r-biopharm®

Product catalogue 2022

Clinical Diagnostics

clinical.r-biopharm.com

Product catalogue 2022

Clinical Diagnostics

Content

R-Biopharm test systems

at a glance

RIDASCREEN®

- ELISA for antigen and antibody detection
- Ready-to-use reagents
- Easy test procedure
- Standardized incubation time
- Possibility of processing on automated ELISA systems

RIDA®QUICK

- Reliable rapid test for antigen detection
- High sensitivity and specificity
- Agents distinguished by color

RIDA®GENE

- Real-time PCR
- Contains all necessary components
- Reliable results due to included extraction control

SeraSpot®

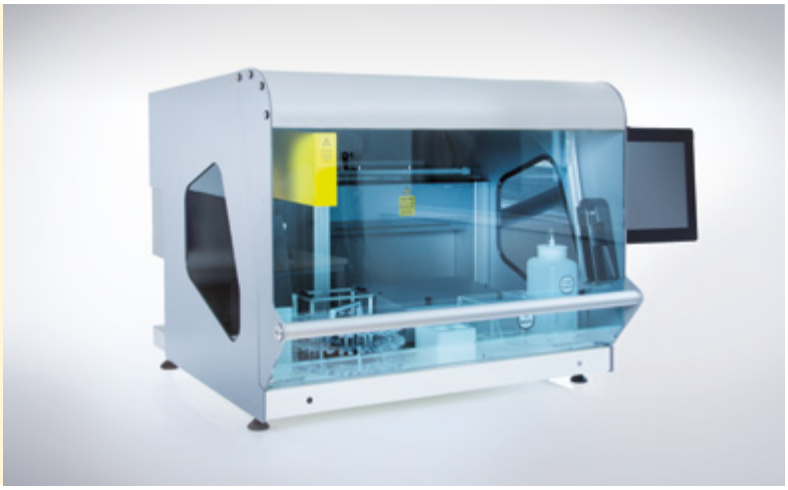
- Microspot array for antibody detection in autoimmune or infectious diseases
- For high throupghput on common ELISA processors
- Ready-to-use reagents and universal test protocol
- Built-in controls and reference curve
- Cost and time efficient multiplex diagnostics

RIDA qLine®

- Quantitative immunoblot for antibody detection (IgE) in serum
- Various allergen panels available

Systems

- Flexible range of automated solutions
- Automated solutions for immunological and molecular tests
- ELISA automation solutions from small to high sample throughput
- Assistance in installation and routine by our application specialists



Allergology

The spread of allergies in developed countries is steadily increasing.

Nowadays an allergy is called a specific hypersensitivity of the immune system against substances that are actually harmless. Type V has now been added to the four allergy types (types I - IV) originally classified by Coombs and Gell.

Type I allergy
The most frequent allergic reactions are type I reactions, which take place primarily on epithelial surfaces (skin, lungs, gastrointestinal tract) and are characterized by the formation of specific immunoglobulin E against the allergens. These type I reaction is the cause of allergic rhinitis, asthma, atopic dermatitis, etc.. The occurrence of this allergy type involves TH2 lymphocytes, which cause B lymphocytes to produce specific IgE antibodies, which are then bound to the surface of mast cells. On repeated contact with this allergen and cross-linking of mast cell-bound IgE antibodies, the mast cell secretes the biogenic amine histamine, which causes the symptoms of the allergy.

Type II and III allergies
Type II and III allergies are characterized by the formation of immunoglobulin M or G, with type II reactions acting against cell surfaces and type III reactions against soluble antigens. Type III reactions lead by the formation of IgG antibodies immune complexes with the allergens leading for example to the clinical picture of exogenous allergic alveolitis. Furthermore, IgG antibodies against food stuff are suspect to mediate delayed food allergies.

Type IV and V allergies
Type IV reactions are cellular reactions which predominantly involve T lymphocytes. Granulomatous type V allergy can be considered a variant of type IV allergy, as it also triggers a cell-mediated immune response, but involves macrophages instead of T-lymphocytes.

Immunoblot Accessories

Allergy diagnostics

Usually the allergens are proteins from natural sources such as pollens, animal epithelia, insect venoms, foodstuffs, mites etc., can trigger type I allergies. Patients show often a wide range of varying symptoms and sensitization patterns against several allergens. It is necessary to test the blood of a patient when suspected of having an allergic reaction. With RIDA qLine® Allergy R-Biopharm offers an immunoblot for the quantitative detection of specific IgE antibodies.

Allergology

Immunoblots

Product	Description	Matrix	Tests	Art. No.
	Immunoblots for antibody detection			
RIDA qLine®Allergy Panel 1	Immunoblot for quantitative determination of specific IgE in human serum or plasma (citrate) ▪ Standard curve on each strip ▪ 13 inhalative and 7 food allergens ▪ Test membranes (nitrocellulose) in reaction troughs	Serum/ plasma (citrate)	10	A6142
RIDA qLine®Allergy Panel 2	Immunoblot for quantitative determination of specific IgE in human serum or plasma (citrate) ▪ Standard curve on each strip ▪ 20 inhalative allegens ▪ Test membranes (nitrocellulose) in reaction troughs	Serum/ plasma (citrate)	10	A6242
RIDA qLine®Allergy Panel 3	Immunoblot for quantitative determination of specific IgE in human serum or plasma (citrate) ▪ Standard curve on each strip ▪ 20 Food allegens ▪ Test membranes (nitrocellulose) in reaction troughs	Serum/ plasma (citrate)	10	A6342
RIDA qLine®Allergy Panel 4	Immunoblot for quantitative determination of specific IgE in human serum or plasma (citrate) ▪ Standard curve on each strip ▪ 20 Allergens Pediatric panel ▪ Test membranes (nitrocellulose) in reaction troughs	Serum/ plasma (citrate)	10	A6442
	Accessory			
RIDA®CCD-Inhibitor	Accessory for the inhibition of false positive results by cross-reactive anti-CCD IgE in human serum and plasma in in vitro diagnostics	Serum/ plasma (citrate)	25	ZA0601

24 country specific panel compositions are available in addition. For further information please contact R-Biopharm AG.

Autoimmunity

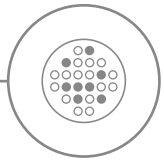
SeraSpot® – an innovative multiplex diagnostic of autoimmune disease.

In autoimmunity, the immune system attacks structures of its own body. Depending on the attacked structure (e.g. nerves, joints, liver), the symptoms and thus the kind of disease vary. Today, around 81 different autoimmune diseases are known. These can be either localized, i.e. organ-specific, or systemic autoimmune diseases.

Many autoimmune diseases are characterized by autoantibodies. The autoantibodies are either directly pathogenic (e.g. anti-GBM) or disease associated. They can be valuable as prognostic markers (e.g. anti-AMA-M2), helpful in patient monitoring (e.g. anti-dsDNA) or necessary for differential diagnosis (e.g. anti-Mi2).

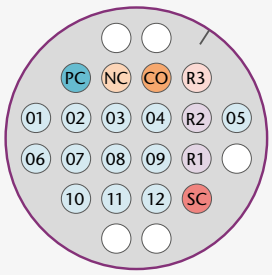
Importantly, the earlier the diagnosis of AID is made the better the outcome is for the patient. This is especially important in progressive e.g. rheumatic, fibrotic diseases that lead to irreversible deficits.

Diagnostics of autoimmune diseases
Autoantibody testing is a central element in the diagnosis and treatment of AID. R-Biopharm offers *SeraSpot*®, a new microspot array for the diagnosis of autoimmune and infectious diseases. Today, the *SeraSpot*® platform comprises 4 different microspot arrays plus the microspot array scanner for the diagnosis of connective tissue disease, autoimmune liver diseases or systemic vasculitis and goodpasture disease.



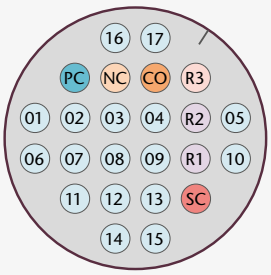
Microspot array

Overview of *SeraSpot*® tests with respective target antigens:



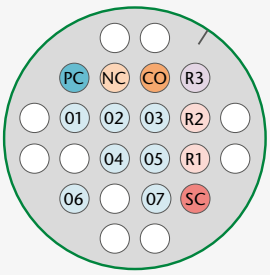
01 U1 - snRNP
02 CENP - B
03 Nucleosomes
04 Histones
05 dsDNA
06 Jo - 1
07 Scl - 70
08 Sm
09 P0
10 La/SS - B
11 Ro/SS - A 52
12 Ro/SS - A 60

ANA-12 IgG



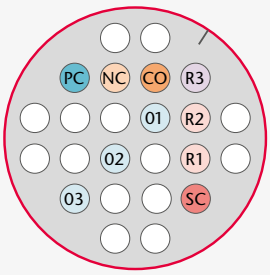
01 U1 - snRNP
02 CENP - B
03 Nucleosomes
04 Histones
05 dsDNA
06 Jo - 1
07 Scl - 70
08 Sm
09 P0
10 PCNA
11 La/SS - B
12 Ro/SS - A 52
13 Ro /SS - A 60
14 AMA - M2
15 PM/Scl - 100
16 Mi - 2
17 Ku

ANA-17 IgG



01 LKM1
02 AMA - M2
03 LC1
04 SLA
05 SP100
06 F - Actin
07 gp210

HepAk-7 IgG



01 GBM
02 MPO
03 PR3

Vasculitis-3 IgG

Autoimmunity

Autoimmune diseases

Product	Description	Matrix	Tests	Art. No.
	Microspot arrays			
SeraSpot® ANA-12 IgG	Specific detection of IgG antibodies against 12 nuclear and cytoplasmatic antigens	Serum/ plasma	1 x 48 1 x 96	SP-002-12 G-S6 SP-002-12 G-S12
SeraSpot® ANA-17 IgG	Specific detection of IgG antibodies against 17 nuclear and cytoplasmatic antigens	Serum/ plasma	1 x 48 1 x 96	SP-002-17 G-S6 SP-002-17 G-S12
SeraSpot® HepAk-7 IgG	Specific detection of IgG antibodies in autoimmune liver diseases	Serum/ plasma	1 x 48 1 x 96	SP-004-7 G-S6 SP-004-7 G-S12
SeraSpot® Vaskulitis-3 IgG	Specific detection of IgG antibodies in systemic vasculitis	Serum/ plasma	1 x 48 1 x 96	SP-003-3 G-S6 SP-003-3 G-S12

Bacteriology

Bacterial infections still play a significant role around the world.

The health services are presented with a significant challenge in terms of diagnosis and treatment of infectious diseases. Effective use of the various diagnostic solutions can significantly improve the detection and control of infectious diseases caused by bacteria. The laboratory procedure must ensure that the information derived from the diagnostic test is reliable and delivered in a timely manner.

Diagnostic solutions in clinical bacteriology
Although the media culture is still the most established method in clinical bacteriology, there is a rising number of diagnostic bacteriology laboratories that deploy commercial IVD kits in their procedures. The validated, reliable and rapid solutions offer a great advancement over the labour- and time-consuming culture method, in particular with respect to specificity and sensitivity.

The bacteriology test portfolio from R-Biopharm offers a wide range of solutions that meets the diagnostic and organizational needs of small to large laboratories. You may choose from a variety of systems to test for a wide range of parameters including *Legionella* spp., *Mycoplasma* spp., *Bordetella* spp. and *Clostridium difficile*.

ELISA | Rapid test | Real-time PCR | Accessories | Microspot array

Bordetella spp.

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Bordetella	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Bordetella pertussis, Bordetella parapertussis* and *Bordetella holmesii* DNA in untreated human nasopharyngeal swabs	Nasopha-ryngeal swabs	100	PG2505

Borrelia spp.

	Microspot arrays			
SeraSpot® Anti-Borrelia-10 IgG	Specific detection of IgG antibodies against *Borrelia burgdorferi sensu lato*	Serum/ plasma	1 x 96 10 x 96	SP-006-10 G-S12 SP-006-10 G-S120
SeraSpot® Anti-Borrelia-10 IgM	Specific detection of IgM antibodies against *Borrelia burgdorferi sensu lato*	Serum/ plasma	1 x 96 10 x 96	SP-006-10 M-S12 SP-006-10 M-S120

Campylobacter spp.

	Real-time PCR			
RIDA®GENE Bacterial Stool Panel	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni)* and *Yersinia enterocolitica* DNA in untreated human stool samples	Stool	100	PG2405
RIDA®GENE Bacterial Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni),* EIEC/ *Shigella* spp. and STEC DNA in untreated human stool samples	Stool	100	PG2415
	Enzyme immunoassay			
RIDASCREEN® Campylobacter	Enzyme immunoassay for the detection of *Campylobacter jejuni* and *Campylobacter coli* in human stool samples	Stool	96	C2401
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Campylobacter Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP2404
	Rapid test			
RIDA®QUICK Campylobacter	Immunochromatographic lateral flow rapid assay for the detection of *Campylobacter jejuni* und *Campylobacter coli* in human stool samples Single pouched cassettes	Stool	25	N2403
	Control for RIDA®QUICK			
RIDA®QUICK Campylobacter Control	Positive control	–	1.8 mL	NP2404

Bacteriology

Chlamydophila pneumoniae

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE CAP Bac	Multiplex real-time PCR for the direct qualitative detection of *Chlamydophila pneumoniae*, *Legionella pneumophila* and *Mycoplasma pneumoniae* DNA in untreated human bronchoalveolar lavage (BAL)	BAL	100	PG2705

Clostridium difficile

	Real-time PCR			
RIDA GENE CD Toxin A/B	Multiplex real-time PCR for the direct qualitative detection of *Clostridium difficile* toxin genes A (tcdA) and B (tcdB) in untreated human stool and culture samples	Stool/ Culture	100	PG0825*
RIDA®GENE Clostridium difficile	Multiplex real-time PCR for the direct qualitative detection of *Clostridium difficile* DNA and *Clostridium difficile* toxin genes A (tcdA) and B (tcdB) in untreated human stool samples	Stool	100	PG0835
RIDA®GENE Hospital Stool Panel	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA (genogroup I and II), Rotavirus RNA and *Clostridium difficile* toxin genes A (tcdA) and B (tcdB) in untreated human stool samples	Stool	100	PG0705
	Enzyme immunoassays			
RIDASCREEN® Clostridium difficile GDH	Enzyme immunoassay for the detection of glutamate dehydrogenase of *Clostridium difficile* in human stool samples	Stool	96	C0701
RIDASCREEN® Clostridium difficile Toxin A/B	Enzyme immunoassay for the detection of toxin A and B of *Clostridium difficile* in human stool samples	Stool	96	C0801
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Clostridium difficile GDH Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP0704
RIDASCREEN® Clostridium difficile Toxin A/B Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP0804

* From 2022 possible limitation in product availability.

Clostridium difficile

Product	Description	Matrix	Tests	Art. No.
	Rapid tests			
RIDA®QUICK Clostridium difficile GDH	Immunochromatographic lateral flow rapid assay for the detection of glutamate dehydrogenase of *Clostridium difficile* in human stool samples Single pouched cassettes	Stool	25	N0703
RIDA®QUICK Clostridium difficile Toxin A/B	Immunochromatographic lateral flow rapid assay for the detection of Toxins A and B of *C. difficile* in human stool samples Single pouched cassettes	Stool	25	N0803
	Controls for RIDA®QUICK			
RIDASCREEN® Clostridium difficile GDH Control	Positive control	–	1.8 mL	NP0704
RIDA®QUICK Clostridium difficile Toxin A/B Control	Positive control	–	1.8 mL	NP0804

Clostridium perfringens

	Enzyme immunoassay			
RIDASCREEN® Clostridium perfringens Enterotoxin	Enzyme immunoassay for detection of enterotoxin of *Clostridium perfringens* in human stool samples	Stool	96	C0601
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Clostridium perfringens Enterotoxin Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP0604

Bacteriology

Escherichia coli

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE EHEC/EPEC	Multiplex real-time PCR for the direct qualitative detection of DNA for virulence factors of EHEC, STEC, EPEC, and EIEC/*Shigella* spp. in untreated human stool and culture samples	Stool/ cultures	100	PG2205
RIDA®GENE EAEC	Multiplex real-time PCR for the direct qualitative detection of enteroaggregative *E. coli* (EAEC) DNA in untreated human stool and culture samples	Stool/ cultures	100	PG2215
RIDA®GENE ETEC/EIEC	Multiplex real-time PCR for the direct qualitative detection of DNA for virulence factors of ETEC and EIEC/Shigella spp. in untreated human stool samples and culture samples	Stool/ cultures	100	PG2225
RIDA®GENE E. coli Stool Panel I	Multiplex real-time PCR for the direct qualitative detection of DNA for virulence factors of EHEC, STEC, and EPEC in untreated human stool samples	Stool	100	PG2285
RIDA®GENE Bacterial Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni),* EIEC/*Shigella* spp. and STEC DNA in untreated human stool samples	Stool	100	PG2415
	Enzyme immunoassay			
RIDASCREEN® Verotoxin	Enzyme immunoassay for the detection of verotoxins 1 and 2 (shigatoxins 1 and 2) of *Escherichia coli* in a stool enrichment	mTSB-Bouillon	96	C2201
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Verotoxin Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP2204
Enrichment broth	**Accessory**			
RIDA® Anreicherungsbouillon	mTSB-bouillon with Mitomycin C for the enrichment of verotoxin (shigatoxin)-producing *E. coli* bacteria	–	100	Z1000

Helicobacter pylori

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Helicobacter pylori	Multiplex real-time PCR for the direct qualitative detection of *Helicobacter pylori* DNA and DNA for clarithromycin resistance in untreated human biopsy samples	Biopsy	100	PG2305
	Microspot arrays			
SeraSpot® Anti-Helicobacter-6 IgA	Specific detection of IgA antibodies against *Helicobacter pylori*	Serum/ plasma	1 x 48 1 x 96	SP-007-6 A-S6 SP-007-6 A-S12
SeraSpot® Anti-Helicobacter-6 IgG	Specific detection of IgG antibodies against *Helicobacter pylori*	Serum/ plasma	1 x 48 1 x 96	SP-007-6 G-S6 SP-007-6 G-S12
	Enzyme immunoassay			
RIDASCREEN® Helicobacter	Enzyme immunoassay for the detection of *Helicobacter pylori* in human stool samples	Stool	96	C2302
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® H. pylori Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP2304
	Rapid test			
RIDA®QUICK Helicobacter	Immunochromatographic lateral flow rapid assay for the detection of *Helicobacter pylori* in human stool samples Single pouched cassettes	Stool	25	N2303
	Control for RIDA®QUICK			
RIDA®QUICK Helicobacter Control	Positive control	–	1.8 mL	NP2304

Bacteriology

Legionella spp.

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Legionella	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Legionella* spp. and *Legionella pneumophila* DNA in untreated human bronchoalveolar lavage (BAL)	BAL	100	PG8005*
RIDA®GENE CAP Bac	Multiplex real-time PCR for the direct qualitative detection of *Chlamydophila pneumoniae, Legionella pneumophila* and *Mycoplasma pneumoniae* DNA in untreated human bronchoalveolar lavage (BAL)	BAL	100	PG2705
	Enzyme immunoassay			
RIDASCREEN® Legionella	Enzyme immunoassay for the detection of *Legionella pneumophila* in human urine samples	Urine	96	C8001
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Legionella Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP8004

Methicillin-resistant/methicillin-sensitive *Staphylococcus aureus*

	Real-time PCR			
RIDA®GENE MRSA	Multiplex real-time PCR for the direct qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-susceptible *Staphylococcus aureus* (MSSA) DNA in untreated human nasal/throat swabs, wound swabs and culture	Swab specimens (nasal/ throat/ wound)/ cultures	100	PG0605
RIDA®GENE PVL	Multiplex real-time PCR for the direct qualitative detection of the PVL-gene (Panton-Valentine leukocidine) in culture	Cultures	100	PG0645*

Mycoplasma spp.

	Real-time PCR			
RIDA®GENE STI Mycoplasma Panel	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Mycoplasma hominis, Mycoplasma genitalium* and *Ureaplasma urealyticum/parvum* DNA in human genital swabs and urine	Genital swab/urine	100	PG4945*
RIDA®GENE CAP Bac	Multiplex real-time PCR for the direct qualitative detection of *Chlamydophila pneumoniae, Legionella pneumophila* and *Mycoplasma pneumoniae* DNA in untreated human bronchoalveolar lavage (BAL)	BAL	100	PG2705

* From 2022 possible limitation in product availability.

Salmonella spp.

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Bacterial Stool Panel	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni)* and *Yersinia enterocolitica* DNA in untreated human stool samples	Stool	100	PG2405
RIDA®GENE Bacterial Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni),* EIEC/ *Shigella* spp. and STEC DNA in untreated human stool samples	Stool	100	PG2415

Treponema pallidum

	Microspot arrays			
SeraSpot® Anti-Treponema-4 IgG	Specific detection of IgG antibodies against *Treponema pallidum*	Serum/ plasma	1 x 48 1 x 96	SP-010-4 G-S6 SP-010-4 G-S12
SeraSpot® Anti-Treponema-4 IgM	Specific detection of IgM antibodies against *Treponema pallidum*	Serum/ plasma	1 x 48 1 x 96	SP-010-4 M-S6 SP-010-4 M-S12

Yersinia enterocolitica

	Real-time PCR			
RIDA®GENE Bacterial Stool Panel	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Salmonella* spp., *Campylobacter* spp. *(C. coli, C. lari, C. jejuni)* and *Yersinia enterocolitica* DNA in untreated human stool samples	Stool	100	PG2405
	Microspot arrays			
SeraSpot® Anti-Yersinia-6 IgA	Specific detection of IgA antibodies against *Yersinia enterocolitica*	Serum/ plasma	1 x 48 1 x 96	SP-005-6 A-S6 SP-005-6 A-S12
SeraSpot® Anti-Yersinia-6 IgG	Specific detection of IgG antibodies against *Yersinia enterocolitica*	Serum/ plasma	1 x 48 1 x 96	SP-005-6 G-S6 SP-005-6 G-S12

Bacteriology

Various

Product	Description	Matrix	Tests	Art. No.
Akkermansia muciniphila	**Real-time PCR**			
RIDA®GENE Akkermansia muciniphila	Multiplex real-time PCR for the direct qualitative or quantitative detection of *Akkermansia muciniphila* DNA in untreated human stool samples	Stool	100	PG0145*
Faecalibacterium prausnitzii	**Real-time PCR**			
RIDA®GENE Faecalibacterium prausnitzii	Multiplex real-time PCR for the direct qualitative or quantitative detection of *Faecalibacterium prausnitzii* DNA in untreated human stool samples	Stool	100	PG0155*
Bacteroides/Clostridium Cluster XIVa – Real-time PCR				
RIDA®GENE Gut Balance	Multiplex real-time PCR for the direct qualitative or quantitative detection and differentiation of Bacteroides and *Clostridium Cluster* XIVa DNA in untreated human stool samples	Stool	100	PG0105*

Accessories

	Color compensation			
RIDA®GENE Color Compensation Kit IV	To generate a Color Compensation File for RIDA®GENE real-time PCR experiments on the LightCycler® 480II	–	3	PG0004
	DNA/RNA extraction			
RIDA® Xtract	Spin-filter based extraction kit for the simultaneous isolation and purification of DNA and RNA in various matrices (serum/plasma/cerebral fluid/cell culture supernatant/other cell free body fluids (e.g. urine)/swabs/tissue biopsies/stool)	See description	250 pre-parations	PGZ001

* From 2022 possible limitation in product availability.

Gastroenterology

Modern diagnostics for the detection of diseases of the digestive tract and for therapeutic drug monitoring.

The ELISA tests are suited for single plate or medium-high-throughput analysis on automated readers. Below, you can find the biological markers and their diagnostic relevance at a glance.

Biomarkers for clinical diagnostics
Biological markers (biomarkers) are measurable indicators for specific conditions. The following biomarkers are relevant in gastroenterology:

- **Calprotectin** is a highly specific indicator of gastrointestinal inflammation which is used for the differentiation of IBD and IBS and for treatment monitoring.
- **α1-antitrypsin and sIgA** are two markers which can be helpful for statements about the condition of the intestinal mucosa in inflammatory bowel diseases.
- **Pancreatic elastase** is used for the detection of pancreatic insufficiency.
- **Therapeutic drug monitoring**
  Therapeutic drug monitoring of infliximab (IFX), adalimumab (ADM), vedolizumab (VDZ) and golimumab (GLM) and ustekinumab (UST) supports the treatment optimization and the reduction of treatment costs.

ELISA Rapid tests Accessories

Inflammatory Bowel Disease and Leaky-Gut Syndrom

Product	Description	Matrix	Tests	Art. No.
	Enzyme immunoassays			
RIDASCREEN® Calprotectin	Enzyme immunoassay for the quantitative determination of calprotectin	Stool	96	G09036
RIDASCREEN® α_1-Antitrypsin	Enzyme immunoassay for the quantitative determination of α_1-Antitrypsin	Stool	96	G09034
RIDASCREEN® sIgA	Enzyme immunoassay for the quantitative determination of secretoric IgA	Stool	96	G09035
	Stool collection tubes			
RIDA®TUBE Calprotectin	For the collection and preparation of stool samples, ▪ Only for use with RIDASCREEN® Calprotectin (Art. No. G09036)	Stool	50	GZ3016
RIDA®TUBE	For collection and preparation of stool samples, ▪ Unfilled; to use after internal validation	Stool	50	GZ3013

Pancreatic Diagnostics

	Enzyme immunoassays			
Pancreatic Elastase ELISA	Enzyme immunoassay for the quantitative determination of pancreatic elastase	Stool	96	G09038
Pancreatic Elastase ELISA (SK15)	Enzyme immunoassay for the quantitative determination of pancreatic elastase; additional standard (SK15)	Stool	96	G09040
	Stool collection tubes			
Stool Preparation Set	For collection and preparation of stool samples, ▪ Only use with Pancreatic Elastase ELISA (Art. No. G09038 and Art. No. G09040)	Stool	45	GZ3008

Gastroenterology

Therapeutic drug monitoring (TDM)

Product	Description	Matrix	Tests	Art. No.
	Enzyme immunoassays			
RIDASCREEN® IFX Monitoring	Enzyme immunoassay for the quantitative determination of infliximab (IFX) and its biosimilars	Serum/ plasma	96	G09041
RIDASCREEN® Anti-IFX Antibodies	Enzyme immunoassay for the quantitative determination of antibodies to infliximab (IFX) and its biosimilars	Serum/ plasma	96	G09042
RIDASCREEN® ADM Monitoring	Enzyme immunoassay for the quantitative determination of adalimumab (ADM)	Serum/ plasma	96	G09043
RIDASCREEN® Anti-ADM Antibodies	Enzyme immunoassay for the quantitative determination of antibodies to adalimumab (ADM)	Serum/ plasma	96	G09044
RIDASCREEN® VDZ Monitoring	Enzyme immunoassay for the quantitative determination of vedolizumab (VDZ)	Serum/ plasma	96	G09045
RIDASCREEN® GLM Monitoring	Enzyme immunoassay for the quantitative determination of golimumab (GLM)	Serum/ plasma	96	G09047
RIDASCREEN® UST Monitoring	Enzyme immunoassay for the quantitative determination of ustekinumab (UST)	Serum/ plasma	96	G09049
	Rapid tests			
RIDA®QUICK IFX Monitoring	Immunochromatographic lateral flow assay for the quantitative determination of infliximab (IFX) and its biosimilars	Serum/ plasma	25	GN3041
RIDA®QUICK ADM Monitoring	Immunochromatographic lateral flow assay for the quantitative determination of adalimumab (ADM)	Serum/ plasma	25	GN3043
	Control sets for RIDA®QUICK			
RIDA®QUICK IFX Monitoring Control Set	Control set • Accessory for Art. No. GN3041	–	–	GP3041
RIDA®QUICK ADM Monitoring Control Set	Control set • Accessory for Art. No. GN3043	–	–	GP3043

Human genetics

Modern diagnostics for the detection of HLA-B27 alleles in genomic DNA.

For in-vitro diagnostics. With the RIDA®GENE HLA-B27 Kit, HLA-B27 alleles are detected in genomic DNA isolated from human EDTA whole blood samples by real-time PCR. The RIDA®GENE HLA-B27 Kit is intended to aid the diagnosis in the evaluation of patients with suspected ankylosing spondylitis and other autoimmune diseases. The test is not to be used for tissue typing.

About 400,000 people in Germany suffer from Ankylosing spondylitis, a chronic inflammatory disease that primarily affects the spine. In addition to the physical examination and imaging examinations (CT, MRI), , HLA-B27 blood tests are an important tool for the diagnostic. Patients with ankylosing spondylitis often carry a specific genetic marker the HLA-B27 gene.

The human leukocyte antigen-B27 (HLA-B27) is a cell surface antigen class I of the major Histocompatibility complex and is encoded on chromosome 6. Its function is to present microbial antigens to T cells. On almost all nucleated cells in the body HLA class I molecules are present.

The presence of the HLA-B27 allele has been associated with certain inflammatory rheumatic diseases, the spondyloarthritides (SpA), especially with ankylosing spondylitis (AS). This association is particularly pronounced in the Caucasian population with a prevalence of HLA-B27 in AS patients of 90 - 95%. In the population, the prevalence of HLAB27 varies significantly between ethnic groups. AS is a chronic rheumatic inflammatory condition, in which the spine and sacroiliac joints are mainly affected. Other rheumatic diseases with which HLA-B27 is associated are Reiter‘s syndrome, acute anterior uveitis, and inflammatory bowel disease. The pathogenic mechanism by which HLA-B27 causes an increased susceptibility for the development of arthritic diseases is still unknown despite intensive research.

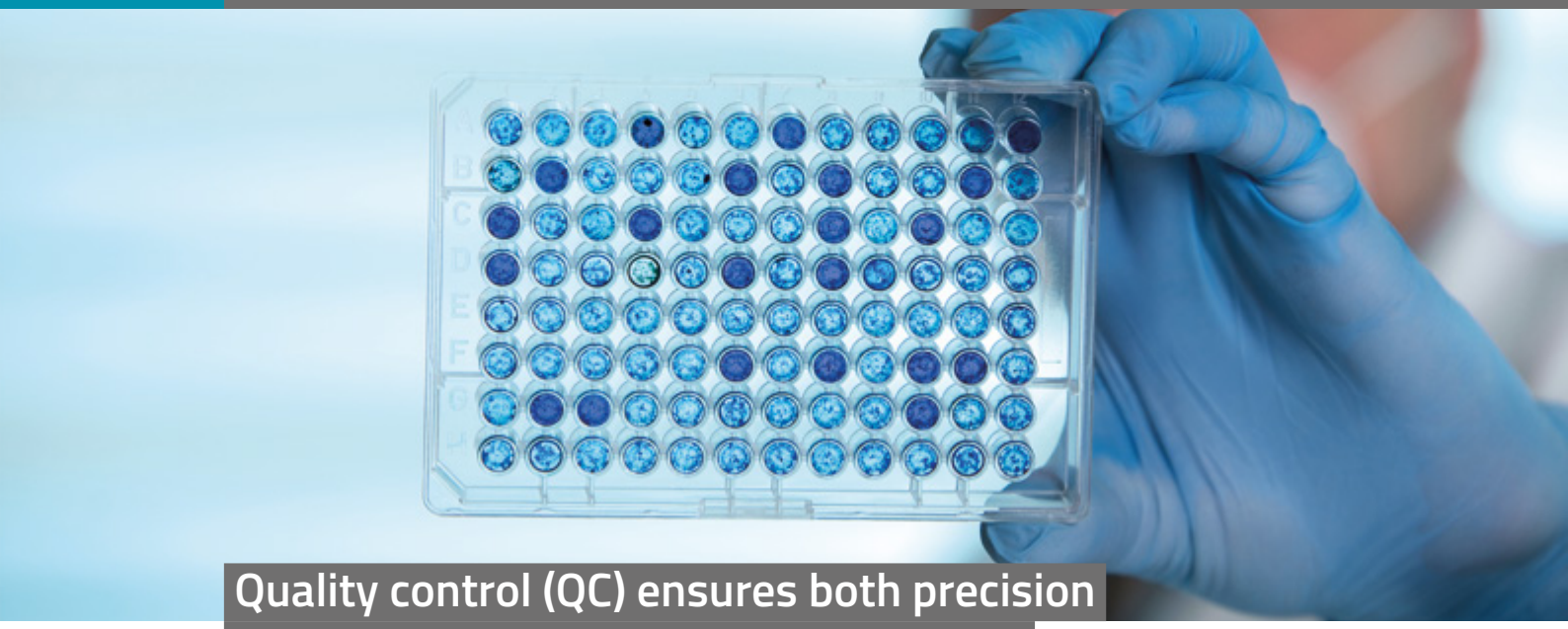
Real-time PCR

HLA-B27

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE HLA-B27	Real time RT-PCR for the qualitative detection of HLA-B27 alleles from humane EDTA whole blood samples	humane EDTA whole blood samples	100	PY0205*
	Real-time PCR			
RIDA®PRECISION ABCB1	Qualitative detection of ABCB1 Genpoly-morphisms, rs2032583 and rs2235015	humane EDTA whole blood samples	50	Y5500*

* From 2022 possible limitation in product availability.

Quality assessment controls by Microbix



Quality control (QC) ensures both precision and accuracy of patient sample results.

Effectively, QC is able to find and correct flaws in the analytical processes of a lab before potentially incorrect patient results are released. Maintaining accurate and frequent checks of laboratory sample testing through quality control is vital to ensuring that patient testing is done right and that it produces accurate results

The Microbix's quality assessment products (QAPs™) are composed of QAPs across the PROCEEDx™ , ONBOARDxTM and REDx™ Controls tradenames – to support whole-process accuracy of molecular and immunological tests for bacterial and viral diseases by emulating patient samples while being consistent, non-infectious, stable, and cross-instrument compatible. The QAPs ™ products are quality controls to support the accuracy of testing for respiratory viruses such as SARS-CoV-2 (COVID-19), Flu A, Flu B, and RSV, as well as the leading edge QAPs ™ for high-risk types of HPV and other sexually-transmitted infections

REDx™ Controls (CE) to ensure day-to-day consistency of an analytical process and assists in determining reliable patient test results.

PROCEEDx™ (RUO) to ensure whether a device complies with its specification or imposed condition. Intended for use in internal processes (verification). In addition, PROCEEDx™ can also be used to assure that a product meets customer needs and involves acceptance criteria for external users (validation).

ONBOARDx™ (RUO) is a all-encompassing validation and verification kit for instrument/kit/assay qualification and operator training. Kit contains PROCEEDx™ (RUO) material.

Respiratory infections

Product	Test compatibility	Art. No.	
		PROCEEDx™	REDx™ controls
Adenovirus Positive	Nucleic acid*; Immunoassay	VP-15-01	
Adenovirus + Rotavirus Positive	Nucleic acid*; Immunoassay	VP-15-02	
HSV 1 & 2 Positive	Nucleic acid; Immunoassay	VP-02-M2	
Influenza A Positive	Nucleic acid; Immunoassay	VP-13-01	
Influenza A Positive (swab)	Nucleic acid; Immunoassay	VP-S-13-01	
Influenza A + Adenovirus Positive	Nucleic acid; Immunoassay	VP-13-04	
Influenza A + B Positive	Nucleic acid; Immunoassay	VP-13-02	
Influenza A + Rotavirus Positive	Nucleic acid*; Immunoassay	VP-13-05	
Influenza A + RSV Positive	Nucleic acid; immunoassay	VP-13-03	
Influenza B Positive	Nucleic acid; immunoassay	VP-14-01	
Influenza B Positive (swab)	Nucleic acid; immunoassay	VP-S-14-01	
Influenza B + Adenovirus Positive	Nucleic acid*; Immunoassay	VP-14-03	
Influenza B + Rotavirus Positive	Nucleic acid*; Immunoassay	VP-14-04	
Influenza B + RSV Positive	Nucleic acid; immunoassay	VP-14-02	
MDx Negative	Nucleic acid	VP-99-M1	RED-99-M1
Parainfluenza 3 Positive	Nucleic acid	VP-10-M1	
RSV Positive	Nucleic acid; immunoassay	VP-07-01	
RSV Positive (swab)	Nucleic acid; immunoassay	VP-S-07-01	
RSV + Adenovirus Positive	Nucleic acid*, Immunoassay	VP-07-02	
RSV + Rotavirus Positive	Nucleic acid*, Immunoassay	VP-07-03	
SARS-CoV-2 Negative (vial)	Nucleic acid	VP-99-M3	RED-99-M3
SARS-CoV-2 Positive (vial)	Nucleic acid	VP-19-01	RED-19-01
SARS-CoV-2 Negative (swab)	Nucleic acid	VP-S-99-M4	RED-S-99-M4
SARS-CoV-2 Positive (swab)	Nucleic acid	VP-S-19-01	RED-S-19-01
SARS-CoV-2 Positive Ag (swab)	Immunoassay	VP-S-19-02	RED-S-19-02
SARS-CoV-2 P.1 Swab Positive Sample	Nucleic acid	VP-S-19-05	
SARS-CoV-2 B.1.1.7 Swab Positive Sample	Nucleic acid	VP-S-19-03	
SARS-CoV-2 B.1.351 Swab Positive Sample	Nucleic acid	VP-S-19-04	
FLOQ® Respiratory Swab Negative Control	Immunoassay	VP-S-99-01	RED-S-99-01

Only available in selected countries.

* Products are compatible with nucleic acid tests by design and QC released only by immunological tests.

Quality assessment controls by Microbix

Respiratory infections

Product	Test compatibility	Kit components	Art. No.
			ONBOARDx™ Kit
ONBOARDx™ SARS-CoV-2 Vial Kit 01	Nucleic acid	SARS-CoV-2 Positive (0.5mL) vial x 8 SARS-CoV-2 Negative (0.5mL) vial x 4	VP-K-CoV2-01
ONBOARDx™ FLOQ SARS-CoV-2 Swab Kit 01	Nucleic acid	SARS-CoV-2 Positive Swab x 8 SARS-CoV-2 Negative Swab x 4	VP-SK-CoV2-01
ONBOARDx™ FLOQ Respiratory Swab Kit (RUO)	Nucleic acid	SARS-CoV-2 Positive Swab x 3 Influenza A Positive Swab x3 Influenza B Positive Swab x3 RSV Positive Swab x3	VP-SK-RESP-01
ONBOARDx™ Respiratory Vial Kit (RUO)	Nucleic acid	SARS-CoV-2 Positive Sample 3 x 0.5 mL vial Influenza A Positive Sample 3 x 1.0 mL vial Influenza B Positive Sample 3 x 1.0 mL vial RSV Positive Sample 3 x 1.0 mL vial	VP-K-RESP-01
ONBOARDx™ FLOQ SARS-CoV-2 Variant Swab Kit	Nucleic acid	B.1.1.7 wohle genome variant swab x3 B.1.351 whole genome variant swab x3 P.1 whole genome variant swab x3 wild type (WT) whole genome swab x3	VP-SK-CVAR-01
			ONBOARDx™ Kit
ONBOARDx™ FLOQ® SARS-CoV-2 Ag Swab Kit (RUO)	Immunoassay	SARS-CoV-2 Ag Positive swab x8 Respiratory Negative swab x4	VP-SK-COV2AG-01
ONBOARDx™ FLOQ® SARS-CoV-2 Ag Swab Kit B (RUO)	Immunoassay	Sars-CoV-2 AG Positive swab x15 Respiratory Negative swab x5	VP-SK-COV2AG-02
ONBOARDx™ FLOQ® Respiratory Swab Kit B (RUO)	Immunoassay	SARS-CoV-2 Ag Positive swab x5 Influenza A Positive swab x5 Influenza B Positive swab x5 RSV Positive swab x5	VP-SK-RESPAG-02

Gastrointestinal infections

Product	Test compatibility	Art. No.	
		PROCEEDx™	REDx™ controls
Cryptosporidium Positive	Immunoassay	VP-37-01	
Giardia Positive	Immunoassay	VP-38-01	
Negative	Nucleic acid; immunoassay	VP-99-01	
Rotavirus Positive	Immunoassay	VP-35-01	

Only available in selected countries.

Sexually transmitted infections

Product	Test compatibility	Art. No.	
		PROCEEDx™	REDx™ Controls
Chlamydia trachomatis Positive	Nucleic acid	VP-12-M1	
Chlamydia trachomatis Positive	Immunoassay	VP-12-01	
Chlamydia trachomatis + *Neisseria gonorrhoeae* Positive	Nucleic acid	VP-12-M2	
HPV 16 Positive	Nucleic acid	VP-62-16	RED-62-16
HPV 18 Positive	Nucleic acid	VP-62-18	RED-62-18
HPV 31 Positive	Nucleic acid	VP-62-31	
HPV 33 Positive	Nucleic acid	VP-62-33	
HPV 39 Positive	Nucleic acid	VP-62-39	
HPV 45 Positive	Nucleic acid	VP-62-45	RED-62-45
HPV 67 Positive (hr Negative)	Nucleic acid	VP-62-67	
HSV 1 Positive	Nucleic acid	VP-02-M1	
HSV 2 Positive	Nucleic acid	VP-23-M1	
Mycoplasma genitalium	Nucleic acid	VP-63-01	RED-63-01
Neisseria gonorrhoeae Positive	Nucleic acid	VP-17-M1	
Trichomonas vaginalis Positive	Nucleic acid	VP-61-02	
Trichomonas vaginalis Positive	Nucleic acid; immunoassay	VP-61-01	

Only available in selected countries.

Mycology

In recent years, fungi have gained as pathogens more and more importance.

Although fungi play many essential roles in human homeostasis, they may also constitute health burden for certain groups of patients. When the host-fungal pathogen balance is disturbed, a fungal infection may lead to serious consequences. Proper detection of the growth of the fungal agents is therefore of high importance in clinical microbiology.

Pneumocystis jirovecii does not cause any harm in healthy people and is widely spread among the normal population. However, immunocompromised people infected with *Pneumocystis jirovecii*, develop pneumonia with symptoms including dry cough, shortness of breath, tachypnoe and fever. *Pneumocystis jirovecii* causes respiratory infections and is the most common opportunistic illness in HIV-infected people.

Diagnostic solutions for mycology

The mycology tests portfolio from R-Biopharm offers PCR technology that meet the diagnostic needs of laboratories.

Real-time PCR

Accessories

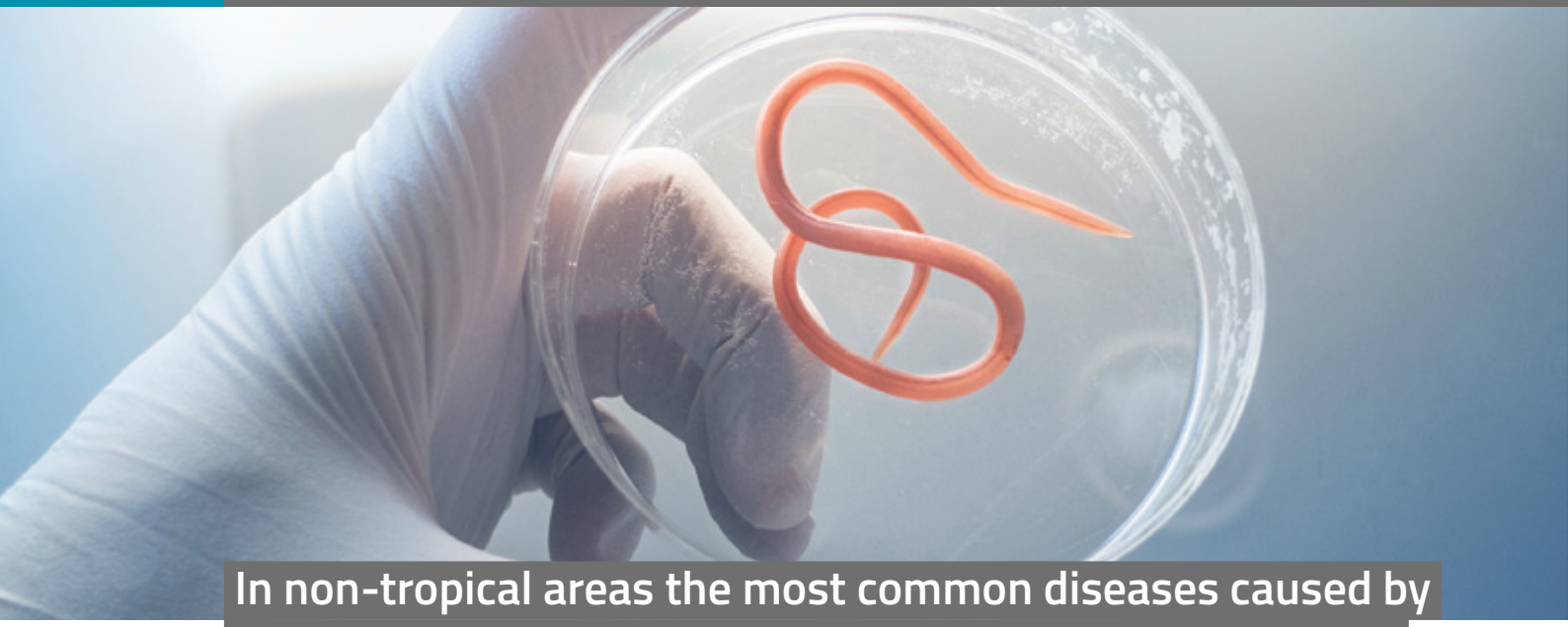
Pneumocystis jirovecii

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Pneumocystis jirovecii	Multiplex real-time PCR for the direct qualitative detection of *Pneumocystis jirovecii* DNA in untreated human bronchoalveolar lavage (BAL)	BAL	100	PG1905

Accessories

	Color compensation			
RIDA®GENE Color Compensation Kit IV	To generate a Color Compensation File for RIDA®GENE real-time PCR experiments on the LightCycler® 480II	–	3	PG0004
	DNA/RNA extraction			
RIDA® Xtract	Spin-filter based extraction kit for the simultaneous isolation and purification of DNA and RNA in various matrices (serum/plasma/ cerebral fluid/cell culture supernatant/other cell free body fluids (e.g. urine)/swabs/tissue biopsies/stool)	See description	250 preparations	PGZ001

Parasitology



In non-tropical areas the most common diseases caused by parasites are Giardiasis, Cryptosporidiosis and Amebiasis.

Parasitic infections are caused by three types of organisms: protozoa, helminths and ectoparasites. Infections with protozoa can occur by, for instance, drinking water containing the protozoa organisms' cells or though food that was undercooked. *Giardia lamblia, Cryptosporidium parvum, Entamoeba histolytica* and *Dientamoeba fragilis* are the most important diarrhea-causing protozoa.

Due to the ease of spread, fast and reliable diagnosis of a parasitic infection at an early stage is crucial for an effective therapy. Immunoassays and molecular diagnostics enable detection and differentiation of parasitic infections sooner than traditional methods, such as microscopy.

Innovative diagnostic solutions for parasitology
R-Biopharm offers various technologies for parasitology that meet the diagnostic and organizational needs of small to large laboratories. You may choose from different diagnostic systems to test for a variety of parasites including *Entamoeba, Giardia* and *Cryptosporidium*. We also offer a parasitic stool panel.

ELISA | Rapid tests | Real-time PCR | Accessories

Cryptosporidium spp.

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Parasitic Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica, Cryptosporidium* spp. and *Dientamoeba fragilis* DNA in untreated human stool samples	Stool	100	PG1715
RIDA®GENE Parasitic Stool Panel II	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica* and *Cryptosporidium* spp. DNA in untreated human stool samples	Stool	100	PG1725
	Enzyme immunoassay			
RIDASCREEN® Cryptosporidium	Enzyme immunoassay for the detection of *Cryptosporidium* in human stool samples	Stool	96	C1201
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Cryptosporidium Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1204
	Rapid tests			
RIDA®QUICK Cryptosporidium	Immunochromatographic rapid assay for the detection of *Cryptosporidium* in human stool samples Single pouched cassettes	Stool	20	N1203
RIDA®QUICK Cryptosporidium/Giardia Combi	Immunochromatographic rapid assay for the detection of *Cryptosporidium* and/or *Giardia* in human stool samples Single pouched cassettes	Stool	20	N1123
RIDA®QUICK Cryptosporidium/Giardia/ Entamoeba Combi	Immunochromatographic rapid assay for the detection of *Cryptosporidium* and/or *Giardia* and/or *Entamoeba* in human stool samples Single pouched cassettes	Stool	20	N1723
	Control for RIDA®QUICK			
RIDA®QUICK Parasite Combi Control	Positive control	–	1.8 mL	NP1704

Parasitology

Dientamoeba fragilis

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Parasitic Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica, Cryptosporidium* spp. and *Dientamoeba fragilis* DNA in untreated human stool samples	Stool	100	PG1715
RIDA®GENE Dientamoeba fragilis	Multiplex real-time PCR for the direct qualitative detection of *Dientamoeba fragilis* DNA in untreated human stool samples	Stool	100	PG1745

Entamoeba spp.

	Real-time PCR			
RIDA®GENE Parasitic Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica, Cryptosporidium* spp. and *Dientamoeba fragilis* DNA in untreated human stool samples	Stool	100	PG1715
RIDA®GENE Parasitic Stool Panel II	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica* and *Cryptosporidium* spp. DNA in untreated human stool samples	Stool	100	PG1725
Entamoeba	**Enzyme immunoassays**			
RIDASCREEN® Entamoeba histolytica IgG	Specific detection of IgG antibodies against *Entamoeba histolytica*	Serum	96	K1721
RIDASCREEN® Entamoeba	Enzyme immunoassay for the detection of *Entamoeba histolytica/Entamoeba dispar* in human stool samples	Stool	96	C1701
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Entamoeba Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1704
	Rapid tests			
RIDA®QUICK Entamoeba	Immunochromatographic rapid assay for the detection of *Entamoeba* in human stool samples Single pouched cassettes	Stool	20	N1703
RIDA®QUICK Cryptosporidium/Giardia/ Entamoeba Combi	Immunochromatographic rapid assay for the detection of *Cryptosporidium* and/or *Giardia* and/ or *Entamoeba* in human stool samples Single pouched cassettes	Stool	20	N1723
	Control for RIDA®QUICK			
RIDA®QUICK Parasite Combi Control	Positive control	–	1.8 mL	NP1704

Giardia lamblia

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Parasitic Stool Panel I	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica, Cryptosporidium* spp. and *Dientamoeba fragilis* in untreated human stool samples	Stool	100	PG1715
RIDA®GENE Parasitic Stool Panel II	Multiplex real-time PCR for the direct qualitative detection and differentiation of *Giardia lamblia, Entamoeba histolytica* and *Cryptosporidium* spp. in untreated human stool samples	Stool	100	PG1725
	Enzyme immunoassay			
RIDASCREEN® Giardia	Enzyme immunoassay for the detection of *Giardia lamblia* in human stool samples	Stool	96	C1101
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Giardia Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1104
	Rapid tests			
RIDA®QUICK Giardia	Immunochromatographic rapid assay for the detection of *Giardia* Single pouched cassettes	Stool	20	N1103
RIDA®QUICK Cryptosporidium/Giardia Combi	Immunochromatographic rapid assay for the detection of *Cryptosporidium* and/or *Giardia* in human stool samples Single pouched cassettes	Stool	20	N1123
RIDA®QUICK Cryptosporidium/Giardia/ Entamoeba Combi	Immunochromatographic rapid assay for the detection of *Cryptosporidium* and/or *Giardia* and/or *Entamoeba* in human stool samples Single pouched cassettes	Stool	20	N1723
	Control for RIDA®QUICK			
RIDA®QUICK Parasite Combi Control	Positive control	–	1.8 mL	NP1704

Parasitology

Various

Product	Description	Matrix	Tests	Art. No.
E. granulosus/multiloculrais	**Enzyme immunoassay**			
RIDASCREEN® Echinococcus IgG	Specific detection of IgG antibodies against *Echinococcus granulosus* and *Echinococcus multilocularis*	Serum	96	K7621*
Leshmania infantum	**Enzyme immunoassay**			
RIDASCREEN® Leishmania IgG	Specific detection of IgG antibodies against *Leishmania infantum*	Serum	96	K7321*
Taenia solium	**Enzyme immunoassay**			
RIDASCREEN® Taenia solium IgG	Specific detection of IgG antibodies against the larval forms of *Taenia solium* (cysticercosis)	Serum	96	K7721*
Toxocara canis	**Enzyme immunoassay**			
RIDASCREEN® Toxocara IgG	Specific detection of IgG antibodies against *Toxocara canis*	Serum	96	K7421*
Trichinella spiralis	**Enzyme immunoassay**			
NovaLisa™Trichinella spiralis	Specific detection of IgG antibodies against *Trichinella spiralis*	Serum/ plasma (citrate)	96	TRIG0480*

Accessories

Accessories	Color compensation			
RIDA®GENE Color Compensation Kit IV	To generate a Color Compensation File for RIDA®GENE real-time PCR experiments on the LightCycler® 480II	–	3	PG0004
	DNA/RNA extraction			
RIDA® Xtract	Spin-filter based extraction kit for the simultaneous isolation and purification of DNA and RNA in various matrices (serum/plasma/ cerebral fluid/cell culture supernatant/other cell free body fluids (e.g. urine)/swabs/tissue biopsies/stool)	See description	250 preparations	PGZ001

* From 2022 possible limitation in product availability.

Virology

Viruses are by far the most important pathogens of infections of the upper respiratory tract as well as diarrhea infections.

Effective use of these diagnostic platforms enables the timely detection and control of infectious diseases caused by viral agents. We offer a broad portfolio of parameters and technologies for clinical virology, with a particular focus on viruses causing gastrointestinal infections and respiratory infections.

Norovirus diagnostics: fast diagnostics in outbreaks – always on the forefront
Noroviruses are a major cause of gastroenteritis world-wide with estimated 23 million cases a year in the USA. They are frequently the reason for outbreaks in communal facilities, for instance nursing homes, hospitals, prisons and cruise ships. Since norovirus outbreaks are reported more often than outbreaks caused by bacterial pathogens, they may have a considerable impact on public health.

The reliable norovirus diagnostic tests from R-Biopharm help clinical laboratories of all sizes to detect norovirus infections in a simple and fast manner. Depending on their needs, laboratories may pick from our ELISA, rapid tests or PCR product portfolio.

Innovative diagnostic solutions for virology
Our virology catalogue offers technologies that meet the diagnostic and organizational needs of small to large laboratories. You may choose from different systems to test for a variety of viral pathogens such as SARS-CoV-2, Norovirus, Adenovirus, Astrovirus, Enterovirus, Rotavirus, Influenzavirus, Parainfluenzavirus and RSV.

ELISA | Rapid test | Real-time PCR | Accessories | Microspot array

Adenovirus

Product	Description	Matrix	Tests	Art. No.
	Real-time RT-PCR			
RIDA®GENE Adenovirus	Multiplex real-time PCR for the direct qualitative detection of Adenovirus DNA in untreated human nasal/throat swabs and untreated human bronchoalveolar lavage (BAL)	Nasal/throat swabs/BAL	100	PG1005
RIDA®GENE Viral Stool Panel I	Multiplex real-time RT-PCR for the direct qualitative detection and differentation of Norovirus RNA, Rotavirus RNA, Adenovirus (subtype 40/41) DNA, and Astrovirus RNA in untreated human stool samples	Stool	100	PG1315
RIDA®GENE Viral Stool Panel II	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Rotavirus RNA, Astrovirus RNA, and Adenovirus (subtype 40/41) DNA in untreated stool samples	Stool	100	PG1325
RIDA®GENE Viral Stool Panel III	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA, Rotavirus RNA and Adenovirus (subtype 40/41) DNA in untreated human stool samples	Stool	100	PG1335
	Enzyme immunoassay			
RIDASCREEN® Adenovirus	Enzyme immunoassay for the detection of Adenoviruses in human stool samples	Stool	96	C1001
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Adenovirus Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1004
	Rapid tests			
RIDA®QUICK Rotavirus/Adenovirus Combi	Immunochromatographic rapid assay for the detection of Rotaviruses and/or Adenoviruses in human stool samples Single pouched cassettes	Stool	20	N1003
RIDA®QUICK Rotavirus/Adenovirus/Norovirus Combi	Immunochromatographic rapid assay for the detection of Rotaviruses and/or Adenoviruses and/or Noroviruses in human stool samples Single pouched cassettes	Stool	20	N1903
	Control for RIDA®QUICK			
RIDA®QUICK Rotavirus/Adenovirus Combi Control	Positive control	–	1.8 mL	NP1904
	Sample diluent for RIDA®QUICK			
RIDA®QUICK Rotavirus/Adenovirus Sample diluent	Tubes with 1.5 mL sample diluent	Stool	25	ZN1004

Virology

Astrovirus

Product	Description	Matrix	Tests	Art. No.
	Real-time RT-PCR			
RIDA®GENE Viral Stool Panel I	Multiplex real-time RT-PCR for the direct qualitative detection and differentation of Norovirus RNA, Rotavirus RNA, Adenovirus (subtype 40/41) DNA, and Astrovirus RNA in untreated human stool samples	Stool	100	PG1315
RIDA®GENE Viral Stool Panel II	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Rotavirus RNA, Astrovirus RNA, and Adenovirus (subtype 40/41) DNA in untreated stool samples	Stool	100	PG1325
	Enzyme immunoassay			
RIDASCREEN® Astrovirus	Enzyme immunoassay for the detection of Astroviruses in human stool samples	Stool	96	C1301
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Astrovirus Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1304

Coronavirus

	Real-time RT-PCR			
RIDA®GENE Coronavirus	Multiplex real-time RT-PCR for the direct qualitative detection and differentation of coronaviruses (HKU1, NL63, 229E, OC43) and MERS-CoV RNA in untreated human nasal/throat swabs	Nasal/ throat swab	100	PG6805
RIDA®GENE SARS-CoV-2	Multiplex real-time RT-PCR for the direct qualitative detection of coronavirus (SARS-CoV-2) RNA in untreated human nasal/throat swabs	Nasal/ throat swab	100 200	PG6815* PG6820*
RIDA®GENE Flu & SARS-CoV-2	Multiplex real-time RT-PCR for the direct qualitative detection and differentation of Flu A/Flu B and coronavirus (SARS-CoV-2) RNA in untreated human nasal/throat swabs	Nasal/ throat swab	200	PG6825
RIDA®GENE SARS-CoV-2 Lineage RUO	For research use only. Not intended for diagnostic procedures. The RIDA®GENE SARS-CoV-2 Lineage RUO test is a multiplex real-time RT-PCR for the detection of SARS-CoV-2 mutations.*	–	100	**
	Microspot-Arrays			
SeraSpot® Anti-SARS-CoV 2 IgG	Specific detection of IgG antibodies against SARS-CoV 2	Serum/ plasma	48 96	SP-015-4 G-S6 SP-015-4 G-S12
SeraSpot® Anti-SARS-CoV 2 IgA	Specific detection of IgA antibodies against SARS-CoV 2	Serum/ plasma	48 96	SP-015-4 A-S6 SP-015-4 A-S12

* From 2022 possible limitation in product availability.

** The RIDA®GENE lineage tests are continuously adapted to the currently occurring SARS-CoV-2 variants. For the current article number, please contact us.

Enterovirus

Product	Description	Matrix	Tests	Art. No.
Enterovirus	**Real-time RT-PCR**			
RIDA®GENE Enterovirus	Multiplex real-time RT-PCR for the direct qualitative detection of Enterovirus RNA (Polioviruses, Echoviruses, Coxsackieviruses and human Enteroviruses) in untreated human stool samples and cerebrospinal fluid	Stool/CSF	100	PG4705

Epstein-Barr-Virus

	Microspot arrays			
SeraSpot® Anti-EBV-4 IgG	Specific detection of IgG antibodies against Epstein-Barr-Virus	Serum/ plasma	96	SP-013-4 G-S12
SeraSpot® Anti-EBV-3 IgM	Specific detection of IgM antibodies against Epstein-Barr-Virus	Serum/ plasma	96	SP-013-3 M-S12

Influenzavirus

	Real-time RT-PCR			
RIDA®GENE Flu	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Influenza A, Influenza B and H1N1v RNA in untreated human nasal/throat swabs	Nasal swab/ throat swab	100	PG0505
RIDA®GENE Flu & RSV	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Influenza A, Influenza B and RSV RNA in untreated human nasal/throat swabs and untreated human bronchoalveolar lavage (BAL)	Nasal swab/ throat swab/BAL	100	PG0545

Metapneumovirus

RSV & hMPV	**Real-time RT-PCR**			
RIDA®GENE RSV & hMPV	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of RSV and hMPV RNA in untreated human nasal/throat swabs and untreated human bronchoalveolar lavage (BAL)	Nasal/ throat swabs, BAL	100	PG5905

Virology

Norovirus

Product	Description	Matrix	Tests	Art. No.
	Real-time PCR			
RIDA®GENE Hospital Stool Panel	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA (genogroup I and II), Rotavirus RNA and *Clostridium difficile* toxin genes A (tcdA) and B (tcdB) in untreated human stool samples	Stool	100	PG0705
RIDA®GENE Norovirus	Multiplex real-time RT-PCR for the direct qualitative detection of Norovirus RNA of genogroups I (GI) and II (GII) in untreated human stool samples	Stool	100	PG1405
RIDA®GENE Norovirus I & II	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA of genogroups I (GI) and II (GII) in untreated human stool samples	Stool	100	PG1415
RIDA®GENE Norovirus GI/GII	Multiplex real-time RT-PCT for the simultaneous qualitative detection and differentiation of Norovirus genogroup I (GI) and II (GII) nucleic acid in untreated human stool samples	Stool	100	PG1445**
RIDA®GENE Viral Stool Panel I	Multiplex real-time RT-PCR for the direct qualitative detection of Norovirus RNA, Rotavirus RNA, Adenovirus (subtype 40/41) DNA, and Astrovirus RNA in untreated stool samples	Stool	100	PG1315
RIDA®GENE Viral Stool Panel III	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA, Rotavirus RNA and Adenovirus (subtype 40/41) DNA in untreated human stool samples	Stool	100	PG1335*
	Enzyme immunoassay			
RIDASCREEN® Norovirus	Enzyme immunoassay for the detection of Noroviruses (genogroup I and II) in human stool samples	Stool	96	C1401
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Norovirus Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP1404
	Rapid tests			
RIDA®QUICK Norovirus	Immunochromatographic rapid assay for the detection of Noroviruses (genogruop I and II) in human stool sample Single pouched cassettes	Stool	25	N1402
RIDA®QUICK Rotavirus/Adenovirus/Norovirus Combi	Immunochromatographic rapid assay for the detection of Rotaviruses and/or Adenoviruses and/or Noroviruses genogruop I and II in human stool sample Single pouched cassettes	Stool	20	N1903
	Control for RIDA®QUICK			
RIDA®QUICK Norovirus Control	Positive control	–	1.8 mL	NP1404

* From 2022 possible limitation in product availability.

** Only for sale in the US.

Parainfluenzavirus

Product	Description	Matrix	Tests	Art. No.
Parainfluenza	**Real-time RT-PCR**			
RIDA®GENE Parainfluenza	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of human Parainfluenza 1, 3 and 2/4 RNA in untreated human nasal/throat swabs	Nasal swab/ throat swab	100	PG5805

Parvovirus

	Microspot arrays			
SeraSpot® Anti-Parvovirus-6 IgG	Specific detection of IgG antibodies against Parvovirus	Serum/ plasma	48	SP-012-6 G-S6
SeraSpot® Anti-Parvovirus-5 IgM	Specific detection of IgM antibodies against Parvovirus	Serum/ plasma	48	SP-012-5 M-S6

Rotavirus

	Real-time PCR			
RIDA®GENE Hospital Stool Panel	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA (genogroup I and II), Rotavirus RNA and *Clostridium difficile* toxin genes A (tcdA) and B (tcdB) in untreated human stool samples	Stool	100	PG0705
RIDA®GENE Viral Stool Panel I	Multiplex real-time RT-PCR for the direct qualitative detection and differentation of Norovirus RNA, Rotavirus RNA, Adenovirus (subtype 40/41) DNA, and Astrovirus RNA in untreated human stool samples	Stool	100	PG1315
RIDA®GENE Viral Stool Panel II	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Rotavirus RNA, Astrovirus RNA, and Adenovirus (subtype 40/41) DNA in untreated human stool samples	Stool	100	PG1325
RIDA®GENE Viral Stool Panel III	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Norovirus RNA, Rotavirus RNA and Adenovirus (subtype 40/41) DNA in untreated human stool samples	Stool	100	PG1335*
	Enzyme immunoassay			
RIDASCREEN® Rotavirus	Enzyme immunoassay for the detection of Rotaviruses in human stool samples	Stool	96	C0901
	Reference controls for RIDASCREEN® ELISA			
RIDASCREEN® Rotavirus Reference Controls	Reference controls A (positive) and B (negative)	–	2.0 mL (A) 2.0 mL (B)	CRP0904

* From 2022 possible limitation in product availability.

Virology

Rotavirus

Product	Description	Matrix	Tests	Art. No.
	Rapid tests			
RIDA®QUICK Rotavirus	Immunochromatographic rapid assay for the detection of Rotaviruses in human stool samples Single pouched cassettes	Stool	20	N0903
RIDA®QUICK Rotavirus/Adenovirus Combi	Immunochromatographic rapid assay for the detection of Rotaviruses and/or Adenoviruses in human stool samples Single pouched cassettes	Stool	20	N1003
RIDA®QUICK Rotavirus/Adenovirus/Norovirus Combi	Immunochromatographic rapid assay for the detection of Rotaviruses and/or Adenoviruses and/or Noroviruses in human stool samples Single pouched cassettes	Stool	20	N1903
	Controls for RIDA®QUICK			
RIDA®QUICK Rotavirus/Adenovirus Combi Control	Positive control	–	1.8 mL	NP1904
	Sample diluent for RIDA®QUICK			
RIDA®QUICK Rotavirus/Adenovirus Sample diluent	Tubes with 1.5 mL sample diluent	Stool	25	ZN1004

Respiratory Syncytial Virus

RSV & hMPV	Real-time RT-PCR			
RIDA®GENE RSV & hMPV	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of RSV and hMPV RNA in untreated human nasal/throat swabs and untreated human bronchoalveolar lavage (BAL)	Nasal/ throat swabs, BAL	100	PG5905
RIDA®GENE Flu & RSV	Multiplex real-time RT-PCR for the direct qualitative detection and differentiation of Influenza A, Influenza B and RSV RNA in untreated human nasal/throat swabs and untreated human bronchoalveolar lavage (BAL)	Nasal/ throat swabs, BAL	100	PG0545

Sapovirus

Product	Description	Matrix	Tests	Art. No.
Sapovirus	**Real-time RT-PCR**			
RIDA®GENE Sapovirus	Multiplex real-time RT-PCR for the direct qualitative detection of Sapovirus RNA in untreated human stool samples	Stool	100	PG1605*

Accessories

Accessories	Color compensation			
RIDA®GENE Color Compensation Kit IV	To generate a Color Compensation File for RIDA®GENE real-time PCR experiments on the LightCycler® 480II	–	3	PG0004
	DNA/RNA extraction			
RIDA® Xtract	Spin-filter based extraction kit for the simultaneous isolation and purification of DNA and RNA in various matrices (serum/plasma/ cerebral fluid/ cell culture supernatant/other cell free body fluids (e.g. urine)/swabs/tissue biopsies/stool)	See description	250 preparations	PGZ001

* From 2022 possible limitation in product availability.

Systems

Tailored system solutions considering your workflow.

Reliable products and high quality are standard in clinical laboratories. Moreover, time and costs play an increasingly important role which can optimally be addressed with suitable automation solutions. This is where R-Biopharm comes in with its automation products and services. In cooperation with renowned partners, R-Biopharm offers equipment and software solutions from small to high sample throughput for your specific laboratory requirements.

Systems & software
R-Biopharm offers different platforms for ELISA, real-time PCR, immunoblots and rapid tests.

- The lateral flow reader RIDA®QUICK SCAN II is R-Biopharm's solution for secure analysis and quality-assured documentation in the field of therapeutic drug monitoring.

- For molecular diagnostics R-Biopharm offers the automated interpretation software RIDA®SEEK for RIDA®GENE real-time PCR kits. RIDA®SEEK enables qualitative interpretation of results from PCR cycler raw data. The RIDA®CYCLER is a compact and flexible 4 channel real-time PCR instrument based on innovative magnetic induction technology (for research use only).

- R-Biopharm tests systems are verified on various automation systems. Further, R-Biopharm provides convenient software solutions for measurement, evaluation and documentation of RIDASCREEN® and RIDA qLine®.

Services
It is R-Biopharm's ambition to accompany you as a reliable partner during planning, installation and also later in your daily routine. Therefore, R-Biopharm's application specialists are always on your disposal and work continuously on the improvement, updating and validation of all systems and instruments.

Molecular diagnostics

Product	Description	Units		Art. No.
RIDA®CYCLER	qPCR thermocycler 4 channels, incl. 1 box with reaction tubes (for research use only)	1	–	ZRCYCLER
RIDA®CYCLER-MIC-Tubes	Box with 960 reaction tubes and caps	1	–	ZRC-MIC-TUBES
RIDA®CYCLER TVS	Temperature verification system for RIDA®CYCLER	1	–	ZRCYCLER-TVS
RIDA®SEEK	Software for evaluation and documentation of RIDA®GENE real-time PCR kits	1	–	ZRIDASEEK

Immunoassay systems and evaluation software

	ELISA systems			
Dynex DSX®	Fully automated 4-microtiter plate analyzer with 2/4 incubators	1	–	Z65200 Z65400
Dynex Agility®	Fully automated 12-microtiter plate analyzer with 12 incubators	1	–	ZAGILITY
	ELISA reader and evaluation software			
RIDA®ABSORBANCE 96	Microtiterplate reader	1	–	ZRA96
RIDASOFT® Win.NET	Software for measurement, evaluation and documentation of RIDASCREEN® ELISA tests	1	–	Z9996

Rapid tests

RIDA®QUICK SCAN II - IVD SET	Lateral flow reader (CE-IVD) and 2D barcode scanner	1	–	ZRQS2-KD-SET
RIDA®QUICK SCAN II	Lateral flow reader (CE-IVD)	1	–	ZRQS2-KD
Honeywell Xenon 1900	2D barcode scanner for ZRQS2-KD	1	–	ZBS
RIDA®QUICK SCAN II Control strip	Control strip for control measurement on ZRQS2-KD	1	–	ZRQS2-KS-KD

Systems

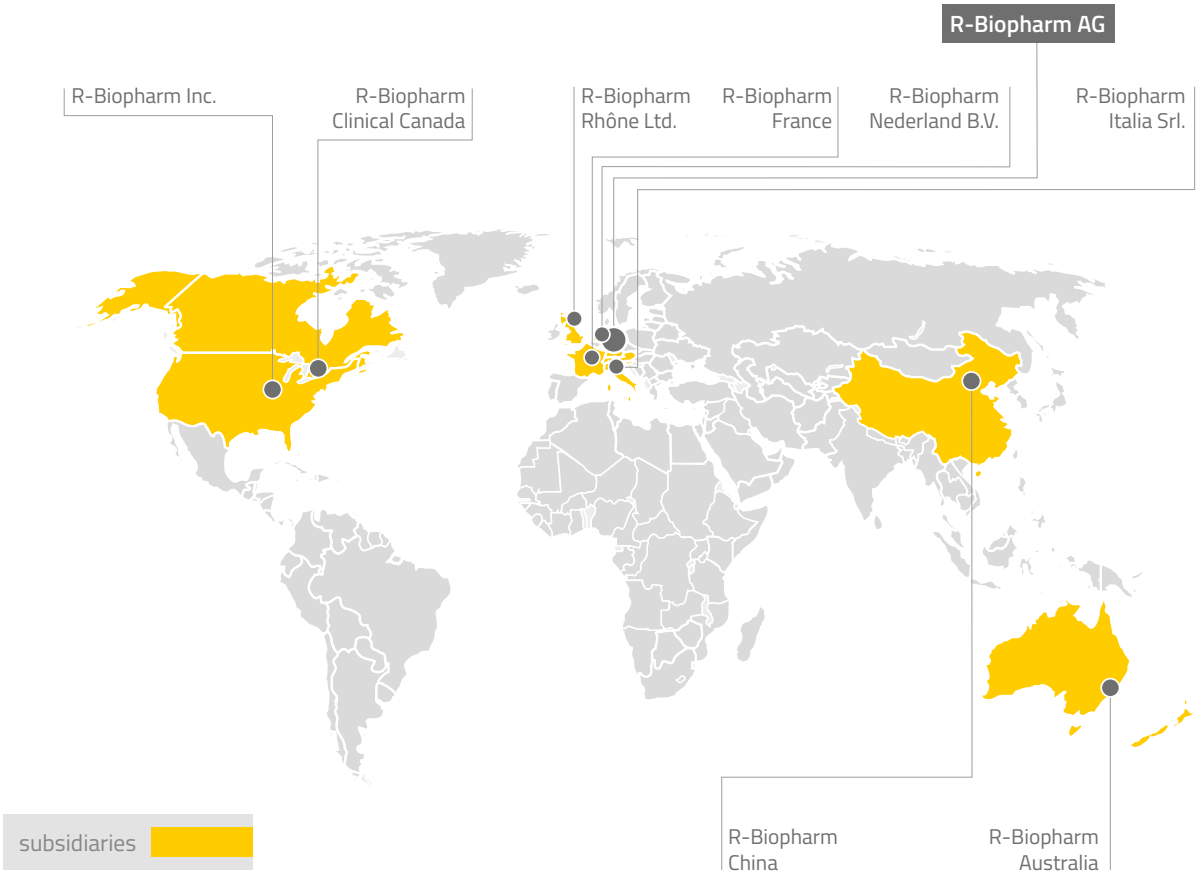
Blot systems and evaluation software

Product	Description	Units		Art. No.
RIDA qLine® autoBlot	Fully automated analyzer for 36 RIDA qLine® Allergy test strips	1	–	ZG3101
RIDA qLine® Orbital Shaker	Orbital shaker (100 - 240 V)	1	–	ZG2601
RIDA qLine® Scan	Reader for RIDA qLine® Allergy (CE-IVD)	1	–	ZG1109
RIDA qLine® QC-Kit	10 test strips for function control of the evaluation unit	1	–	ZG1108
RIDA qLine® Soft	Software for measurement, evaluation and documentation of RIDA qLine® test strips	1	–	Z9995
RIDA qLine® autoBlot Screw cap bottle 20 mL	Screw cap bottle (20 mL) for RIDA qLine® autoBlot Box of 120 pcs.	1	–	Z0011
RIDA qLine® autoBlot Screw cap for Z0011	Screw cap for Z0011 Box of 120 pcs.	1	–	Z0012
RIDA qLine® autoBlot Pipet tips	Pipet tips for RIDA qLine® autoBlot, Box of 100 trays á 96 tips = 9600 pcs.	1	–	Z0013
RIDA qLine® autoBlot Maintenance Pack	Maintenance pack for RIDA qLine® autoBlot	1	–	ZATB-F-MPK

Microspot array diagnostics

SpotSight® strip	Scanner for image acquisition and interpretation (strip)	1	–	Z-SP-STRIP-B
SpotSight® plate mono	Scanner for image acquisition and interpretation (plate)	1	–	Z-SP-PLATE-C

R-Biopharm Clinical – contact us



Headquarter
R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt, Germany
Phone: +49 (0) 61 51 - 81 02-0
E-mail: *csi@r-biopharm.de*

clinical.r-biopharm.com

Australia
R-Biopharm Australia
34 Woodfield Boulevard
Caringbah, NSW 2229
Phone: +61 (2) 2 - 9668 0600
Fax: +61 (2) 2 - 9668 8533
E-mail: *sales@labdiagnostics.com.au*

Canada
R-Biopharm Clinical Canada, Ltd.
181 Exeter Rd. Unit D
London, Ontario N6L 1A4
Canada
Phone: +1 (647) 667-1477
E-mail: *orders@r-biopharm.ca*

China
Suite 1903, Office Building A,
No. 6 Futong East Avenue
Chaoyang District, Beijing 100102
P.R. China
Phone: +86 (0) 10 – 84 58 32 18 -215
Fax: +86 (0) 10 – 84 58 06 91
Email: *info@r-biopharm.cn*

France
R-Biopharm France
Parc d'affaires de Crécy
5c rue Claude Chappe
69370 Saint-Didier au Mont D'Or
Phone: +33 (0) 4 78 64 32 00
Fax: +33 (0) 4 78 47 84 04
E-mail: *standard@r-biopharm.fr*

Italy
R-Biopharm Italia Srl
Via Morandi 10
20077 Melegnano MI
Phone: +39 (0) 2 - 9 82 33 330
Fax: +39 (0) 2 - 9 83 41 00
E-mail: *info@r-biopharm.it*

The Netherlands
R-Biopharm Nederland B.V.
Beijerinckweg 18
6827 BN Arnhem
Phone: +31 (0) 26 363 0 364
E-mail: *info@r-biopharm.nl*

United Kingdom
R-Biopharm Rhône Ltd.
Block 10 Todd Campus
West of Scotland Science Park
Acre Road, Glasgow
Scotland, G20 0XA
Phone: +44 (0) 141 - 945 - 2924
Fax: +44 (0) 141 - 945 - 2925
E-mail: *info@r-biopharmrhone.com*

USA
R-Biopharm Inc.
870 Vossbrink Dr.
Washington, MO 63090, USA
Phone: +1 (0) 8 77 - 7 89 - 30 33
Fax: +1 (0) 8 66 - 9 22 - 58 56
E-mail: *info@r-biopharm.com*

General terms & conditions of R-Biopharm AG

Stand: 11/2021

I. GENERAL PROVISIONS

1. Scope

1.1 These General Terms and Conditions ("GTC") apply to any and all deliveries as well as all work and services rendered by R-Biopharm AG, provided nothing to the contrary has been agreed. The GTC become a contractual component upon acceptance of an order and/or commission by R-Biopharm AG. The acceptance by R-Biopharm AG of the customer's order/ commission is subject to the express condition of the customer's agreement to the GTC of R-Biopharm AG.

1.2 R-Biopharm AG does not supply and render performance to consumers. Consequently these GTC are applicable solely to contractors, legal entities under public law and special funds under public law as defined in Section 310 of the German Civil Code [Bürgerliches Gesetzbuch ("BGB")] (hereinafter referred to as "customer"). Customer and R-Biopharm AG are referred to collectively below as "parties".

1.3 General terms and conditions of purchase and/or terms of business of the customer which conflict with these GTC shall have no validity even if there has been no express objection thereto, unless their validity has been expressly agreed by e-mail, fax, (text form) or in writing.

1.4 These GTC shall apply in the version applicable at the time. R Biopharm shall inform the customer promptly of any amendments to the GTC where business relations are ongoing.

2. Sub-contractors and Assignment

2.1 In the absence of any personal performance being agreed, R Biopharm AG shall be entitled to use the services of third parties to perform its contractual obligations.

2.2 The assignment to third parties of rights and obligations from an order/commission is permitted, in particular in the case of Section 354a HGB [German Commercial Code] (Assignment of pecuniary claims in commercial transactions). In particular, orders of R Biopharm AG may be assigned to other companies belonging to the R Biopharm Group without the consent of the customer.

3. Order Confirmation and Conclusion of the Contract

3.1 Orders and/or the commissioning of work and services may be placed by mail, by phone, by fax, by e-mail using the contact details of R Biopharm AG available from https://r-biopharm.com/de/kontakt/. The webshop GTC apply to orders made via the R-Biopharm AG webshop.

3.2 Orders and/or the commissioning of work and services, in any form, are only legally binding if they have been confirmed by R Biopharm AG in text form or in writing ("order confirmation").

3.3 It is tantamount to an order confirmation if R-Biopharm AG makes the delivery or, in the case of work/service, commences performance of service or accepts the customer's payment for the supply or service.

3.4 The order confirmation ensues subject to correct and timely supply by our suppliers.

3.5 R-Biopharm AG is entitled to make over- or under-deliveries of up to 5% compared to the order amount.

4. Place of Performance, Transportation, Partial Delivery and Delivery Period

4.1 All deliveries/services are provided in accordance with Incoterms 2020 ex works; place of performance is the registered office of R-Biopharm AG, An der neuen Bergstrasse 17, 64297 Darmstadt.

4.2 The customer agrees to partial deliveries and/or partial services.

4.3 Where delivery/performance times are given in the order confirmation, these dates are estimated and non-binding.

4.4 Para. 4.1. to 4.2 shall apply unless agreed otherwise between the parties. For reasons of proof, these agreements must at least be in text form.

4.5 Should R-Biopharm AG be unable to meet the stated delivery/ performance time, it will inform the customer in text form, stating the anticipated new delivery/performance time.

5. Retention of Title

5.1 The goods/work supplied to the customer by R-Biopharm AG shall remain the property of R-Biopharm AG until such time as payment has been made in full ("retained goods").

5.2 The customer has the right to use and dispose of the retained goods in the normal course of business, provided said customer is not in default. The customer hereby assigns the claims for payment resultant from any such re-sale to R-Biopharm AG in full. R-Biopharm AG shall have the right to collect these receivables in its own name and for its own account. R-Biopharm AG shall revocably authorize the customer to collect the receivables in their own name but for the account of R Biopharm AG unless the customer is in default. In the event of default, the customer will not be entitled to resell the goods until ownership thereof is passed to them.

In the event of third parties accessing the retained goods, the customer must inform R-Biopharm AG promptly in writing and also advise the third parties in writing of the ownership of R-Biopharm AG. Furthermore, the customer is not entitled to use the retained goods or dispose of them.

6. Safety Data Sheets

6.1 The customer agrees to have the safety data sheets provided in the form of a direct link in the test kit instructions for use. If this link does not work, R Biopharm AG shall furnish the required data at first request during normal business hours.

6.2 If the customer wishes to receive the safety data sheets in paper form, they shall inform R Biopharm AG of this when placing the order/commission.

7. Export Control

7.1 R-Biopharm AG is under no obligation to provide deliveries of goods which, due to their nature or their intended use or envisaged end place of use, are subject with regard to export control to a duty to obtain a permit as a result of relevant export regulations and embargos, in particular those of the European Union (EU), Germany or other EU Member States and the USA;

7.2 The goods supplied to the customer are in principle intended to remain at the customer's. The provided goods must not be resold without the written consent of R-Biopharm AG. In the event of said consent, the customer must ensure that the buyers or end-users of the goods are not the military, paramilitary, the police or intelligence services or that

the goods are not intended for the administrations of the aforementioned bodies or for other administrations working for the aforementioned bodies. The customer must also ensure that the goods do not pertain to nuclear or weapons facilities and/or uses or are used for these purposes, they are not passed on to companies and persons who are abstractly or specifically named in the context of an embargo and/or export restriction of the Federal Republic of Germany, the EU or the USA, and no military recipients are supplied with them.

7.3 The customer must furnish R-Biopharm AG free of charge with all the information the latter requires as regards meeting its obligations in the context of export control.

7.4 The customer shall indemnify R Biopharm AG against any and all damage which R Biopharm AG sustains as the result of culpable breach of the obligations pursuant to para. 7.1-7.3 above.

8. Remuneration/Price

8.1 R-Biopharm AG may charge the customer a small order surcharge of 10 EUR for orders of goods with a value of up to 300 EUR ("small order").

8.2 Unless agreed otherwise, the remuneration shall be taken to be exclusive of the respective statutory value added tax.

8.3 Fees, commissions and costs charged by financial institutions for the services they have provided shall in each case be borne by the parties.

8.4 In the case of importing abroad, additional taxes or costs (e.g. customs duties) may accrue which are not paid or billed by R Biopharm AG, but are payable directly to the competent customs or tax authorities by the customer; unless agreed otherwise in text form, these shall be borne by the customer.

8.5 Expenses for outlays (e.g. cost of travel and overnight stay) will be reimbursed upon presentation of the original receipts. Travel times are regarded as working times and are in principle included in the remuneration.

9. Invoice, Due Date and Default

9.1 If the customer has registered for electronic billing, the customer will receive the bill by e-mail when their order is ready for dispatch or when performance can commence; otherwise the customer will receive the bill in paper form.

9.2 Unless agreed otherwise, payments fall due after 30 (thirty) days.

9.3 The customer may settle bills before the due date; there is in principle no right for deduction of a discount.

9.4 The customer may pay exclusively by bank transfer.

9.5 R-Biopharm AG may refuse deliveries/services or only render them against pre-payment if the customer is in default with other payment obligations vis-à-vis R-Biopharm AG.

9.6 Should any circumstances occur subsequent to concluding the contract which indicate that the customer cannot meet their payment obligation (e.g. because the customer is in default with another payment obligation vis-à-vis R Biopharm AG), R Biopharm AG shall be entitled to set the customer a reasonable period within which they must either contemporaneously pay for the service or furnish security. After fruitless expiration of this period, R Biopharm AG shall have the right to withdraw from the contract and demand compensation for the damage incurred or reimbursement of fruitless expenditure.

9.7 The customer shall only be entitled to setoff if their claim is uncontested or declared non-appealable in a court of law or if there is a reciprocity between their counter-claim and that of R Biopharm AG as defined in Section 320 BGB or their claim has been recognized by R Biopharm AG.

9.8 If the customer is in arrears with a payment, interest will be payable pursuant to Section 288 (2) BGB, as well as lump-sum damage due to delay pursuant to Section 288 (5) BGB. We reserve the right to claim higher interest and further damage. The flat fee for default will be credited against any damages.

10. Force Majeure

10.1 If, subsequent to concluding the contract, a force majeure event or circumstance should occur which prevents a party from meeting one or more contractual obligations (e.g. war or civil war, terrorist acts, piracy, trade restrictions, embargo, sanctions, plague, pandemic, epidemic, natural disaster, or extreme natural event, general industrial unrests etc.), the party shall be released from their contractual obligations, liability for damages or other contractual legal remedies based on breach of contract from the point in time when the obstacle rendered performance of service impossible if they inform the other party promptly; otherwise from the point the notification was received.

10.2 If the effect of the asserted obstacle is temporary, the consequences will apply for as long as the obstacle prevents performance of the contract by the affected party. Where the effects persist for longer than 120 (one hundred and twenty) days and the result is that the parties are deprived of what they might justifiably expect by virtue of the contract, both parties shall be entitled to terminate the contract in writing at 2 (two) weeks' notice.

10.3 A party may then only plead force majeure if they demonstrate that the obstacle is beyond their reasonable control, was not reasonably foreseeable at the time the contract was concluded and the effects could not reasonably have been prevented or overcome by the party concerned. The affected party must take all reasonable steps to limit the effects of the obstacle.

11. Obligations to Give Notice of Defect, Acceptance, Defect Claims

11.1 R-Biopharm AG warrants that its products are consistent with the communicated specifications.

11.2 The customer shall inspect the goods immediately upon delivery. Obvious material defects (damage in transit, missing or inadequate packaging, incorrect delivery, incorrect quantity etc.) must be notified promptly by the customer, at the latest on the working day following delivery. The customer shall also inspect the goods for identifiable quality defects without delay, at the latest within 3 (three) working days from delivery, and shall inform R Biopharm AG of these no later than 2 (two) working days after completing the inspection. If inspection of the goods takes longer e.g. because a time-consuming analysis is necessary, the customer must inform R-Biopharm AG of this in writing at the latest at the time when the contract is concluded; otherwise the inspection and notification periods above will apply.

Notice of hidden material defects that are not revealed during an inspection as defined in para. 11.2 but only in the course of later use or later processing must be given in writing or in text form immediately upon detection, at the latest within 2 (two) working days after detection, and within the warranty period pursuant to para. 11.4.

11.3 Any notification of defects not made in due time or form shall preclude any claim by the customer based on breach of duty due to material defects. This does not apply in the case of intentional, grossly negligent or malicious acts by R-Biopharm AG, in the event of injury to life, limb or health

or assumption of a guarantee of freedom from defects, or a procurement risk pursuant to Section 276 BGB or other bases of liability mandatorily specified by law.

11.4 In the absence of anything to the contrary expressly agreed in writing or in text form, R-Biopharm AG will provide guarantee for defects in quality and title for a period of 12 months (or in the case of products with a shorter shelf life, until expiration of the use-by date), calculated from the date of the passing of risk (see para.11.1), or in the case of the customer's rejection or refusal to take delivery, from the time of notification that the goods are made available until their acceptance. This does not apply to damage claims from a warranty, assumption of a procurement risk within the meaning of Section 276 BGB, claims in respect of injury to life, limb or health, malicious, intentional or grossly negligent acts by R-Biopharm AG, or if otherwise a longer limitation period is mandatorily stipulated by law. Section 305 b BGB (the priority of individually agreed terms in verbal or text or written form) remain unaffected. The provision above does not entail a reversal of the burden of proof.

11.5 The guarantee of R-Biopharm AG (claims arising from breach of duty through defective performance in the case of material defects) and the liability resultant therefrom is excluded to the extent that defects and damage associated with them are not demonstrably based on defective material, defective design, or on defective execution, or defective manufacturer materials or, if provided, defective instructions for use. In particular, the guarantee and liability for breach of duty through defective performance arising therefrom is excluded for the consequences of incorrect use, unsuitable storage conditions, and for the consequences of chemical, electromagnetic, mechanical or electrolytic effects. The aforegoing does not apply if this is consistent with the average standard effects in our product description or in a differently agreed product specification or the R Biopharm AG product-specific data sheet in each case or those envisaged by the manufacturer as well as in the case of malicious, grossly negligent or intentional acts by R Biopharm AG, or injury to life, limb or health, the assumption of a warranty, procurement risk pursuant to Section 276 BGB, or any basis for liability mandatorily specified by law.

11.6 R-Biopharm AG assumes no guarantee pursuant to Sections 478, 479 BGB (Recourse in the supply chain - supplier's recourse) if the customer has treated or processed or otherwise changed the products supplied by R-Biopharm AG under the contract, unless this is consistent with the contractually agreed intended purpose of the products. The aforegoing does not apply in the case of malicious, grossly negligent or intentional acts by R-Biopharm AG, or injury to life, limb or health, the assumption of a warranty, procurement risk pursuant to Section 276 BGB, or any basis for liability mandatorily specified by law.

11.7 In the event of a defect in title R-Biopharm AG may at its own discretion either change or replace the material and/or product or the commissioned performance in such a way that there is no longer any defect in title or procure a usufructuary right for the customer. If the above is not possible, R-Biopharm AG shall have a right of termination.

11.8 The recognition of breaches of duty always requires written form. Section 305b BGB (priority of individually agreed terms) remains unaffected.

11.9 The exceeding of use-by dates subsequent to performance is not a material defect unless a specific storage life has been agreed between the parties.

12. Liability

12.1 R-Biopharm AG has unlimited liability for any damage resultant from intentional or grossly negligent breach of duty, injury to life, body or health, breach of material contractual obligations (obligations that are material to achieving the contractual purpose and on whose compliance the other party to the contract may generally rely), in the event of delay where a fixed delivery date has been agreed, in the event of the assumption of a guarantee for quality or successful performance or assumption of acquisition risk and bases of liability mandatorily specified by law, in particular the German Product Liability Act [Produkthaftungsgesetz] and intent to deceive. In all other cases, liability for slight negligence is limited to damage that is typical and foreseeable for this type of agreement. The liability provisions set forth above also apply to the liability of the legal representatives, salaried staff and agents of R Biopharm AG.

12.2 Further claims in respect of or in connection with defects or consequential harm caused by a defect on any grounds whatsoever exist solely in accordance with the provisions under para. 10.

13. Intellectual Property

13.1 Unless agreed otherwise in writing, each party shall remain sole proprietor and beneficial owner of their intellectual property, including specialist knowledge, copyrights, trade secrets and other intellectual property, regardless of their protection under registry law.

13.2 Unless agreed otherwise in writing, the simple, non-transferrable, non-sublicensable right of use and exploitation, limited to the contractual purpose in terms of time, territory and content, of all the services provided individually for the customer (in particular but not limited to documentation, graphs, drafts, concepts etc.) in all known and unknown types of use and exploitation for commercial and non-commercial purposes passes to the customer upon acceptance in the case of work performance, upon rendering of the service in the case of services. The customer accepts this transfer of rights.

13.3 As regards services not provided individually for the customer and/or materials to which R-Biopharm AG held proprietary rights or rights of disposal prior to contractual performance e.g. to standard works ("starting material") developed or used before being commissioned, R Biopharm AG shall grant the customer a simple, non-transferrable, non-sublicensable right of use, limited to the contractual purpose in terms of time, territory and content, in all known and unknown types of use, if this starting material is incorporated in the results of performance.

13.4 The customer is not entitled to use the name of R-Biopharm AG, its corporate logo or trade marks of R-Biopharm AG and its affiliated companies as a reference or for self-promotion without prior consent in written or text form. In the event of consent, the customer agrees to comply with the design specifications of R-Biopharm AG and to use logos of the best possible quality and give them equivalent prominence to other logos displayed; distortions, color adaptations, retouching or other changes are not permitted. Consent may be revoked at any time; it is not transferrable to third parties and will expire upon termination of the contractual relationship.

14. Staging and Samples

14.1 Items required for performance of the contract provided or otherwise made available by R-Biopharm AG (in particular substances, materials or other documents) remain the property of R-Biopharm AG. They may only be used to achieve the contractual purpose; reverse engineering is not permitted.

14.2 Any utilization for other purposes and the disclosure to third parties is only permitted with prior consent by R-Biopharm AG in text form. Subject to the assertion of further claims, R-Biopharm AG may demand the return of its items if the contractual party breaches these obligations.

14.3 R-Biopharm AG shall be or become joint owner of the products made using its items in proportion to the value of the staging and/or the item provided as compared with the value of the product. The contracting party must pay compensation for impairment or loss.

15. Exchange/Returns/Complaints

15.1 Exchange/returns is in principle only possible on legal grounds (in particular in the event of a material defect within the warranty period).

15.2 In principle, goods are not taken back for any other reason (e.g. products ordered incorrectly).

15.3 In the event of a complaint, the customer shall ask R Biopharm AG regarding the process to be followed by means of which the complaint can be filed.

15.4 Should the analysis of material be required for a complaint, personal details on these materials must be removed and only the data required for processing the complaint should be communicated. The material can be destroyed once the complaint has been processed, unless agreed otherwise between the parties in text form.

15.5 If, despite the absence of any legal obligation, R Biopharm AG should by way of exception be prepared to take back items, R Biopharm AG may charge a fee in the sum of 25% of the respective gross selling price for handling the returns, inspecting the goods and returning them to stock or disposal (fee for returns). In the event of any such return as a goodwill gesture, shipping costs and other fees (e.g. customs duties) and the fee for returns are deducted from the total amount credited or billed to the customer subsequently.

15.6 Each product return must be pre-authorized by R Biopharm AG customer service, available on working days from 9 am -1 pm on +49 (0) 6151/8202-0. The customer will not be given credit for products returned without prior consent in text form from R-Biopharm AG. If, at its own discretion, R-Biopharm AG authorizes a product for return, the product must arrive at R-Biopharm AG in a satisfactory condition for resale (including original packaging and refrigerated packaging if applicable). The products must be sent in accordance with Incoterms 2020 “free to destination“, DDP R-Biopharm AG, An der neuen Bergstraße 17, 64297 Darmstadt, Germany, and arrive at the destination between 9 am -5 pm on working days.

15.7 The claims of the customer in respect of defective, damaged or incorrect products as defined in para. 11 and the liability of R Biopharm AG pursuant to para. 12 remain unaffected.

16. Confidentiality

16.1 Our customer agrees to treat the confidential information of R Biopharm AG as confidential and to use, exploit, disclose it and/or make it accessible solely for the contractual purpose, unless the parties have agreed otherwise in writing.

16.2 Confidential Information is any and all information communicated for the contractual purpose, in particular all financial, technical, legal, fiscal information relating to the business activities of R Biopharm AG, confidential know-how i.e. identifiable knowledge or experience that is only accessible to a very limited group of people, can be objectively customized and has a commercial value, trade secrets within the meaning of Section 2 (1) German Act on the Protection of Trade Secrets [Gesetz zum Schutz von Geschäftsgeheimnissen (“GeschGehG”)] and items provided for performance of the contract or samples of R Biopharm AG and collaboration with R Biopharm AG.

16.3 Confidential information that at the time of disclosure is common knowledge, has been published, is part of common general knowledge, is general state of the art, is individually known to the recipient customer, was developed by the customer without recourse to the confidential information is an exception to this. If the customer wishes to rely on these exceptions, they must inform R Biopharm at least in text form within 14 (fourteen) days of notification of the information.

16.4 If, due to a binding official or judicial order or mandatory legal provisions, the customer is obligated to communicate confidential information of R-Biopharm AG to a court, government agency or another body, they may disclose the confidential information only to the extent that is strictly necessary, and only when they have informed R Biopharm AG without delay beforehand in writing as regards the obligation to communicate and R-Biopharm AG has been given the opportunity to take measures to protect its Confidential Information. This does not apply if prior notification of R-Biopharm AG is impossible due to the nature of the measure.

16.5 Confidential Information shall only be disclosed on a “need-to-know” basis to persons inside the customer’s company who have accordingly been bound to maintain confidentiality and restricted use. The customer may disclose confidential information to third parties to the extent strictly required for performance of the contract and if the third party has accordingly been bound to maintain confidentiality and restricted use.

16.6 The customer shall prevent the unauthorized disclosure, use or publication of confidential information, in particular its dissemination or publication, destruction or loss with the same degree of diligence as they use to protect their own information of a similar kind; however at least with entrepreneurial due diligence (where “entrepreneurial due diligence” shall have the same meaning as in Section 2 (7) German Act on Unfair Competition [Gesetz gegen den unlauteren Wettbewerb (“UWG”)]: “standard of special skill and care towards consumers to which an entrepreneur can reasonably be expected to conform, commensurate with good faith and having regard to honest market practices in the entrepreneur’s field of activity).

16.7 Reverse engineering is not permitted.

16.8 R-Biopharm AG shall hand over the confidential information as it stands. It makes no warranty and/or guarantee that the confidential information provided is complete, correct or customary in the trade or can be used by the customer for the contractual purpose. R Biopharm AG shall not be held responsible for damage incurred by the customer through the use or disclosure of Confidential Information or as the result of their reliance on the completeness, correctness, being standard commercial practice, or suitability for the contractual purpose. In particular, R-Biopharm AG shall not be responsible for the potential infringement of rights of third parties.

16.9 No provision of this confidentiality agreement shall be understood explicitly or implicitly as the transfer of a right or granting of a license with regard to the Confidential Information or matters which the Confidential Information contains. The Confidential Information and matters contained in the Confidential Information shall remain the property of R Biopharm AG.

16.10 The use of Confidential Information must cease immediately upon request by R-Biopharm AG, at the latest after achieving the contractual purpose, unless otherwise agreed. Confidential Information in tangible form, in particular but not limited to documents, items and storage media, samples, specimens, other materials etc., must be returned to R Biopharm AG by the customer or destroyed if so requested. Confidential information stored electronically must be erased completely and irrevocably. This does not apply to automatic back-up copies of the electronic data flow and those of a disaster recovery system up to the usual erasure thereof. The customer shall be entitled to keep a copy of each in their confidential files in order to demonstrate that they are complying with para. 16; the same applies if a statutory retention period stands in the way of the return or destruction. The provisions of this para. 16 apply to these copies.

16.11 The confidentiality obligation applies for up to 5 (five) years after order confirmation by R-Biopharm AG.

17. Data Protection

17.1 The customer agrees to comply with the principles of the European General Data Protection Regulation (EU GDPR) and those of the German Federal Data Protection Act (BDSG new). In so doing the customer shall in particular ensure that the employees entrusted with the processing of the data are bound to confidentiality (formerly data secrecy) and have been instructed as to the relevant data protection provisions. The customer is also obligated to protect the personal data in accordance with the state of the art, having regard for Article 32 GDPR.

17.2 The customer may only disclose information and data of R Biopharm AG to third parties with express written consent.

17.3 If the customer processes personal data in order to provide the contractual service for R-Biopharm AG, the parties shall conclude a separate contract processing agreement to this end in accordance with Article 28 EU GDPR.

17.4 R-Biopharm AG processes the data transmitted to it exclusively for the purpose of performing the contract with the respective customer. Further information concerning data protection pursuant to Article 13 and Article 14 GDPR is available from the Privacy Notice on the R Biopharm AG website: https://r-biopharm.com/de/datenschutzerklaerung/

18. Compliance, Anti-corruption

The customer shall not either themselves or through third parties, within their company and supply chain, offer, promise or grant inducements and/or other advantages to employees and/or members of executive bodies of R-Biopharm and its members so that they are favored in competition or certain acts are performed or omitted. The same applies vis-à-vis third parties, in particular public bodies.

19. Miscellaneous (Written Form, Escape Clause, Choice-Of-Law)

19.1 Amendments and addenda require written form for reasons of proof.

19.2 German law shall apply, to the exclusion of the conflict-of-law provisions and the United Nations Convention on the International Sale of Goods. The place of jurisdiction is Darmstadt, Germany.

19.3 The English version serves purely as a translation. The German language shall be authoritative for the interpretation of the GTC.

II. ADDITIONAL PROVISIONS FOR SOFTWARE

The following applies as regards software contained in our products: however we do not license or sell it. Unless agreed otherwise, our licenses are non-exclusive, non-transferrable, non-sublicensable, revocable licenses to use the software for internal company purposes on the purchased hardware products at the registered office or site where the device is located.

R-Biopharm AG will install the software, unless provided for otherwise. R-Biopharm AG is not in principle under any obligation to provide updates. R-Biopharm AG agrees to support the software only within the warranty period as defined in para. 11.4.

Our customer agrees to treat the software as confidential pursuant to para. 16 of these GTC and not to sell, rent, lend, license it or otherwise make it available to third parties. Reverse engineering, decompiling, other modifications or additions are not permitted. Copies are only permitted with prior written consent of R-Biopharm AG. In the event of an infringement of this section, R-Biopharm AG shall be entitled to immediate termination of the license without notice. Upon receipt of the notice of termination, the customer must return the software to R Biopharm AG immediately, including documentation pertaining to it.

The provisions concerning guarantee and indemnity in para. 11 do not relate to third-party software which we provide for our customers. In this case, however, we assign to the customers any and all the warranty rights we hold vis-à-vis the third party. Software must be used in accordance with the user documentation supplied to the customer. R-Biopharm shall not be held responsible for damage that is incurred because the customer does not use the software in accordance with the user documentation.

R-Biopharm only accepts liability for data loss on its premises up to the amount of the typical cost of recovery in the case of normal data backup consistent with the state of the art.

R-Biopharm
An der neuen Bergstraße 17, 64297 Darmstadt, Germany
E-mail: *orders@r-biopharm.de*
clinical.r-biopharm.com

01/2022