



IvD Controls

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Controls for infection serology

ToRCH M Plus	6
ToRCH G Plus	7
MaPaMuVa M	8

Controls for blood bank marker

Optitrol A	9
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Controls for immunoassays

Hormone & Drug	10
Tumor Marker	11

Controls for cardiac marker

Cardiac Marker	12
----------------	----

Immunology and proteincontrols

Plasma Protein	13
----------------	----

Controls for molecular diagnostics

NAT/PCR	14
---------	----

Controls for allergy tests

Respiratory Allergenes	15
Food Allergenes	

About DiaMex

The center of our efforts is the medical laboratory, where we supply high quality in-vitro-diagnostic products. We offer a range of manufacturer independent controls which are always designed to the customer's requests forming our **ready-to-use** concept. DiaMex controls fit perfectly into the day-to-day routine of the medical laboratory testing. Our focus is based on the highest standard of quality for a reasonable price. The permanent development of our products and the longterm cooperation with our partners is the drive of our growth. Based on the experience of our associated donor centers in Heidelberg and Munich the development to produce diagnostics for the medical laboratory was a logical step. Regulatory requirements as well as constant improvements determine our efforts to develop quality products. DiaMex is a DIN EN ISO 13485 certified company.

Controls

The controls of the **OPTITROL** series are liquid or lyophilized single- and multi-analyte-controls and can be used to test the precision of laboratory systems and help to identify random or systematic errors. Within the technical borderlines they are produced with human raw material and are therefore very similar to a patient sample.



The ready-to-use concept*

Our **ready-to-use** concept means, that the controls may remain directly in the carrier or roboter of the test system. A manual refilling of the controls from the conventional dropper bottles into the vials of the carrier is no longer necessary. Relevant dead volumes at the end of the measurement therefore can be prevented.

Advantages of the ready-to-use concept

- ▶ vials developed according to the individual platform (e. g. for ARCHITECT®, PRISM®, LIAISON®, Cobas®- or IMMULITE®-Systems and others)
- ▶ multimarker controls instead of single controls
- ▶ barcoded controls
- ▶ **easy handling:**
 - ready to use solutions
 - no reconstitution of lyophilizates
 - no manual refilling
 - no source of fault
 - no contamination
 - no dead volume
- ▶▶ **cost-effective**
- ▶ with target values
- ▶ lotreservations are possible
- ▶▶ **efficient and time saving**



* Dropper bottles are also available for manual test procedures for all common systems.

Optitrol ToRCH M Plus

Optitrol ToRCH M Plus is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining IgM/IgG antibodies to *Toxoplasma gondii*, Rubella virus, Cytomegalo virus (CMV), Epstein-Barr Virus (EBV-VCA) and only IgG-antibodies to Herpes simplex Virus 1/2 (HSV) and Epstein-Barr Virus (EBV-EBNA) in human plasma and human serum.

The **ready-to-use** vials fit into the carrier of LIAISON®- and ARCHITECT® i-systems.

Fillings in dropper bottles are optimized for microplates.

- ▶ produced with human plasma
- ▶ no additional monoclonal antibodies
- ▶ liquid multi control with coloured screw caps (green = negative control, red = positive control)
- ▶ positive control: contains IgM-/IgG-antibodies to *Toxoplasma gondii*, Rubella virus, CMV, HSV 1/2, EBV-VCA and EBV-EBNA
- ▶ negative control: contains no antibodies to *Toxoplasma gondii*, Rubella virus, CMV, HSV, 1/2 EBV-VCA and EBV-EBNA
- ▶ positive control: contains target values for LIAISON® and ARCHITECT®

General information

Storage and Stability

Closed: 18 months at 2 to 8°C

After opening: 90 days at 2 to 8°C

Analytes included

Toxo IgM/IgG	HSV 2 IgG
Rubella IgM/IgG	EBV-VCA IgM/IgG
CMV IgM/IgG	EBV-EBNA IgG
HSV 1 IgG	



6



Order information Optitrol ToRCH M Plus, vials, ready-to-use

Cat. No.	Content		Kit
IN0107	Negative control	2 x 2.5 ml	2 x 2.5 ml
IN0108	Positive control	2 x 2.5 ml	2 x 2.5 ml
IN0109	Negative control Positive control	2 x 2.5 ml 2 x 2.5 ml	4 x 2.5 ml
IN0110	Negative control Positive control	4 x 2.5 ml 4 x 2.5 ml	8 x 2.5 ml

Order information Optitrol ToRCH M Plus, dropper bottles

Cat. No.	Content		Kit
IN0155	Negative control	1 x 5 ml	1 x 5 ml
IN0156	Positive control	1 x 5 ml	1 x 5 ml
IN0157	Negative control Positive control	1 x 5 ml 1 x 5 ml	2 x 5 ml
IN0158	Negative control Positive control	2 x 5 ml 2 x 5 ml	4 x 5 ml

Further information see package insert

Optitrol ToRCH G Plus

Optitrol ToRCH G Plus is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining IgG antibodies to *Toxoplasma gondii*, Rubella virus, Cytomegalo virus (CMV), Herpes simplex Virus 1/2 (HSV), Epstein-Barr Virus (EBV), Measles virus, Mumps virus, Parvovirus B19, Varizella-Zoster-Virus (VZV) and *Helicobacter pylori* in human plasma and human serum.

The **ready-to-use** vials fit into the carrier of LIAISON®- and ARCHITECT® i-systems.

Fillings in dropper bottles are optimized for microplates.

- ▶ produced with human plasma
- ▶ no additional monoclonal antibodies
- ▶ liquid multi control with coloured screw caps
- ▶ positive control: contains IgG-antibodies to *Toxoplasma gondii*, Rubella virus, CMV, HSV 1/2, EBV, Measles virus, Mumps virus, Parvovirus B19, VZV and *Helicobacter pylori*
- ▶ negative control: contains no antibodies to *Toxoplasma gondii*, Rubella virus, CMV, HSV 1/2, EBV, Measles virus, Mumps virus, Parvovirus B19 and *Helicobacter pylori*
- ▶ positive control: contains target values for LIAISON® and ARCHITECT®

General information

Storage and Stability

Closed: 24 months at 2 to 8°C

After opening: 90 days at 2 to 8°C

Analytes included

Toxo IgG	EBV-EBNA IgG
Rubella IgG	Measles IgG
CMV IgG	Mumps IgG
HSV 1/2 IgG	Parvo B19 IgG
<i>Helicobacter pylori</i> IgG	VZV IgG
EBV-VCA IgG	



Order information Optitrol ToRCH G Plus, vials, ready-to-use

Cat. No.	Content		Kit
IN0101	Negative control	2 x 2.5 ml	2 x 2.5 ml
IN0102	Positive control	2 x 2.5 ml	2 x 2.5 ml
IN0103	Negative control Positive control	2 x 2.5 ml 2 x 2.5 ml	4 x 2.5 ml
IN0104	Negative control Positive control	4 x 2.5 ml 4 x 2.5 ml	8 x 2.5 ml



Order information Optitrol ToRCH G Plus, dropper bottles

Cat. No.	Content		Kit
IN0151	Negative control	1 x 5 ml	1 x 5 ml
IN0152	Positive control	1 x 5 ml	1 x 5 ml
IN0153	Negative control Positive control	1 x 5 ml 1 x 5 ml	2 x 5 ml
IN0154	Negative control Positive control	2 x 5 ml 2 x 5 ml	4 x 5 ml



Further information see package insert

Optitrol MaPaMuVa M

Optitrol MaPaMuVa M is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining IgM/IgG antibodies to Measles virus, Parvovirus B19, Mumps virus, Varizella-Zoster-Virus (VZV) in human plasma and human serum.

The **ready-to-use** vials fit into the carrier of LIAISON® systems. Fillings in dropper bottles are optimized for microplates.

- ▶ produced with human plasma
- ▶ no additional monoclonal antibodies
- ▶ liquid multi control with coloured screw caps (green = negative control, red = positive control)
- ▶ positive control: contains IgM-/IgG-antibodies to Measles virus, Parvovirus B19, Mumps virus and VZV
- ▶ negative control: contains no antibodies to Measles virus, Parvovirus B19 and Mumps virus

General information

Storage and Stability

Closed: 18 months at 2 to 8°C
After opening: 90 days at 2 to 8°C

Analytes included

Measles IgM/IgG
Parvo B19 IgM/IgG

Mumps IgM/IgG
VZV IgM/IgG



8



Order information Optitrol MaPaMuVa M, vials, ready-to-use

Cat. No.	Content		Kit
IN0301	Negative control	2 x 2.5 ml	2 x 2.5 ml
IN0302	Positive control	2 x 2.5 ml	2 x 2.5 ml
IN0303	Negative control Positive control	2 x 2.5 ml 2 x 2.5 ml	4 x 2.5 ml

Order information Optitrol MaPaMuVa M, dropper bottles

Cat. No.	Content		Kit
IN0351	Negative control	1 x 5 ml	1 x 5 ml
IN0352	Positive control	1 x 5 ml	1 x 5 ml
IN0353	Negative control Positive control	1 x 5 ml 1 x 5 ml	2 x 5 ml

Further information see package insert

Optitrol A

Optitrol A is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining antibodies in human plasma and human serum to Human Immunodeficiency-Virus Type 1, 2 and group O, Human T-lymphotropic Virus I, II, Hepatitis C Virus, Hepatitis B core antigen, Cytomegalovirus and Treponema pallidum, as well as Hepatitis B surface antigen with target values for different analyzers. The **ready-to-use** vials fit into the carrier of PRISM®- and ARCHITECT® i-systems. Fillings in dropper bottles are optimized for microplates.

- ▶ produced with human plasma
- ▶ no additional monoclonal antibodies
- ▶ liquid multi control with coloured screw caps
- ▶ positive control: contains IgG-antibodies to CMV, HBc, HCV, HIV 1/2, HTLV I/II, Treponema pallidum and additional HBsAg
- ▶ negative control: contains no antibodies to CMV, HBc, HCV, HIV 1/2, HTLV I/II, Treponema pallidum and no HBsAg
- ▶ both positive- and negative controls are PCR-negative to HBV, HCV and HIV

General information

Storage and Stability

Closed: 18 months at 2 to 8°C


After opening: 60 days at 2 to 8°C

Order information Optitrol A, vials ARCHITECT®, ready-to-use

Cat. No.	Content	Kit
IN0201	Negative control 2 x 2.5 ml	2 x 2.5 ml
IN0202	Positive control 2 x 2.5 ml	2 x 2.5 ml
IN0203	Negative control 2 x 2.5 ml Positive control 2 x 2.5 ml	4 x 2.5 ml
IN0204	Negative control 4 x 2.5 ml Positive control 4 x 2.5 ml	8 x 2.5 ml

Analytes included ARCHITECT

Anti-HIV 1	Anti-HTLV II
Anti-HIV 1 group O	Anti-Treponema pallidum IgG
Anti-HIV 2	Anti-HBc IgG
Anti-HCV IgG	Anti-CMV IgG
HBsAg	
Anti-HTLV I	




Order information Optitrol A, vials Prism®, ready-to-use

Cat. No.	Content	Kit
IN0205	Negative control 6 x 5 ml	6 x 5 ml
IN0206	Positive control 6 x 5 ml	6 x 5 ml
IN0207	Negative control 3 x 5 ml Positive control 3 x 5 ml	6 x 5 ml

Analytes included Prism

Anti-HIV 1	Anti-HTLV II
Anti-HIV 1 group O	Anti-HTLV I
Anti-HIV 2	Anti-HCV IgG
HBsAg	Anti-HBc IgG




Order information Optitrol A, dropper bottles

Cat. No.	Content	Kit
IN0251	Negative control 1 x 5 ml	1 x 5 ml
IN0252	Positive control 1 x 5 ml	1 x 5 ml
IN0253	Negative control 1 x 5 ml Positive control 1 x 5 ml	2 x 5 ml
IN0254	Negative control 2 x 5 ml Positive control 2 x 5 ml	4 x 5 ml

Analytes included

Anti-HIV 1	Anti-HTLV II
Anti-HIV 1 group O	Anti-Treponema pallidum IgG
Anti-HIV 2	Anti-HBc IgG
Anti-HCV IgG	Anti-CMV IgG
HBsAg	
Anti-HTLV I	



Further information see package insert

Optitrol Hormone & Drug

Optitrol Hormone & Drug is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations.

The most important analytes in the area hormone and drug level are covered with this control.

The **ready-to-use** vials fit into the carrier of LIAISON®, Cobas®- and ARCHITECT® i-Systems.

- ▶ on the base of human serum as matrix
- ▶ great range of analytes
- ▶ available in three clinical relevant concentrations
- ▶ liquid multi control with coloured screw caps (green = level 1, yellow = level 2, red = level 3)
- ▶ positive control: contains target values for all common analyzers

General information

Storage and Stability

Closed: 5 years at -20°C
6 months at 2 to 6°C
After opening: 30 days at 2 to 6°C

Analytes included

AFP	Aldosterone	Amikacin	Carbamacepine	Chinidin	Chloramphenicol
CK-MB (mass)	Cortisol	DHEA-Sulfate	Digoxin	Disopyramide	Estradiol
Estriol	Ethosuximide	Ferritin	free T 3	free T 4	FSH
Gentamicin	HCG	hGH	Hydroxyprogesterone	IgE	Insulin
LH	Lidocaine	NAPA	Paracetamol	Phenobarbital	Phenytoin
Primidone	Procainamide	Progesterone	Prolactin	Salicylate	β-HCG
Testosterone	Theophylline	Tobramycin	total T 3	total T 4	TSH
Valproic Acid	Vancomycin	Vitamin B 12			



Order information Optitrol Hormone & Drug, vials, ready-to-use

Cat. No.	Content	Kit
HD0101	Control Level 1 6 x 2.5 ml	6 x 2.5 ml
HD0102	Control Level 2 6 x 2.5 ml	6 x 2.5 ml
HD0103	Control Level 3 6 x 2.5 ml	6 x 2.5 ml
HD0104	Control Level 1 2 x 2.5 ml Control Level 2 2 x 2.5 ml Control Level 3 2 x 2.5 ml	6 x 2.5 ml

Further information see package insert

Optitrol Tumor Marker

Optitrol Tumor Marker is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations.

The **ready-to-use** vials fit into the carrier of IMMULITE®- and ARCHITECT® i-systems.

Fillings in dropper bottles are optimized for microplates.

- ▶ on the base of human serum as matrix
- ▶ available in two clinical relevant concentrations
- ▶ liquid multi control with coloured screw caps (green = level 1, yellow = level 2)
- ▶ positive control: contains target values for all common analyzers

General information

Storage and Stability

Closed: 5 years at -20°C
6 months at 2 to 6°C
After opening: 60 days at 2 to 8°C

Analytes included

AFP	CA 125	CA 15-3	CA 19-9
CA 50	CA 549	CA 72-4	CEA
Cyfra 21-1	Ferritin	HCG	MCA
PSA	SCC	TPA	TPS

Order information Optitrol Tumor Marker, vials, ready-to-use

Cat. No.	Content	Kit
TM0101	Control Level 1 2 x 2 ml	2 x 2 ml
TM0102	Control Level 2 2 x 2 ml	2 x 2 ml
TM0103	Control Level 1 2 x 2 ml Control Level 2 2 x 2 ml	4 x 2 ml



Order information Optitrol Tumor Marker, dropper bottles

Cat. No.	Content	Kit
TM0151	Control Level 1 4 x 2 ml	4 x 2 ml
TM0152	Control Level 1 4 x 2 ml	4 x 2 ml
TM0153	Control Level 1 2 x 2 ml Control Level 2 2 x 2 ml	4 x 2 ml



Further information see package insert

Optitrol Cardiac Marker

Optitrol Cardiac Marker is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations.

The **ready-to-use** vials fit into the carrier of the ARCHITECT® i-Systems.

Fillings in dropper bottles are optimized for microplates.

- ▶ on the base of human serum as matrix
- ▶ available in two clinical relevant concentrations
- ▶ liquid multi control with coloured screw caps (green = level 1, yellow = level 2)
- ▶ positive control: contains target values for all common analyzers

General information

Storage and Stability

Closed: 5 years at -20°C
30 days at 2 to 6°C*

After opening: 30 days at 2 to 6°C*

*TnT und NT-proBNP 14 days at 2 to 6°C
Tn I 4 days at 2 to 6°C

Analytes included

CK-MB (mass)	NT-proBNP
Homocysteine	Troponin I
Myoglobin	Troponin T

12



Order information Optitrol Cardiac Marker, vials, ready-to-use

Cat. No.	Content		Kit
CM0101	Control Level 1	4 x 2 ml	4 x 2 ml
CM0102	Control Level 2	4 x 2 ml	4 x 2 ml
CM0103	Control Level 1 Control Level 2	2 x 2 ml 2 x 2 ml	4 x 2 ml

Order information Optitrol Cardiac Marker, dropper bottles

Cat. No.	Content		Kit
CM0151	Control Level 1	4 x 2 ml	4 x 2 ml
CM0152	Control Level 2	4 x 2 ml	4 x 2 ml
CM0153	Control Level 1 Control Level 2	2 x 2 ml 2 x 2 ml	4 x 2 ml



Further information see package insert

Optitrol Plasma Protein

Optitrol Plasma Protein is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations.

The **ready-to-use** vials fit into the carrier of BN ProSpec® and ARCHITECT® i-Systems.

Fillings in dropper bottles are optimized for microplates.

- ▶ on the base of human serum as matrix
- ▶ available in three clinical relevant concentrations
- ▶ liquid multi control with coloured screw caps (green = level 1, yellow = level 2, red = level 3)
- ▶ positive control: contains target values for all common analyzers

General information

Storage and Stability

Closed: 5 years at -20°C
6 months at 2 to 6°C*

After opening: 60 days at 2 to 6°C*

*Apo A1 1 month, Coeruloplasmin 3 months at 2 to 6°C

Analytes included

Albumin	Antistreptolysin O	Antithrombin III	Apo A1	Apo B
C 3	C 4	Coeruloplasmin	CRP	Ferritin
Haptoglobin	Hemopexin	IgA	IgE	IgG
IgM	Prealbumin	RBP	Rheumatoid Factor	Transferrin
Transferrin-Receptor	α-1-Antitrypsin	α-1-Glycoprotein	α-2-Macroglobulin	β-2-Microglobulin
κ-Light Chains	λ-Light Chains			

Order information Optitrol Plasma Protein, vials, ready-to-use

Cat. No.	Content	Kit
PP0101	Control Level 1 6 x 2 ml	6 x 2 ml
PP0102	Control Level 2 6 x 2 ml	6 x 2 ml
PP0103	Control Level 3 6 x 2 ml	6 x 2 ml
PP0104	Control Level 1 2 x 2 ml Control Level 2 2 x 2 ml Control Level 3 2 x 2 ml	6 x 2 ml



Order information Optitrol Plasma Protein, dropper bottles

Cat. No.	Content	Kit
PP0151	Control Level 1 4 x 2 ml	4 x 2 ml
PP0152	Control Level 2 4 x 2 ml	4 x 2 ml
PP0153	Control Level 3 4 x 2 ml	4 x 2 ml
PP0154	Control Level 1 1 x 2 ml Control Level 2 1 x 2 ml Control Level 3 1 x 2 ml	3 x 2 ml



Further information see package insert

Optitrol NAT/PCR Controls

Optitrol NAT/PCR Controls can be used as run-to-run controls to verify the precision of laboratory systems and to detect analytical deviations.

The range of **Optitrol NAT/PCR Controls** offers single controls for HIV 1, Hepatitis B (HBV), Hepatitis C (HCV). When using NAT based in-vitro-diagnostic tests against HIV 1, HBV and HCV there will always be a positive result. Target values were detected for the following test systems with n=10: mSample Preparation System / m2000sp-System (Abbott), QIAamp DSP Virus Kit / Rotor-Gene Q 5-plex (Qiagen), COBAS® AmpliPrep / COBAS® TaqMan (Roche), High Pure System Viral Nucleic Acid Kit / COBAS® TaqMan (Roche). The controls can also be used for different analyzers and procedures, like e.g. TMA or manual preparation.

Optitrol NAT/PCR Controls are directly produced with positive human plasma. Therefore they contain native viruses and no artificial samples of sequences of nucleic acids. This guarantees a high comparability to native patient samples.

Optitrol NAT/PCR Controls are set up for a concentration of viruses at ≈ 5000 IU/ml (COBAS® AmpliPrep / COBAS® TaqMan).

- ▶ produced with human plasma
- ▶ liquid single control
- ▶ contains native viruses
- ▶ with coloured screw caps
(green = HBV, yellow = HIV, blue = HCV)

14

General information

Storage and Stability

Closed: 1 year at -20°C
After opening: 4 hours at 2 to 8°C

Analytes included

HIV HBV HCV



Order information Optitrol NAT/PCR, vials

Cat. No.	Content		Kit
NT0101	NAT HIV	8 x 1.2 ml	8 x 1.2 ml
NT0102	NAT HIV	30 x 1.2 ml	30 x 1.2 ml
NT0103	NAT HBV	8 x 1.2 ml	8 x 1.2 ml
NT0104	NAT HBV	30 x 1.2 ml	30 x 1.2 ml
NT0105	NAT HCV	8 x 1.2 ml	8 x 1.2 ml
NT0106	NAT HCV	30 x 1.2 ml	30 x 1.2 ml

Further information see package insert

Optitrol Allergy Controls

Optitrol Food Control is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining IgE-antibodies to various foods.

- ▶ produced with human plasma
- ▶ liquid multi control
- ▶ no additional monoclonal antibodies
- ▶ positive control: contains IgE-antibodies to foods like described below
- ▶ with target values

Optitrol Respiratory Control is a multi-control which can be used to verify the precision of laboratory systems and to detect analytical deviations while determining IgE-antibodies to different aeroallergenes.

- ▶ produced with human plasma
- ▶ liquid multi control
- ▶ no additional monoclonal antibodies
- ▶ positive control: contains IgE-antibodies to aeroallergenes like described below
- ▶ with target values

General information

Storage and Stability

Closed: 18 months at 2 to 8 °C

After opening: 90 days at 2 to 8 °C

Analytes included food:

f 13	peanut	f 85	celery	f 25	tomato
f 14	soybean	f 49	apple, green	f 218	pepper, spice
f 17	hazelnut	f 33	orange	f 48	onion
f 256	walnut	f 84	kiwi	f 91	mango
f 12	pea	f 4	wheat flour	f 92	banana
f 31	carrot	f 5	rye flour		

Analytes included respiratory:

d 1	dermatophagoides pteronyssinus	g 12	rye	i 1	bee venom
d 2	dermatophagoides farinae	w 1	ambrosi, artemisiifolia	i 3	wasp venom
d 70	acarus siro	w 2	ambrosi, perennial ragweed	k 82	latex (hevea brasil.)
i 6	cockroach	w 6	mugwort	e 1	cat epithelia
t 2	alder	w 7	maguerite	e 3	horse epithelia
t 3	birch	w 9	buckhorn plantain	e 5	dog epithelia
t 4	hazel	w 20	nettle		
t 7	oak	w 206	camomile pollen		

