cartridge CCS Comp 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53463	Prime Calibrator Cartridge ABG 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53464	Prime Calibrator Cartridge ABG 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53465	Prime Calibrator Cartridge ABG 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53466	Prime Calibrator Cartridge CCS 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53467	Prime Calibrator Cartridge CCS 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53468	Prime Calibrator Cartridge CCS 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53469	Prime Calibrator Cartridge CCS Comp 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53470	Prime Calibrator Cartridge CCS Comp 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52865	Stat Profile Prime Calibrator Flush Fixture	56672	Point-of-Care blood gas/haemoximetry analyzer IVD	21-02-02

nova® biomedical

CERTIFICATE OF COMPLETION

This is to certify that

Alexandru Grigoret

has successfully completed ***Stat Profile Prime Plus*** *Service and Application Training.*

April 10-11, 2023

Date of Training

Chișinău / Moldova

Location of Training

Huseyin Dibekkaya

Support Training Program Facilitator
International Regional Support Manager

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 120500 0002 Rev. 00

Holder of Certificate: **ORGENTEC Diagnostika GmbH**
Carl-Zeiss-Str. 49-51
55129 Mainz
GERMANY

Facility(ies): **ORGENTEC Diagnostika GmbH**
Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

See Scope of Certificate

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Design & development, manufacturing and distribution of in-vitro diagnostic reagents, test kits and controls for infectious diseases, sample collection device, and immunochemistry. Design & development, manufacturing, distribution and servicing of in-vitro diagnostic instruments/analysers for infectious diseases, and immunochemistry. Distribution of in-vitro diagnostic test kits and controls for immunochemistry and haematology.**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120500 0002 Rev. 00

Report No.: 713317921_ISO

Valid from: 2025-07-24
Valid until: 2028-07-23

Date, 2025-07-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10036 rev. 12

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

SEBIA

Parc Technologique Léonard de Vinci, CP 8010 - Lisses

91008 EVRY CEDEX FRANCE

pour les activités

for the activities

Conception, développement, production, distribution et activités liées au service de dispositifs médicaux de diagnostic in vitro d'électrophorèse, d'immunoélectrophorèse et de test immuno-enzymatique (ELISA) dans le domaine du diagnostic et du suivi des cancers, du métabolisme protéique, des statuts immunitaire et pathologique, des désordres endocriniens, des analytes sanguins, des composants sanguins et des hémoglobinopathies. (Voir addendum)

Design, development, production, distribution and servicing activities of electrophoresis, immunoelectrophoresis and enzyme-linked immunosorbent assay (ELISA) in vitro diagnostic medical devices in the field of cancer diagnosis and management, protein metabolism, immune status, disease status, endocrine disorders, blood analytes, blood components and hemoglobin disorders. (See addendum)

réalisées sur le(s) site(s) de

performed on the location(s) of

SEBIA
Parc Technologique Léonard de Vinci, CP 8010 Lisses - 91008 EVRY CEDEX - FRA
SEBIA
7 Allée du Brevent Bâtiment Aneto – 91080 Evry-Courcouronnes - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **June 25th, 2024 (included)**
Valable jusqu'au */ Expiry date :* **June 30th, 2027 (included)**
Etabli le */ Issued on :* **July 1st, 2024**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA0...
GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 10036–12
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Annule et remplace le certificat 10036-11

Ce certificat couvre les activités et le site suivant :

This certificate covers the following activities and site:

SEBIA
Parc Technologique Léonard de Vinci
CP 8010 Lisses
91008 EVRY CEDEX
FRANCE

Version française *:*

Conception, développement, production, distribution et activités liées au service (installation, service après-vente et formation) de dispositifs médicaux de diagnostic in vitro d'électrophorèse, d'immunoélectrophorèse et de test immuno-enzymatique (ELISA) (kits, réactifs, instruments et logiciels) dans le domaine du diagnostic et du suivi des cancers, du métabolisme protéique, des statuts immunitaire et pathologique, des désordres endocriniens, des analytes sanguins, des composants sanguins et des hémoglobinopathies.

Version anglaise:

Design, development, production, distribution and servicing activities (installation, after-sales and training) of electrophoresis, immunoelectrophoresis and enzyme-linked immunosorbent assay (ELISA) in vitro diagnostic medical devices (test kits, reagents, analyzers and softwares) in the field of cancer diagnosis and management, protein metabolism, immune status, disease status, endocrine disorders, blood analytes, blood components and hemoglobin disorders.

****

Le contrat concerne les sites :

SEBIA - Parc Technologique Léonard de Vinci - CP 8010 Lisses - 91008 EVRY CEDEX France
Conception, développement, production, distribution et service
Design, development, production, distribution and servicing

SEBIA - 7 Allée du Brevent Bâtiment Aneto – 91080 Evry-Courcouronnes
Distribution et service FRANCE
Distribution and servicing FRANCE

2 sites / *2 sites*

DocuSigned by:
EE33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51
55129 Mainz - Germany
Phone: +49 (0) 61 31 / 92 58-0
Fax: +49 (0) 61 31 / 92 58-58
Internet: www.orgentec.com

sebia
The new language of life

CE

IVD

Electronic Instruction For Use: version

270_7

www.orgentec.com

REF ORG 270 25-OH Vitamin D_3/D_2

INTENDED PURPOSE

25-OH Vitamin D_3/D_2 for Alegria® is an ELISA based test system intended for the quantitative measurement of the total concentration of 25-(OH)-Vitamin D_2 and 25-(OH)-Vitamin D_3 in human serum or plasma samples (EDTA plasma, heparin plasma, citrate plasma). This product is intended for professional in vitro diagnostic use only.

The concentration of 25-OH vitamin D is an indicator of the vitamin D supply in the body. Concentrations of 25-OH vitamin D over 20 ng/ml are considered to indicate a sufficient supply of vitamin D; values of 12-20 ng/ml indicate a lack of vitamin D; concentrations below 12 ng/ml indicate severe vitamin D deficiency. The level of 25-OH vitamin D correlates with the clinical symptoms of vitamin D deficiency.

SYMBOLS USED

IVD	In vitro diagnostic medical device		
	Manufacturer	ALEGRIA TEST STRIPS	Alegria® Test Strips
REF	Catalogue number	WASH	Wash Buffer
Σ	Sufficient for ... determinations	SYSTEM FLUID	System Fluid
LOT	Batch code	RTU	Ready to use
	Use by	50 x	50 x concentrate
	Temperature limitation	1000 x	1000 x concentrate
	Consult electronic Instructions For Use		
	Keep away from sunlight		
	Do not reuse		
	Date of manufacture		
CE	CE marked according to 98/79/EC		
270_7	Electronic Instruction For Use: version		

PRINCIPLE OF THE TEST

The Alegria® assay features barcoded 8-well-microstrips, called Alegria® Test Strips. Each strip is designed for a single determination of one patient sample. The Alegria® Test Strip holds a complete set of reagents. Included are enzyme conjugate, enzyme substrate, sample buffer and a test specific control. Two wells of the Alegria® Test Strip are coated with a 25-OH vitamin D_3/D_2 antibody and serve as reaction wells for one control and one patient sample. Two more wells of the Alegria® Test Strip are coated with a 25-OH vitamin D tracer or a 25-OH vitamin D control respectively.

The determination is based on a competitive enzyme linked immunosorbent assay (ELISA) with the following steps: The sample is pipetted into well No 1. Inside the Alegria® Random Access Analyser the sample is mixed with tracer reagent and the 25-OH vitamin D_3/D_2 is delivered from vitamin D binding protein. 25-OH vitamin D and tracer reagent coated in well No 2 are suspended with buffer. Sample and control are then transferred to the reaction wells No 3 and No 4 where 25-OH vitamin D_3/D_2 and 25-OH vitamin D tracer reagent compete for binding to the coated 25-OH vitamin D_3/D_2 antibody. Complexes are formed between 25-OH vitamin D_3/D_2 and antibody or 25-OH vitamin D tracer reagent and antibody. After incubation, a first washing step removes unbound and unspecifically bound molecules. Subsequently added enzyme conjugate binds to the immobilized tracer-antibody complexes. After incubation, a second washing step removes unbound enzyme conjugate. Addition of enzyme substrate solution results in hydrolisation and color development during incubation. The intensity of the blue color can be measured photometrically at 650 nm. The intensity of the blue color correlates inversely with the concentration of vitamin D in the sample.

The Alegria® Test Strip utilizes the proprietary SMC®-Technology (Sensotronic Memorized Calibration): information about the assay, analysis and evaluation, and the lot-specific expiry date is contained on the barcode printed on each Alegria® Test Strip. The Alegria® Test Strip can be used with the diagnostic instrument Alegria® - a fully automated Random Access Analyser. By means of SMC®-Technology data encoded on the barcode are transferred from the Alegria® Test Strip to the instrument and the assay is automatically processed and evaluated. The instrument reads the date of expiry and rejects further processing if the Alegria® Test Strip is out of date.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- System fluid contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

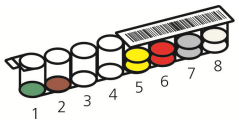
Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store Alegria® strips in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.

CONTENTS OF THE KIT

Σ 24	ORG 270	Sufficient for 24 determinations
ALEGRIA TEST STRIPS	24	**Alegria® Test Strips** are modules of 8 wells each composed of: Well 1: green; coated with 25-OH Vitamin D tracer Well 2: brown; coated with 25-OH Vitamin D tracer + 25-OH Vitamin D control Wells 3 + 4: coated with antibody (reaction wells) Well 5: Buffer: yellow. Well 6: Enzyme Conjugate; light red; containing HRP conjugate; PBS, BSA, detergent, preservative ProClin 0.05%. Well 7: Matrix; opaque; containing human serum matrix, Tris, BSA, preservative sodium azide 0.09%. Well 8: TMB Substrate: clear; containing 3,3', 5,5'- Tetramethylbenzidin. Antibodies detecting 25-OH Vitamin D_2 and 25-OH Vitamin D_3 are bound to reaction wells 3+4.
		Code on barcode: ***VitD*** on printout: ***VitD3/D2***
WASH	1x 20 ml	**Wash Buffer**, containing Tris, detergent, preservative sodium azide 0.09%; 50 x concentrate
SYSTEM FLUID	1x 2.5 ml	**System Fluid**, contains acid; 1000 x concentrate



STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store Alegria® Test Strips sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is **12** months from day of production.
  Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and System Fluid are stable for at least 30 days when stored at 2-8°C.
  Once transferred to the reagent container we recommend consumption on the same day.

MATERIALS REQUIRED

- Vortex mixer
- Pipettes for **80** µl
- Measuring cylinder for 1000 ml and 2500 ml
- Distilled or deionized water

AUXILLIARY REAGENTS

ORG 271 25-OH Vitamin D_3/D_2 Control Set

25-OH Vitamin D_3/D_2 Control Set is an external quality control material for the quantitative Alegria® 25-OH Vitamin D_3/D_2 assay. This product is intended for professional in vitro diagnostic use only.

The Control Set contains Control A und Control B 2.5 ml each with a defined concentration of 25-OH Vitamin D_3/D_2 (see label) in Tris 0.7%, NaCl 0.8% with human serum matrix, BSA 0.5% and sodium azid 0,09% as preservative. Ready to use. For 30 Determinations. Store ORG 271 at 2-8°C in the dark.

Unopened controls are stabil until expiry date (see label). Once opened use up within 4 months.

Procedure in the Alegria® assay: Pipette **80** µl control at the bottom of well 1 of the Alegria test strip.

This Control Set is available separately.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Do not expose specimens to heat, sun, or strong light during storage and usage.
- Avoid repetitive freezing and thawing of serum or plasma samples.
- Testing of heat-inactivated sera is not recommended.

PROCEDURAL NOTES

- **Protect kit components, reagents, and samples from direct sunlight during handling!**
- Do not use kit components beyond their expiration dates.
- All materials must be at room temperature (20-28°C) prior to use.
- To avoid carryover or contamination, change the pipette tip between samples.

PREPARATION OF REAGENTS

WASH

Dilute the content of the Wash Buffer concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use. Transfer the diluted Wash Buffer into the instrument reagent container. If only one Alegria run is to be performed on one day we recommend transferring only 500 ml diluted Wash Buffer.

SYSTEM FLUID

Dilute the content of the System Fluid concentrate (1000x) with distilled or deionised water to a final volume of 2500 ml prior to use. Transfer the diluted System Fluid into the instrument reagent container.

ALEGRIA TEST STRIPS

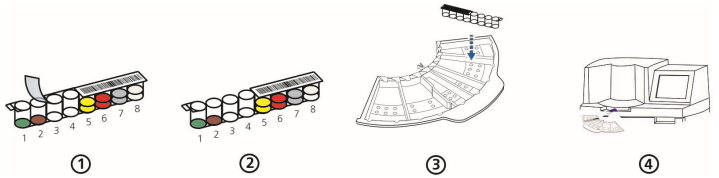
Take the required number of Alegria® Test Strips out of the clip bag and let them reach room temperature (20-28° C). Do not remove foil covering the empty wells until you are ready to start the assay.

TEST PROCEDURE

Alegria® Test Strips with SMC® technology are used with the diagnostic instrument Alegria®.
Detailed information about operating the instrument can be taken from the Instrument User Manual.

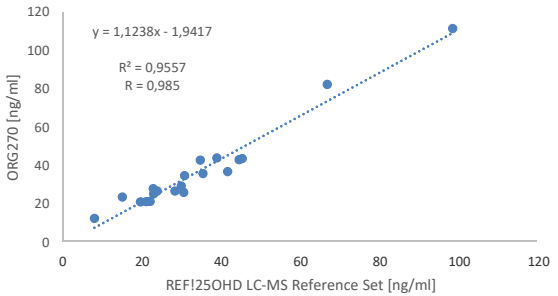
(1) Remove the foil from the empty wells 1 to 4 of the Alegria® Test Strip.
Do not remove foil with printed barcode, covering wells 5 to 8.
(2) Pipette **80** µl undiluted patient sample (serum or plasma) or ready to use control ORG 271 at the bottom of well 1.
(3) Insert the strip into the SysTray.
(4) Place loaded SysTrays into the correct position in the Alegria® instrument and start run. All further steps will be done automatically. The test run is completed when the instrument starts printing the results.

Caution: Alegria® Test Strips 25-OH Vitamin D_3/D_2 need a special performance and therefore they cannot be combined with other Alegria® tests in the same run.



CALIBRATION

The calibration is traceable to the ID-LC/Tandem MS reference preparation REF!25OHD (Labquality, IQAS).



CALCULATION OF RESULTS

By means of SMC® Technology (Sensotronic Memorized Calibration), all test data are transferred to the system through individual barcodes on the Alegria® Test Strip. Calculation and interpretation of results will be performed automatically.

PERFORMANCE CHARACTERISTICS

Measuring range

The calculation range of this Alegria® assay is 5 - 200 ng/ml

Interpretation of results

Suggested classification ranges of vitamin D status according to literature (Ref 5):
(Conversion factors: 1ng/ml = 2.5 nmol/l; 1 nmol/l = 0.4 ng/ml)

Deficiency:	< 12 ng/ml	(< 30 nmol/l)
Insufficiency:	12 - 20 ng/ml	(30 - 50 nmol/l)
Sufficiency:	> 20 - 150 ng/ml	(> 50 - 375 nmol/l)

Limitations of the Procedure

According to literature several reference ranges are suggested. Examples:
Ref 5
Deutsche Gesellschaft für Ernährung (DGE), (ÖGE), (SGE), (SVE), Referenzwerte für die Nährstoffzufuhr, Vitamin D. 2012; ISBN 978-3-86528-128-9).
Deficiency: <12 ng/ml; Insufficiency: 12-20 ng/ml; Sufficiency: >20-160 ng/ml; Hypervitaminosis 160-500 ng/ml
Ref 9
Holick, M.F. Vitamin D deficiency. N. Engl. J.M. 2007, 357: 266-281.
Deficiency: <20 ng/ml; Insufficiency: 21-29 ng/ml; Sufficiency: >30 ng/ml; Intoxication >150 ng/ml
Ref 16
National Osteoporosis Society 2013, Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management. Deficiency: <12 ng/ml; Insufficiency: 12-20 ng/ml; Sufficiency: >20 ng/ml

According to the literature, factors such as nutrition, season, skin color, age or culture affect the normal 25-OH vitamin D levels.
The concentration ranges for the classification of vitamin D supply should be considered a recommendation.
Each laboratory should establish its own ranges according to ISO 15189:2007 Requirements for quality and competence particular to medical laboratories or other applicable criteria.

Linearity

Samples containing high levels 25-OH vitamin D were serially diluted to demonstrate the dynamic range of the assay. 25-OH vitamin D concentration for each dilution was calculated by means of SMC® Technology.

Sample	Dilution	Observed	Expected	O/E
		[ng/ml]	[ng/ml]	%
1	1:1	170.2	200.0	85
	1:2	101.6	100.0	102
	1:4	44.6	50.0	89
	1:8	21.7	25.0	87
	1:16	12.9	12.5	104
2	1:1	129.2	120.0	107
	1:2	62.6	60.0	104
	1:4	25.1	30.0	84
	1:8	15.3	15.0	102
3	1:1	58.5	62.6	94
	1:2	28.5	31.3	91
	1:4	14.7	15.6	94
	1:8	9.7	7.8	124
	1:16	4.1	3.9	105

Detection limit

Smallest ammount of Vitamin D detectable 5 ng/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below

Intra-Assay		
Sample	Mean	% CV
	[ng/ml]	%
1	16.3	10.7
2	50.1	6.1
3	107.5	3.9

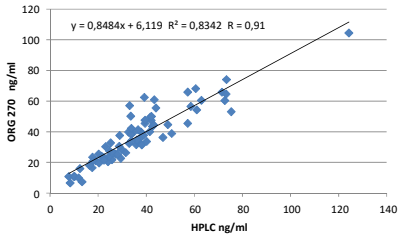
Inter-Assay		
Sample	Mean	% CV
	[ng/ml]	%
1	16.5	14.7
2	45.6	7.9
3	98.9	4.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

In a comparative study 74 vitamin D serum samples from persons aged 8 to 89, 2/3 female and 1/3 male were analyzed. A high correlation was found between Alegria® 25-OH Vitamin D_3/D_2 and HPLC method:
R = 0.91



Specificity

Specificity was determined by measurement of cross-reactivity to 25-OH vitamin D related substances.
Cross-reactivity is stated in % relative to 25-OH Vitamin D_3 reactivity:

25-OH Vitamin D_3	100 %
25-OH Vitamin D_2	100.4 %
Vitamin D_3 (Cholecalciferol)	< 0.1 %
Vitamin D_2 (Ergocalciferol)	< 0.6 %

REFERENCES

1. Ashraf, A. et al. Threshold for effects of vitamin D deficiency on glucose metabolism in obese female African-American adolescents. J Clin Endocrinol Metab 94 (9):3200-3206, 2009.
2. Baker, A. M. et al. A nested case-control study of midgestation vitamin D deficiency and risk of severe preeclampsia. J Clin Endocrinol Metab 95 (11):5105-5109, 2010.
3. Crew, K. D. et al. Association between plasma 25-hydroxyvitamin D and breast cancer risk. Cancer Prev Res (Phila) 2

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6. Garland, C.F. et al. Vitamin D for Cancer Prevention: Global Perspective. Ann. Epidemiol. 2009; 19: 468-483.
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10. Holick, M.F. Sunlight and Vitamin D for bone health and prevention of autoimmune diseases, cancer and cardiovascular disease. Am. J.Clin. Nutr. 2004; 80: 1678-1688.
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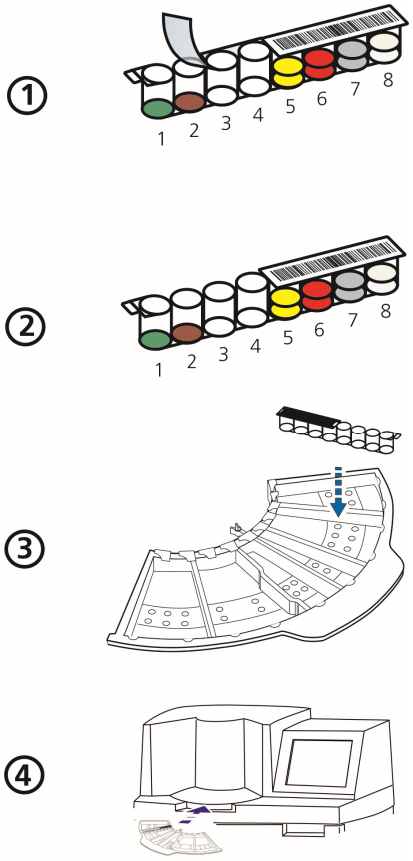
16. National Osteoporosis Society 2013, Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management.
17. Sen, D. and Ranganathan, P. Vitamin D in rheumatoid arthritis: panacea or placebo? Discov Med 14 (78):311-319, 2012.
18. Wen, H. and Baker, J. F. Vitamin D, immunoregulation, and rheumatoid arthritis. J Clin Rheumatol 17 (2):102-107, 2011.
19. Zerwekh, J.E. Blood biomarkers of Vitamin D status, Am. J.Clin. Nutr. 2004; 87: 1087-91.

Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 270_IFU_EN_QM130718_2020-09-01_6* Reason for revision: *Definition of symbols used and symbols updated*



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271_5

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CE

IVD

REF ORG 271 25-OH Vitamin D_3/D_2 Control Set

INTENDED PURPOSE

25-OH Vitamin D_3/D_2 Control Set contains external control materials with defined concentrations of 25-OH Vitamin D_3/D_2 for the quantitative Alegria® 25-OH Vitamin D_3/D_2 assay (order code: ORG 270). This product is intended for professional in vitro diagnostic use only.

SYMBOLS USED

IVD	In vitro diagnostic medical device	CONTROL A	Control A
	Manufacturer	CONTROL B	Control B
REF	Catalogue number	RTU	Ready to use
	Sufficient for ... determinations		
LOT	Batch code		
	Use by		
	Temperature limitation		
	Consult electronic instructions for use		
	Keep away from sunlight		
CE	CE marked according to 98/79/EC		
271_5	Electronic Instruction For Use: version		

PRINCIPLE OF THE TEST

25-OH Vitamin D_3/D_2 Control Set is an accessory for the Alegria® assay 25-OH Vitamin D_3/D_2 (order code: ORG 270). Control A und Control B are used in the same way as a patient sample is used, see instruction for use of ORG 270. Control A und Control B are ready to use.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Controls contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap.

Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.

• Measures to be taken in case of accidental release: follow Good Laboratory Practice safety guidelines. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or wear make-up in areas where samples or components of the product are handled. Pick up spills with inert material and dispose of them appropriately.

• Personal protective equipment: wear protective gloves made of nitrile or latex. Wear safety goggles. When used as intended, no dangerous reactions are known.

• Conditions to avoid: controls are sensitive to light, store in the dark.

• Waste should be disposed of in accordance with state and local environmental regulations.

The guidelines for quality control in the medical laboratory should be followed.

CONTENTS OF THE KIT

ORG 271	30	Sufficient for 30 determinations
CONTROL A	2.5 ml	Control A with defined concentration of 25-OH Vitamin D_3/D_2 (see label) in Tris 0.7%, NaCl 0.8% with human serum matrix, BSA 0.5% and sodium azid 0.09% as preservative. Ready to use. Store at 2-8°C in the dark.
CONTROL B	2.5 ml	Control B with defined concentration of 25-OH Vitamin D_3/D_2 (see label) in Tris 0.7%, NaCl 0.8% with human serum matrix, BSA 0.5% and sodium azid 0.09% as preservative. Ready to use. Store at 2-8°C in the dark.

MATERIALS REQUIRED

- Pipettes for **80** µl
- Alegria® assay order code ORG 270: 25-OH Vitamin D_3/D_2

25-OH Vitamin D_3/D_2 Control Set is suitable for Alegria® - a fully automated Random Access Analyser.

STORAGE AND STABILITY

- Store at 2-8°C in the dark.
- Do not expose to heat, sun, or strong light during storage and usage.
- Unopened Controls are stable until expiry date. See labels for individual batch.
- Once opened use up within 4 months.

SPECIMEN COLLECTION, STORAGE AND HANDLING

not applicable

PROCEDURAL NOTES

- **Protect controls, kit components, reagents, and samples from direct sunlight during handling!**
- Do not use kit components beyond their expiration dates.
- All materials must be at room temperature (20-28°C) prior to use.
- To avoid carryover or contamination, change the pipette tip between samples.

PREPARATION OF REAGENTS

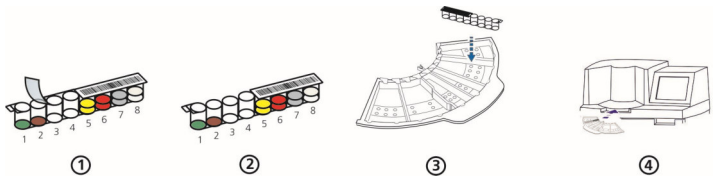
- Control A and Control B are ready to use.

TEST PROCEDURE

Alegria® Test Strips 25-OH Vitamin D_3/D_2 with SMC® technology are used with the diagnostic instrument Alegria®. Detailed information about operating the instrument can be taken from the Instrument User Manual.

(1) Remove the foil from the empty wells 1 to 4 of the Alegria® Test Strip.
Do not remove foil with printed barcode, covering wells 5 to 8.
(2) Pipette **80** µl Control A or Control B at the bottom of well 1.
(3) Insert the strip into the SysTray. Place loaded SysTrays into the correct position in the Alegria® instrument and start run. All further steps will be done automatically.
The test run is completed when the instrument starts printing the results.

Caution: Alegria® Test Strips 25-OH Vitamin D_3/D_2 need a special performance and therefore they cannot be combined with other Alegria® tests in the same run.



Calibration

The calibration is traceable to the ID-LC/Tandem MS reference preparation REF!25OHD (Labquality, IQAS).

CALCULATION OF RESULTS

By means of SMC® Technology (Sensotronic Memorized Calibration), all test data are transferred to the system through individual barcodes on the Alegria® Test Strip. Calculation and interpretation of results will be performed automatically.

PERFORMANCE CHARACTERISTICS

Measuring range

not applicable

Expected values

Expected concentration of 25-OH Vitamin D_3/D_2 and acceptable range : see label

Linearity

not applicable

Detection limit

not applicable

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three lots of Control A and Control B from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.

Inter-assay precision: Coefficient of variation (CV) was calculated for each of three lots of Control A and Control B from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Control A	Mean	% CV
	ng/ml	
lot 1	16.4	5.4
lot 2	18.5	6.7
lot 3	16.5	5.6

Intra-Assay		
Control B	Mean	% CV
	ng/ml	
lot 1	62.9	5.8
lot 2	71.2	8.2
lot 3	56.3	12.0

Inter-Assay		
Control A	Mean	% CV
	ng/ml	
lot 1	18.4	11.3
lot 2	18.3	17.0
lot 3	18.6	9.8

Inter-Assay		
Control B	Mean	% CV
	ng/ml	
lot 1	60.2	10.0
lot 2	61.2	10.9
lot 3	62.6	8.4

Interfering substances

not applicable

Study results

not applicable

Limitations of the Procedure

not applicable

REFERENCES

1. Ashraf, A. et al. Threshold for effects of vitamin D deficiency on glucose metabolism in obese female African-American adolescents. J Clin Endocrinol Metab 94 (9):3200-3206, 2009.
2. Baker, A. M. et al. A nested case-control study of midgestation vitamin D deficiency and risk of severe preeclampsia. J Clin Endocrinol Metab 95 (11):5105-5109, 2010.
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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: *ORG 271_IFU_EN_QM131966_2024-04-24_4* Reason for revision: Adaptation to corporate Sebia branding

INSTRUCTIONS FOR USE

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51
55129 Mainz - Germany
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Fax: +49 (0) 6131 / 92 58-58
Internet: www.orgentec.com

Electronic Instruction for Use: version

310_9 2024/06/05

www.orgentec.com

REF ORG 310 Alegria® Positive Control

INTENDED PURPOSE

Alegria® Positive Control is an ELISA based Alegria® Test Strip intended for functional quality control of the Alegria® instruments. This product is an accessory for the Alegria® instruments, intended for professional in vitro diagnostic use only. The kit is intended for automated use with an Alegria® instrument.

SYMBOLS USED

	Manufacturer	REF	Catalogue number
	Country of manufacture (The date of manufacture is added adjacent to this symbol.)	LOT	Batch code
	Consult Electronic Instruction For Use	310_9	Electronic Instruction For Use: Version
	Contains sufficient for <n> tests	IVD	In vitro diagnostic medical device
	Do not re-use		Use-by date
	Keep away from sunlight		Temperature limit
RTU	Ready to use	SYSTEM FLUID	System Fluid
WASH	Wash Buffer	ALEGRIA TEST STRIPS	Alegria® Test Strips
CONTROL	Control	50x	50x concentrate
1000x	1000x concentrate	CE	CE marked according to Regulation (EU) 2017/746

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Contains biological material of animal origin

Contains biological material of human origin

PRINCIPLE OF THE TEST

The Alegria® assay features barcoded 8-well-microstrips, called Alegria® Test Strips. Each strip is designed for a single determination. The Alegria® Test Strip holds a complete set of reagents. Included are enzyme conjugate, enzyme substrate, sample buffer and a test specific control. Furthermore, each strip has two antigen-coated wells which serve as reaction wells.

In the Alegria® Positive Control the Alegria® Test Strip holds a positive sample in the well which is otherwise used for sample buffer. **No patient sample is used in this assay!**
The determination is based on an indirect enzyme linked immune reaction with the following steps: Antibodies present in positive samples bind to the antigen coated on the surface of the two reaction wells forming an antibody antigen complex. After incubation, a first washing step removes unbound and unspecifically bound molecules. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen complex. After incubation, a second washing step removes unbound enzyme conjugate.

Addition of enzyme substrate solution results in hydrolyzation and color development during incubation. The intensity of the blue color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 650 nm.

The Alegria® Test Strip is based on the proprietary SMC®-Technology (Sensotronic Memorized Calibration): information about the assay, analysis and evaluation, and the lot-specific expiry date is contained on the barcode printed on each Alegria® Test Strip.

The Alegria® Test Strip is intended to be used with the diagnostic instruments Alegria® and Alegria® 2. By means of SMC®-Technology data encoded on the barcode are transferred from the Alegria® Test Strip to the instrument and the assay is automatically processed and evaluated. The instrument reads the date of expiry and rejects further processing if the Alegria® Test Strip is out of date.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Each Test Strip is intended for single use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum-based reagents in this kit must be handled as though capable of transmitting

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infection.

- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- System fluid contains acid, classification is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate, control and sample buffer contain ProClin 300, 0.05% as preservative. This concentration is classified as non-hazardous.
- During handling of all reagents, controls and serum samples follow the existing laboratory safety regulations and good laboratory practice.
- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Accidental release measures: observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.
- Personal protective equipment: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. No dangerous reactions are known when used as intended.
- Conditions to avoid: Since substrate solution is light-sensitive. Store Alegria ® strips in the dark.
- Waste should be disposed of in accordance with state and local environmental protection regulations.
- Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.
- If the packaging has been damaged in any way after leaving our premises or has been opened unintentionally before use or has been exposed to environmental conditions beyond those specified, we do not guarantee the functionality of the product. If you have any questions about how to handle the product in such cases, you can contact your local representative.
- If the blue seal of the MTP strips is open or damaged, the plate should not be used.
- If a printed version of the electronic Instruction for Use (IFU) is required, please contact your local representative.

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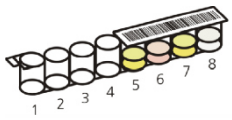
Notice to the user:
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the state in which the user and/or the patient is established.

CONTENTS OF THE KIT

Σ ORG 310 **24**		Sufficient for 24 determinations
ALEGRIA TEST STRIPS	24	Alegria® Test Strips are modules of 8 wells each composed of:
	Wells 1 + 2:	empty and not coated (wells for the sample dilution)
	Wells 3 + 4:	coated with human apolipoprotein H (APOH) (reaction wells)
	Well 5:	**Calibrator**; yellow; containing test specific IgG antibodies (chicken), PBS, BSA, detergent; preservative sodium azide 0.09% and ProClin 300 0.05%
	Well 6:	**Enzyme Conjugate**; light red; containing anti-chicken IgG antibodies (goat), HRP labelled; PBS, BSA, detergent, preservative ProClin 300 0.05%
	Well 7	**Positive Control:** yellow; containing test specific antibodies (chicken), PBS, BSA, detergent, preservative sodium azide 0.09% and ProClin 300 0.05%
	Well 8	**TMB Substrate**: clear; containing 3,3', 5,5'-Tetramethylbenzidin

Reaction wells 3 and 4 are coated with test specific antigen.

Code on barcode: **Pos Contrl** code on printout: **CntrPos**

WASH 1x 20 ml **Wash Buffer**, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.

SYSTEM FLUID 1x 2.5 ml **System Fluid**, contains acid; 1000 x concentrate

MATERIALS REQUIRED

- ORG 300-00 Alegria® or ORG 320 Alegria® 2 instrument
- Measuring cylinder for 1000 ml and 2500 ml
- Distilled or deionized water
- Empty barcoded sample tubes

SPECIMEN COLLECTION, STORAGE AND HANDLING

not applicable, no sample used

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- All materials must be at room temperature (20-28°C) prior to use.

PREPARATION OF REAGENTS

WASH

Dilute the content of the Wash Buffer concentrate (50x) with distilled or deionized water to a final volume of 1000 ml prior to use. Transfer the diluted Wash Buffer into the instrument reagent container. If only one Alegria® run is to be performed on one day we recommend transferring only 500 ml diluted Wash Buffer.

SYSTEM FLUID

Dilute the content of the System Fluid concentrate (1000x) with distilled or deionized water to a final volume of 2500 ml prior to use. Transfer the diluted System Fluid into the instrument reagent container.

ALEGRIA TEST STRIPS

Take the required number of Alegria® Test Strips out of the clip bag and let them reach room temperature (20-28°C).

TEST PROCEDURE

The fully automated random access analyzers of the Alegria® family use Alegria® Test Strips with SMC® technology.

Alegria®:

(1) Remove the foil from the empty wells 1 to 4 of the Alegria® Test Strip.
Do not remove foil with printed barcode, covering wells 5 to 8.
Well 1: leave empty.
(2) Insert the strip into the SysTray.
(3) Place loaded SysTrays into the correct position in the Alegria® instrument and start run. All further steps will be done automatically. The test run is completed when the instrument starts printing the results.
All the above steps should be performed in immediate succession.

Alegria® 2:

(1) Insert Test Strips in Strip Trays as described in the Alegria® 2 User Manual.
(2) Load an empty barcoded sample tube on the Alegria® 2 instrument.
(3) Assign the sample tube to the assay ORG 310 to allow the correct relation.

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(4) Then start measurement as usual.
All the above steps should be performed within one day.
Detailed information on how to load the instruments with Test Strips and other reagents and how to operate the instruments can be found in the respective user manuals:

- Alegria® User Manual
- Alegria® 2 User Manual

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Do not freeze.
- Store Alegria® Test Strips sealed and desiccated in the clip bag provided.
- Shelf life of the unopened test kit is 15 months from day of production.
- Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and System Fluid are stable for at least 30 days when stored at 2-8°C. Once transferred to the reagent container we recommend consumption on the same day.

CALIBRATION

This assay system is calibrated in relative arbitrary units.

A specified target value with a defined target range must be met. The Certificate of Analysis indicates the batch specific target value and the acceptance range.

Test runs are only valid if the following criterion of validity is fulfilled. The positive control must be evaluated positive and present an activity within the validity range indicated on the quality control certificate. If this criterion is not met, the test run is not valid and must be repeated.

In case of an invalid test run, the expiry dates and storage conditions, incubation times and temperatures, and precise calibration of the instrument used should be verified. If no reason for an invalid test run could be identified, please contact the supplier or manufacturer of the product. For technical support, contact your local Sebia offices at www.sebia.com website by selecting your country.

CALCULATION OF RESULTS

By means of SMC® Technology (Sensotronic Memorized Calibration), all test data are transferred to the system through individual barcodes on the Alegria® Test Strip. Calculation and interpretation of results will be performed automatically.

PERFORMANCE CHARACTERISTICS

Alegria® Positive Control, ORG 310 has no diagnostic function. The test is used to demonstrate that the instrument is working within its specification.

Reproducibility

To demonstrate the functional performance of ORG 310 ORGENTEC has performed 24 measurements with one lot of ORG 310 on two Alegria® instruments and two Alegria® 2 instruments. The results of the study are summarized in the table below.

Table-1 Mean values, minimum and maximum results of 24 measurements of ORG 310 on two Alegria® and two Alegria® 2 instruments

Measurement results	Mean [U/ml]	Min[U/ml]	Max[U/ml]
Alegria® Instrument A	*99.9*	*91.2*	*124.4*
Alegria® Instrument B	*102.2*	*89*	*112.6*
Alegria® 2 Instrument C	*119.1*	*108.7*	*134.4*
Alegria® 2 Instrument D	*102.5*	*74.2*	*134.4*

LIMITATIONS OF THE PROCEDURE

This assay is an accessory for the Alegria® instruments. The control is used for checking the correct function of the Alegria® analyzers and has no diagnostic function.

Change Control

Former version: *ORG 310_IFU_EN_QM113127_2023-04-25_8*
Reason for revision: Addition of content under chapter Calibration and symbols updated

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INSTRUCTIONS FOR USE

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CE

IVD

Electronic Instruction for Use: version

311_9 2024/06/05

www.orgentec.com

REF ORG 311 Alegria® Negative Control

INTENDED PURPOSE

Alegria® Negative Control is an ELISA based Alegria® Test Strip intended for functional quality control of the Alegria® instruments. This product is an accessory for the Alegria® instruments, intended for professional in vitro diagnostic use only. The kit is intended for automated use with an Alegria® instrument.

SYMBOLS USED

	Manufacturer	REF	Catalogue number
CC	Country of manufacture (The date of manufacture is added adjacent to this symbol.)	LOT	Batch code
	Consult Electronic Instruction For Use	311_9	Electronic Instruction For Use: Version
Σ	Contains sufficient for <n> tests	IVD	In vitro diagnostic medical device
	Do not re-use		Use-by date
	Keep away from sunlight		Temperature limit
RTU	Ready to use	SYSTEM FLUID	System Fluid
WASH	Wash Buffer	ALEGRIA TEST STRIPS	Alegria® Test Strips
CONTROL	Control	50x	50x concentrate
1000x	1000x concentrate	CE	CE marked according to Regulation (EU) 2017/746

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Contains biological material of animal origin

Contains biological material of human origin

PRINCIPLE OF THE TEST

The Alegria® assay features barcoded 8-well-microstrips, called Alegria® Test Strips. Each strip is designed for a single determination. The Alegria® Test Strip holds a complete set of reagents. Included are enzyme conjugate, enzyme substrate, sample buffer and a test specific control. Furthermore, each strip has two antigen-coated wells which serve as reaction wells.

In the Alegria® Negative Control the Alegria® Test Strip holds a negative sample in the well which is otherwise used for sample buffer. **No patient sample is used in this assay!**

The determination is based on an indirect enzyme linked immune reaction with the following steps: Antibodies present in positive samples bind to the antigen coated on the surface of the two reaction wells forming an antibody antigen complex. After incubation, a first washing step removes unbound and unspecifically bound molecules. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen complex. After incubation, a second washing step removes unbound enzyme conjugate.

Addition of enzyme substrate solution results in hydrolyzation and color development during incubation. The intensity of the blue color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 650 nm.

The Alegria® Test Strip is based on the proprietary SMC®-Technology (Sensotronic Memorized Calibration): information about the assay, analysis and evaluation, and the lot-specific expiry date is contained on the barcode printed on each Alegria® Test Strip. The Alegria® Test Strip is intended to be used with the diagnostic instruments Alegria® and Alegria® 2. By means of SMC®-Technology data encoded on the barcode are transferred from the Alegria® Test Strip to the instrument and the assay is automatically processed and evaluated. The instrument reads the date of expiry and rejects further processing if the Alegria® Test Strip is out of date.

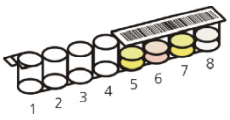
WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Each Test Strip is intended for single use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum-based reagents in this kit must be handled as though capable of transmitting infection.

- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- System fluid contains acid, classification is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate, control and sample buffer contain ProClin 300, 0.05% as preservative. This concentration is classified as non-hazardous.
- During handling of all reagents, controls and serum samples follow the existing laboratory safety regulations and good laboratory practice.
- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Accidental release measures: observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.
- Personal protective equipment: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. No dangerous reactions are known when used as intended.
- Conditions to avoid: Since substrate solution is light-sensitive. Store Alegria ® strips in the dark.
- Waste should be disposed of in accordance with state and local environmental protection regulations.
- Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.
- If the packaging has been damaged in any way after leaving our premises or has been opened unintentionally before use or has been exposed to environmental conditions beyond those specified, we do not guarantee the functionality of the product. If you have any questions about how to handle the product in such cases, you can contact your local representative.
- If the blue seal of the MTP strips is open or damaged, the plate should not be used.
- If a printed version of the electronic Instruction for Use (IFU) is required, please contact your local representative.

Notice to the user:
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the state in which the user and/or the patient is established.

CONTENTS OF THE KIT

Σ 24 ORG 311		Sufficient for 24 determinations
ALEGRIA TEST STRIPS	24	Alegria® Test Strips are modules of 8 wells each composed of:
	Wells 1 + 2:	empty and not coated (wells for the sample dilution)
	Wells 3 + 4:	coated with human apolipoprotein H (APOH) (reaction wells)
	Well 5:	**Calibrator**; yellow; containing test specific IgG antibodies (chicken), PBS, BSA, detergent; preservative sodium azide 0.09% and ProClin 300 0.05%
	Well 6:	**Enzyme Conjugate**; light red; containing anti-chicken IgG antibodies (goat), HRP labelled; PBS, BSA, detergent, preservative ProClin 300 0.05%
	Well 7	**Negative Control:** yellow; containing PBS, BSA, detergent, preservative sodium azide 0.09% and ProClin 300 0.05%
	Well 8	**TMB Substrate**: clear; containing 3,3', 5,5'- Tetramethylbenzidin

Reaction wells 3 and 4 are coated with test specific antigen.
Code on barcode: **Neg Contrl** code on printout: **CntrNeg**

WASH 1x 20 ml **Wash Buffer**, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.

SYSTEM FLUID 1x 2.5 ml **System Fluid**, contains acid; 1000 x concentrate

MATERIALS REQUIRED

- ORG 300-00 Alegria® or ORG 320 Alegria® 2 instrument
- Measuring cylinder for 1000 ml and 2500 ml
- Distilled or deionized water

- Empty barcoded sample tubes

SPECIMEN COLLECTION, STORAGE AND HANDLING

not applicable, no sample used

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- All materials must be at room temperature (20-28°C) prior to use.

PREPARATION OF REAGENTS

WASH

Dilute the content of the Wash Buffer concentrate (50x) with distilled or deionized water to a final volume of 1000 ml prior to use. Transfer the diluted Wash Buffer into the instrument reagent container. If only one Alegria® run is to be performed on one day we recommend transferring only 500 ml diluted Wash Buffer.

SYSTEM FLUID

Dilute the content of the System Fluid concentrate (1000x) with distilled or deionized water to a final volume of 2500 ml prior to use. Transfer the diluted System Fluid into the instrument reagent container.

ALEGRIA TEST STRIPS

Take the required number of Alegria® Test Strips out of the clip bag and let them reach room temperature (20-28°C).

TEST PROCEDURE

The fully automated random access analyzers of the Alegria® family use Alegria® Test Strips with SMC® technology.

Alegria®:

(1) Remove the foil from the empty wells 1 to 4 of the Alegria® Test Strip.
Do not remove foil with printed barcode, covering wells 5 to 8.
Well 1: leave empty.

(2) Insert the strip into the SysTray.

(3) Place loaded SysTrays into the correct position in the Alegria® instrument and start run. All further steps will be done automatically. The test run is completed when the instrument starts printing the results.

All the above steps should be performed in immediate succession.

Alegria® 2:

(1) Insert Test Strips in Strip Trays as described in the Alegria® 2 User Manual.

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(2) Load an empty barcoded sample tube on the Alegria® 2 instrument.

(3) Assign the sample tube to the assay ORG 311 to allow the correct relation.

(4) Then start measurement as usual.

All the above steps should be performed within one day.

Detailed information on how to load the instruments with Test Strips and other reagents and how to operate the instruments can be found in the respective user manuals:

- Alegria® User Manual
- Alegria® 2 User Manual

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Do not freeze.
- Store Alegria® Test Strips sealed and desiccated in the clip bag provided.
- Shelf life of the unopened test kit is 15 months from day of production.
- Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and System Fluid are stable for at least 30 days when stored at 2-8°C. Once transferred to the reagent container we recommend consumption on the same day.

CALIBRATION

This assay system is calibrated in relative arbitrary units.

A specified target value with a defined target range must be met. The Certificate of Analysis indicates the batch specific target value and the acceptance range.

Test runs are only valid if the following criterion of validity is fulfilled. The negative control must be evaluated negative and present an activity within the validity range indicated on the quality control certificate. If this criterion is not met, the test run is not valid and must be repeated.

In case of an invalid test run, the expiry dates and storage conditions, incubation times and temperatures, and precise calibration of the instrument used should be verified. If no reason for an invalid test run could be identified, please contact the supplier or manufacturer of the product. For technical support, contact your local Sebia offices at www.sebia.com website by selecting your country.

CALCULATION OF RESULTS

By means of SMC® Technology (Sensotronic Memorized Calibration), all test data are transferred to the system through individual barcodes on the Alegria® Test Strip. Calculation and interpretation of results will be performed automatically.

PERFORMANCE CHARACTERISTICS

Alegria® Negative Control, ORG 311 has no diagnostic function. The test is used to demonstrate that the instrument is working within its specification.

Reproducibility

To demonstrate the functional performance of ORG 311 ORGENTEC has performed 24 measurements with one lot of ORG 311 on two Alegria® instruments and two Alegria® 2 instruments. The results of the study are summarized in the table below.

Table-1 Mean values, minimum and maximum results of 24 measurements of ORG 311 on two Alegria® and two Alegria® 2 instruments

Measurement results	Mean [U/ml]	Min[U/ml]	Max[U/ml]
Alegria® Instrument A	0.7	0.7	0.7
Alegria® Instrument B	0.79	0.7	1.2
Alegria® 2 Instrument C	0.72	0.7	0.8
Alegria® 2 Instrument D	0.75	0.7	0.8

ORG 311 lot specification: target 0.7 U/ml, range 0 - 4 U/ml

LIMITATIONS OF THE PROCEDURE

This assay is an accessory for the Alegria® instruments. The control is used for checking the correct function of the Alegria® analyzers and has no diagnostic function.

Change Control

Former version: *ORG 311_IFU_EN_QM113128_2023-04-25_8*

Reason for revision: Addition of content under chapter Calibration and symbols updated

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