



Product Service

Certificate

No. Q5 026709 0009 Rev. 00

Holder of Certificate: **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**

IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

Certification Mark:



Scope of Certificate: **Design and development, production and distribution of reagents and reagent products for in-vitro diagnostics as well as distribution of instruments for in-vitro diagnostics including accessories**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: 713146001

Valid from: 2019-03-29

Valid until: 2022-03-28

Date, 2019-03-28

Stefan Preiß



ELISA TESTS & INSTRUMENTS

Product Overview



- AIDS, Hepatitis
- ToRCH
- Other Infectious Diseases
- Fertility
- Steroids
- Tumour Markers
- Thyroids
- Autoimmune Diseases



Features & Benefits

- Enzyme Immunoassay
- Liquid reagents, calibrators and controls
- Quantitative, semi-quantitative or qualitative determination
- For testing in human serum or plasma
- Individual breakaway 8-well-strips
- High accuracy, sensitivity and specificity
- CE marked

Testing Principles

- Enzyme is bound to an immunological assay component
- Results are visible via an enzymatic colour reaction
- Colour intensity is determined by a photometric measurement
- Reaction is based on specific immunological binding reactions between antibodies and antigens
- Assay components are bound to a solid carrier material

AIDS, Hepatitis



	Method	Content	REF	CE
HAV IgM	Cut-off	1 x 96 wells	Z08372	
HBcAb	Cut-off	1 x 96 wells	Z00364	
HBc IgM capture	Cut-off	1 x 96 wells	Z01365	
HBeAb	Cut-off	1 x 96 wells	Z00363	
HBeAg	Cut-off	1 x 96 wells	Z00362	
HBsAb	Cut-off	1 x 96 wells	Z00361	
HBsAb	Quantitative	1 x 96 wells	Z06361	
HBsAg Sensitive	Cut-off	1 x 96 wells	Z12360	✓
		5 x 96 wells	Z12354	✓
HCV Ab Sensitive	Cut-off	1 x 96 wells	Z13370	✓
		5 x 96 wells	Z13500	✓
HEV IgM	Cut-off	1 x 96 wells	V11040	✓
HIV 1&2 Ab	Cut-off	1 x 96 wells	Z01375	✓
		5 x 96 wells	Z03502	✓
HIV 1&2 Ag/Ab	Cut-off	1 x 96 wells	Z04380	✓
		5 x 96 wells	Z13382	✓
HTLV 1&2 Ab one-step	Cut-off	1 x 96 wells	Z07023	

ToRCH

	Method	Content	REF	CE
CMV IgG	Quantitative	1 x 96 wells	V00004	✓
CMV IgM	Cut-off	1 x 96 wells	V00012	✓
HSV 1 IgG	Quantitative	1 x 96 wells	V00017	✓
HSV 1 IgM	Cut-off	1 x 96 wells	V00022	✓
HSV 1+2 IgG	Quantitative	1 x 96 wells	V00025	✓
HSV 1+2 IgM	Cut-off	1 x 96 wells	V00032	✓
HSV 2 IgG	Quantitative	1 x 96 wells	V00036	✓
HSV 2 IgM	Cut-off	1 x 96 wells	V00039	✓
Rubella IgG	Quantitative	1 x 96 wells	V00045	✓
Rubella IgM	Cut-off	1 x 96 wells	V05061	✓
Toxoplasma IgG	Quantitative	1 x 96 wells	V00064	✓
Toxoplasma IgM	Cut-off	1 x 96 wells	V05079	✓

Other Infectious Diseases



	Method	Content	REF	CE
Anti-Syphilis Ab	Cut-off	1 x 96 wells	Z04366	✓
Chlamydia trachomatis IgA	Cut-off	1 x 96 wells	L02140	
Chlamydia trachomatis IgG	Cut-off	1 x 96 wells	L02141	
Chlamydia trachomatis IgM	Cut-off	1 x 96 wells	L02142	
H. pylori Ag	Quantitative	1 x 96 wells	V11210	✓
H. pylori IgG	Quantitative	1 x 96 wells	L02211Q	✓

Fertility

	Method	Content	REF	CE
Anti-Mullerian Hormone (AMH)	Quantitative	1 x 96 wells	Z17301	✓
Beta-hCG	Quantitative	1 x 96 wells	Z03320	✓
FSH	Quantitative	1 x 96 wells	Z05302	✓
LH	Quantitative	1 x 96 wells	Z02301	✓
Prolactin	Quantitative	1 x 96 wells	Z05303	✓

Steroids

	Method	Content	REF	CE
17-alpha-OH-Progesterone	Quantitative	1 x 96 wells	K00192	✓
17-beta-Estradiol	Quantitative	1 x 96 wells	K00194	✓
Androstenedione	Quantitative	1 x 96 wells	K00197	✓
Cortisol	Quantitative	1 x 96 wells	K00201	✓
DHEA-S	Quantitative	1 x 96 wells	K00203	✓
Free Estriol	Quantitative	1 x 96 wells	K03210	✓
Free Testosterone	Quantitative	1 x 96 wells	K01220	✓
Progesterone	Quantitative	1 x 96 wells	K00225	✓
Testosterone	Quantitative	1 x 96 wells	K00234	✓
Total 25-OH Vitamin D	Quantitative	1 x 96 wells	Z13001	✓
Total Estriol	Quantitative	1 x 96 wells	K00206	✓

Tumour Markers

	Method	Content	REF	CE
AFP	Quantitative	1 x 96 wells	K01200	✓
CEA	Quantitative	1 x 96 wells	V11030	✓
Ferritin	Quantitative	1 x 96 wells	K01210	✓
PSA	Quantitative	1 x 96 wells	Z00338	✓

Thyroids



	Method	Content	REF	CE
Anti-TG IgG	Quantitative	1 x 96 wells	R97400	✓
Anti-TPO IgG	Quantitative	1 x 96 wells	R97401	✓
FT3	Quantitative	1 x 96 wells	Q00208	✓
FT4	Quantitative	1 x 96 wells	Q00209	✓
T3	Quantitative	1 x 96 wells	Z01208	✓
T4	Quantitative	1 x 96 wells	Z01232	✓
Thyroglobulin	Quantitative	1 x 96 wells	R97435	✓
TSH	Quantitative	1 x 96 wells	Z01237	✓

Autoimmune Diseases

	Method	Content	REF	CE
AMA-M2 IgG	Quantitative	1 x 96 wells	R97416	✓
ANA Combi 8	Quantitative	1 x 96 wells	R99445	✓
ANA Detect	Quantitative	1 x 96 wells	R05303	✓
ANA Screen 8	Quantitative	1 x 96 wells	R99419	✓
ANA-9-Line Immunoblot 16	Semi-quantitative	16 strips	R05317	✓
ANCA Combi	Quantitative	1 x 96 wells	R97434	✓
Anti-beta-2-Glycoprotein I Screen	Quantitative	1 x 96 wells	R01101	✓
Anti-beta-2-Glycoprotein I IgG/IgM	Quantitative	1 x 96 wells	R97421	✓
Anti-Cardiolipin IgA	Quantitative	1 x 96 wells	R97414	✓
Anti-Cardiolipin IgG/IgM	Quantitative	1 x 96 wells	R97413	✓
Anti-Cardiolipin Screen	Quantitative	1 x 96 wells	R97415	✓
Anti-CRA	Quantitative	1 x 96 wells	R07548	✓
Anti-DGP IgA	Quantitative	1 x 96 wells	R11461	✓
Anti-DGP IgG	Quantitative	1 x 96 wells	R11462	✓
Anti-dsDNA Screen	Quantitative	1 x 96 wells	R05313	✓
Anti-Gliadin IgA	Quantitative	1 x 96 wells	R99457	✓
Anti-Gliadin IgG	Quantitative	1 x 96 wells	R99459	✓
Anti-Insulin	Quantitative	1 x 96 wells	R97420	✓
Anti-Intrinsic Factor	Quantitative	1 x 96 wells	R05315	✓
Anti-Phospholipid Screen IgG/IgM	Quantitative	1 x 96 wells	R99449	✓
Anti-Transglutaminase IgA	Quantitative	1 x 96 wells	R01210	✓
Anti-Transglutaminase IgG	Quantitative	1 x 96 wells	R01211	✓
Anti-Transglutaminase Screen	Quantitative	1 x 96 wells	R10212	✓
ENA-6 Screen	Cut-off	1 x 96 wells	R97402	✓
Nucleo-9-Line Immunoblot 08/16	Semi-quantitative	8 / 16 strips	R05318 / R05319	✓
Rheumatoid Factor IgA	Quantitative	1 x 96 wells	R97425	✓
Rheumatoid Factor IgG	Quantitative	1 x 96 wells	R97423	✓



ELISA INSTRUMENTS



DIARReader ELX800G

8 channel absorbance microplate reader



- Stand alone device with touchscreen
- Optimised for IVD ELISA tests
- On board software for qualitative and quantitative applications
- LCD Touchscreen



Technical Features

Methods:	Absorbance mode (ABS), Cut-Off mode, Single standard mode, Curve mode, %ABS Multi-Point mode, Linear regression mode, Exponent regression mode, Logarithm regression mode, Power regression mode
Microplate types:	96-well microplates and strips
Shaking:	with variable intensity
Onboard software:	100 programmable protocols
Reading speed:	< 5 s (continuous mode)
Memory:	1000 patients, 10000 test data
Light source:	Halogen, 8V/20W
Wavelength selection:	Filters
Reading channels:	8
Filter wheel capacity:	8 positions
Filters supplied:	405, 450, 492, 630 nm; (substitute filters from 400 – 700 nm available)
Absorbance range:	0 to 3.5 OD
Resolution:	0.001 OD
Accuracy:	0 - 2.0 A: ± 1.0 % or ± 0.007 A
Precision:	0 - 2.0 A: ± 0.5 % or ± 0.005 A
Linearity:	± 2.0 % or ± 0.007 A
Power supply:	100 - 240 VAC, 50/60 Hz
Weight:	7.5 kg
Dimensions:	45.5 x 33 x 20 cm (L x W x H)

DIAWasher ELX50/8

For washing single strips or full plates



- Wash, prime, rinse and aspiration programs
- Up to 100 washing programs storable
- Shaking function
- Liquid level alarm



Technical Features

Microplate types:	96-well or other types of plates; Flat, round or V-shaped wells
Shaking:	linear, programmable/variable
Soak time:	0 – 24 hours
Manifold types:	8-channel (standard), 12-channel (optional)
Volume range:	10 – 3000 µL/well; selectable in 1 µL increments
Buffer selection:	Automatic switching for up to 3 wash buffers (optional)
Wash cycles:	max. 99
Dispense precision:	≤ 3 % CV
Residual volume:	≤ 1 µL/well
Supply bottle volume:	2 L
Operating temperature:	10°C – 30°C
Relative humidity:	≤ 70 %
Power supply:	100 – 240 VAC, 50/60 Hz
Weight:	13 kg
Dimensions:	45 x 39 x 19 cm (L x W x H)

DIALISA 2MP

Fully automated 2-plate ELISA system



- Smallest footprint on the market for a fully automated 8 pin wash head ELISA system
- Learned error recovery: Supporting walk-away automation with trained error recovery actions
- LIS and LIMS compatible
- QC monitoring
- Clot detection
- Sample identification with an optional on-board barcode reader
- Compatible with DIALAB® ELISA assays
- CE marked



DIALISA 4MP

Fully automated 4-plate ELISA system



- Modular system: Quick and easy approach for upgrades, repairs and reconfiguration of the whole system
- Rapid pipetting speed minimises assay drift, ensuring consistent results across the plate and plate-to-plate
- Learned error recovery: Supporting walk-away automation with trained error recovery actions
- Automatic cover lock protecting reagents and samples from light and interferences
- LIS and LIMS compatible
- QC monitoring
- Sample identification with an optional on-board barcode reader
- Disposable tips eliminating carryovers
- Compatible with DIALAB® ELISA assays
- CE marked



DIALISA 2MP & 4MP

Technical Specifications



DIALISA 2MP

DIALISA 4MP

GENERAL		
Sample barcode reader	Optional	Optional
Liquid tanks	✓	✓
LIS and LIMS	Optional	Optional
QC monitoring	✓	✓
Disposable tips	✓	✓
Learned error recovery	✓	✓
Disposable tips	✓	✓
Automatic cover lock	—	✓
Clot detection	✓	✓
No. of plates	2	4
No. of sample tubes	100	96
No. of reagents	18	24
No. of standard/control bottles	24	33
SAMPLE PIPETTING		
Sample tip size	300 µL	300 µL
Sample pipetting volume	10 - 250 µL	5 - 250 µL single shot 25 - 100µL multi-shot
Precision	≤ 3% CV (10 - 250 µL)	≤ 3% CV (10 - 250 µL)
Dilution range	1 to 5000	1 part in 190 one-stage dilution 1 part in 36100 two-stage dilution
Number of sample-tips on board	2 racks of 108	4 racks of 108
Sample tube dimensions	10 - 16 mm Ø 40 - 100 mm depth	12 - 16 mm Ø 55 - 100 mm depth
REAGENT PIPETTING		
Reagent tip size	1300 µL	1300 µL
Number of reagent tips on board	20	41
Reagent pipetting volume	20 - 1000 µL	35 - 1000 µL
Reagent pipetting precision	≤ 3% CV (10 µL - 1000 µL)	≤ 3% CV (25 µL - 1000 µL)
WASHER SPECIFICATIONS		
Manifold configuration	8 - way	8 - way
Programmable volumes	50 - 1000 µL	50 - 1000 µL
Wash buffer containers	2 wash bottles each 2 L	4 wash bottles each 2 L
Waste container	1.5 L	8 L
Waste/water level sensor	✓	✓
Residual wash volume	< 3 µL per well	< 3 µL per well
INCUBATOR SPECIFICATIONS		
No. of incubators	1	4
Temperature range	RT + 4°C up to 40°	RT + 7°C up to 50°
Temperature accuracy	± 1°C	± 1°C
Shaking	14 - 20 Hz periodic or continuous	15 Hz periodic or continuous

DIALISA 2MP & 4MP

Technical Specifications



DIALISA 2MP

DIALISA 4MP

READER SPECIFICATIONS		
Photometric range	0.000 – 3.000 OD	0.000 – 3.000 OD
Spectral range	405 – 690 nm	405 – 690 nm
Filters installed	405, 450, 490, 620 nm	405, 450, 490, 620 nm
Precision		± 0.01 OD at 0.000 – 0.500 OD
	< 1% CV (<2.000 OD)	< 1% CV (0.051 – 2.000 OD)
	< 2% CV (2.000 – 3.000 OD)	< 1.5% CV (2.001 – 3.000 OD)
Accuracy	± 0.005 OD or 2.5%	± 0.01 OD or 2.5% (0.000 – 3.000 OD)
Reading time	< 30 seconds, single wavelength	< 10 seconds, single wavelength
PHYSICAL CHARACTERISTICS		
Power	100 – 240 VAC, 50/60 Hz	100 – 240 VAC, 50/60 Hz
Power consumption	300 VA, UPS recommended	800 VA, UPS recommended
Weight	Net/Gross: 45 kg/80 kg	Net/Gross: 136 kg/244 kg
Dimensions (W x D x H)	45 x 68 x 66 cm	106 x 91 x 80 cm
Shipping box (W x D x H)	71 x 102 x 100 cm	123 x 110 x 109 cm
STARTERKIT		
	Sample tips (4 x 108 tips)	Sample tips (4 x 108 tips)
	Reagents tips (1x108 tips)	Reagents tips (1x108 tips)
	Deep well strips 8-well (pack of 12)	Deep well strips 8-well (pack of 24)
	Reagent tubes, 25 mL (pack of 10)	1 mL deep well microplate (2 pieces)
	Reagent tubes, 15 mL (pack of 10)	Reagent tubes, 15 mL (pack of 33)
	Control vials (pack of 33)	Control vials (pack of 33)

ORDER INFORMATION

Instruments



Product	Description	Data Processing	REF
DIAREADER ELX800	Microplate reader		ELX800
DIAWASHER II ELX508	Microplate washer		ELX508
DIALISA 4MP	without barcode reader	PC not included	X13001
DIALISA 4MP	with barcode reader	PC not included	X13002
DIALISA 2MP	without barcode reader	PC not included	X13005
DIALISA 2MP	with barcode reader	PC not included	X13006

Consumables & Accessories

Product	Device	Content	REF
Reagent tips (white)	for 2MP and 4MP	4 x 108 pcs, 1300 µL	65920
Sample tips (blue)	for 2MP and 4MP	4 x 108 pcs, 300 µL	65910
Reagent bottles 15 mL	for 2MP	10 pieces	62930
Reagent bottles 25 mL	for 2MP and 4MP	24 pieces	65950
Standard/Control bottles	for 2MP and 4MP	33 pieces	65940
1 mL Deep well microplates	for 4MP	1 piece	65930
Deep well dilution strips	for 2MP and 4MP	PC not 250 x 8-well	65910
Sample rack for short tubes (40-75 mm)	for 4MP	1 piece	13001940
Sample rack for long tubes (70-100 mm)	for 4MP	1 piece	13001950
Sample rack	for 4MP	1 piece	13500501
LIMS Interface software	for 2MP and 4MP	1 piece	65088-201
Annual Maintenance Kit	for 2MP	1 piece	13002590
Annual Maintenance Kit	for 4MP	1 piece	13002600
Aspirate Pump Maintenance Kit	for 4MP	Seals and valves	60000001
Maintenance Kit, Washer Aspirator	for 4MP	Aspirate tubing kit	13002080
Maintenance Kit, Washer Dispenser	for 4MP	Dispense tubing kit	13001930
Tubing Replacement Kit	for 2MP	1 piece	13002460
Halogen lamp 6V 20W	for 2MP and 4MP	1 piece	50200410





Austria (Head Office)

DIALAB® GmbH
IZ NOE-Sued
Hondastrasse, Objekt M55
A-2351 Wiener Neudorf
Phone: +43-2236-66 09 10-0
Fax: +43-2236-66 09 10-30
E-mail: office@dialab.at
www.dialab.at

China

DIALAB® ZGJ.
Building A, Room 211
No. 36, Huada Road, Zhangjiagang, Suzhou
Jiangsu Province, China
Phone: +86-0512-58711903
E-mail: office@dialab.at
www.dialab.at

Czech Republic

DIALAB® spol. s r.o.
Náměstí Osvoboditelů 1
CZ-153 00 Praha 5 - Radotín
Phone/Fax: +420-2-579 10 255
E-mail: office@dialab.cz
www.dialab.cz

Hungary

DIALAB® Kft.
Pasaréti út 31
H-1026 Budapest
Phone: +36-1-212 25 05
Fax: +36-1-335 73 70
E-mail: info@dialab.hu
www.dialab.hu

Serbia

DIALAB® d.o.o.
Carigradska 1
RS-11 008 Beograd 12
Phone: +381-11-32 38 745
Phone/Fax: +381-11-32 42 777
E-mail: dialab@sbb.rs

Slovak Republic

ALPHA DIALAB® s.r.o.
Sekurisova 16
SK-84102 Bratislava
Phone: +421-917 98 3711
E-mail: alpha@dialab.sk



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Manufacturer:

**DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.**
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

**Product Category(ies): Products according to Directive 98/79/EC
Annex II**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 026709 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:V1_026709_0004_Rev_02)

Report no.: 713205839

Valid from: 2021-04-23

Valid until: 2024-05-26

Date, 2021-04-22

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Model(s):

The products detailed below are covered under the scope of this certificate

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,
AUSTRIA

Products according to Annex II List A Devices:

Product	REF
Anti-A, monoclonal	B05405
Anti-B, monoclonal	B05406
Anti-AB, monoclonal	B05407
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-E, monoclonal	B06412
Anti-c, monoclonal	B06413
Anti-e, monoclonal	B06414
Anti-D Negative Control	B09936
DIAQUICK HIV Plus	H18100
DIAQUICK HIV Plus WB	H18101
DIAQUICK HCV Plus	H18200
DIAQUICK HCV Plus WB	H18201



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 026709 0004 Rev. 02

Products according to Annex II List B Devices:

Product	REF
Anti-HG, polyspecific/monoclonal	B05181
Rubella IgG	V00045
Rubella IgM	V05061
DIAQUICK Rubella IgM Cassette	J15020
Toxoplasma IgG	V00064
Toxoplasma IgM	V05079
DIAQUICK Toxoplasma IgM Cassette	J15011
CMV IgG	V00004
CMV IgM	V00012
DIAQUICK CMV IgM Cassette	J15030
DIAQUICK Chlamydia Cassette	Z98226CE
PSA	Z00338
DIAQUICK PSA Cassette	Z08010
DiaCheck® Pro Blood Glucose Monitoring System	P13110
DiaCheck® Pro Blood Glucose Test Strips	P13125
DiaCheck® Pro Glucose Control Solution	P13134