

RIDASCREEN® Sero ELISAs provided with additional control samples

All RIDASCREEN® Sero ELISA test kits supplied by R-Biopharm AG will contain two additional control samples for internal laboratory quality assurance and are available now.



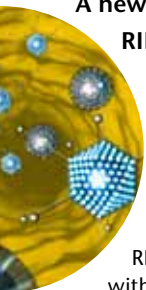
In Germany the new Guidelines of the German Medical Association for Quality Assurance of Laboratory Medical Examinations (also known as the "RiLiBÄK rules") stipulate that medical laboratories should use control samples for quality assurance. In accordance with these guidelines, R-Biopharm AG is currently providing all German customers with two additional control samples in its RIDASCREEN® Sero ELISA tests kits.

To allow our international customers to take advantage of this enhanced capacity for internal laboratory quality assurance, all RIDASCREEN® Sero ELISA test kits will contain two additional control samples

(RIDASCREEN® Sero ELISA Controls A and B). These controls consist of human sera with different antibody concentrations for optimal implementation. The controls are lot-specific, and the target values and nominal ranges of all control sera are documented on the respective certificates of analysis. A successive transition to the new test format will be made with each new batch of the respective RIDASCREEN® Sero ELISA test kits manufactured.

All new versions of the test kits are available under the same article numbers as before, and they contain a yellow note providing information about the version change.

RIDA®QUICK Rotavirus/Adenovirus – Combined positive control available



A new positive control for the RIDA®QUICK Rotavirus and RIDA®QUICK Rotavirus/Adenovirus Combi rapid tests is now available.

RIDA®QUICK Rotavirus/Adenovirus Combi Control is a ready-to-use combined positive control for both rotavirus and adenovirus.

It can be used in the corresponding RIDA®QUICK rapid tests directly without further preparation.

It replaces the former separate controls for rotavirus (NP0904) and adenovirus (NP1004).

The new combined control is available under Art. No. NP1904.

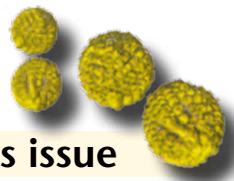
If you are interested in our products,

please contact your local distributor.

Fairs and Conferences



16.04. – 19.04.2011	65 th CMEF Spring 2011 / 12 th ICMD Shenzhen, China
07.05. – 10.05.2011	ECCMID Milan, Italy
08.05. – 11.05.2011	CVS, Daytona Beach Florida, USA
05.06. – 08.06.2011	APHL Omaha, Nebraska, USA
11.06. – 15.06.2011	EAACI Istanbul, Turkey
24.07. – 28.07.2011	AACC Atlanta, Georgia, USA



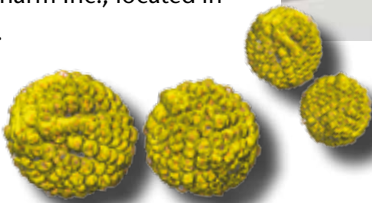
... and the very best at the end of this issue

With effect of February 23th 2011 the FDA has cleared the RIDASCREEN® Norovirus 3rd Generation Elisa as the first assay at all in the USA for detection of Noroviruses of genogroup I and II in human stool samples.

R-Biopharm AG is proud to announce that the test will be marketed very soon in the specially designed US-Version by their US subsidiary R-Biopharm Inc., located in Washington, MO.



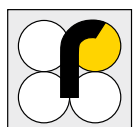
FDA cleared
510(k)-No. K093295



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Lead article

A well coordinated team: Maxwell[®]16 and RIDA[®]GENE

Dr. Andreas Simons

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Automated purification and real-time PCR

The isolation and purification of DNA and RNA has a major impact on the quality, sensitivity, and specificity of subsequent

real-time PCR analysis, which is gaining increasing relevance in the diagnostic laboratory.

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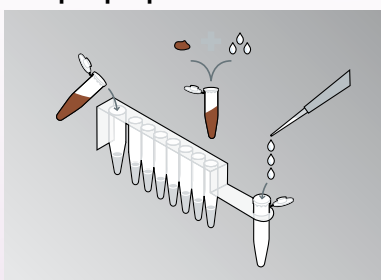
Automated purification and real-time PCR with Maxwell[®] 16 and RIDA[®] GENE

Automated purification using Maxwell[®]16 by Promega Corporation and subsequent real-time PCR analysis using the RIDA[®]GENE test kit by R-Biopharm allows for the reliable detection of noroviruses and *Clostridium difficile* in human fecal samples. Inhibition of the PCR can be nearly excluded. With the Maxwell[®] 16 system, purification is

accomplished using prefilled reagent cartridges containing all of the necessary reagents. Up to 16 samples can be purified in parallel. The detection of pathogens in fecal samples is accomplished in less than 60 minutes in the case of *Clostridium difficile*, and in less than 90 minutes in the case of Norovirus.

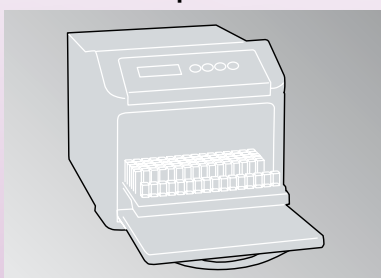
From sample preparation to results in only 3 steps:

1 Sample preparation



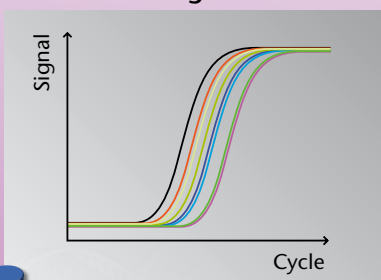
- transfer liquid stool sample or suspended stool sample into cartridge
- pre-load elution buffer

2 Isolation and purification with Maxwell[®] 16

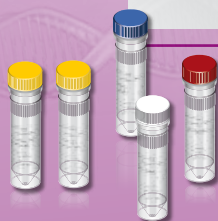


- place cartridge(s) into instrument
- run program
- result: pure DNA/RNA

3 Detection using RIDA[®] GENE kit



- high sensitivity and specificity
- contains all necessary components
- can be run on commonly used real-time PCR instruments
- internal amplification control
- CE-certified and QCMD interlaboratory tested



flexible

reliable

rapid

R-Biopharm AG expands its molecular diagnostics product portfolio

The new RIDA®GENE CD Screen and RIDA®GENE CD Toxin A/B real-time PCR test variants "V" and "LC" are available since the beginning of the year, and can be run on commonly used real-time PCR instruments.



RIDA®GENE CD is a real-time PCR assay for direct, qualitative detection of *Clostridium difficile* (16s-rDNA) in stool specimens, whereas RIDA®GENE CD Toxin A/B detects the *Clostridium difficile* toxin A (tcdA) and B (tcdB) genes.

The RIDA®GENE Norovirus I & II real-time PCR is also now available for detection and differentiation of norovirus genogroups I and II. Likewise, it can also be run on commonly used real-time PCR instruments.

Each RIDA®GENE kit is sufficient for 100 tests. All components needed for the specific pathogen detection are ready-to-use. The analytical sensitivity of the RIDA®GENE CD kits is ≤ 5 DNA copies per reaction. The RIDA®GENE Norovirus I & II kit can detect ≤ 50 RNA copies per reaction. The use of an internal amplification control ensures reliable results and excludes false negative results. All RIDA®GENE kits are CE-certified and are regularly evaluated in Quality Control for Molecular Diagnostics (QCMD)* interlaboratory testing.

* (Quality Control for Molecular Diagnostics)

RIDASCREEN® Parvovirus B19 – New ELISA Version

A new and improved version of the RIDASCREEN® Parvovirus B19 IgG test by R-Biopharm is now available.



In the new version of the RIDASCREEN® Parvovirus B19 IgG ELISA the baculovirus expression system will be used for production of the recombinant viral capsid proteins VP1 and VP2 starting immediately. The previous version of the test kit utilized the prokaryote *Escherichia coli* for expression of the proteins.

The switch to the baculovirus expression system results in a significant enhancement of the detection of parvovirus B19 in human serum.

Patients infected with parvovirus B19 develop not only IgM antibodies, but also specific IgG antibodies that are directed against linear and conformational epitopes of the viral capsid proteins VP1 and VP2.

The IgG antibodies directed against the linear epitopes significantly decrease in number or completely disappear within a period of about 6 months.

After this period, the bulk of the antibodies present in the serum are mainly comprised of antibodies directed against the conformational epitopes. Consequently, the systems that use the antigens expressed by *E. coli* can be less effective at detecting past infections (> 6 months old) because the *E. coli* bacteria only express denatured antigens with linear epitopes.

Baculovirus, on the other hand, expresses both the linear and the conformational epitopes of VP1 and VP2, making it possible to detect both acute and past parvovirus B19 infections.

This switch to the baculovirus expression system makes the optimized RIDASCREEN® Parvovirus B19 IgG ELISA test kit by R-Biopharm AG a highly specific and sensitive assay that meets all requirements for state-of-the-art serological Parvovirus B19 diagnostics.

The new version of the assay has the same catalog number (K6021) as before but the words „New Version“ are stamped on the

outer packaging and a yellow note containing information about the version change is enclosed.

Products for the specific detection of parvovirus B19:

Products	Assays	Art.No.
RIDASCREEN® Parvovirus B19 IgG	96	K6021
RIDASCREEN® Parvovirus B19 IgM	96	K6031
RIDA®BLOT Parvovirus B19 IgG/IgM	20	L6003
RIDA®LINE Parvovirus B19 IgG	20	LB6023
RIDA®LINE Parvovirus B19 IgM	20	LB6033

Automated allergy diagnostics now possible with Gemini and DS2

Allergy diagnostic tests by R-Biopharm can now be run on automated ELISA systems and is available now. Application protocols are now available for the DS2 system by Dynex Technologies and for the Gemini system by Stratec.

Plates which are either preloaded with allergen discs by R-Biopharm or are individually assembled by the customer can now be performed in a fully automated process on these two ELISA machines.

With the aid of the A.M.Sys Allergy Management Software, the systems import the external pipetting work lists and then evaluate the test results and compile test reports after the test run is completed.

The allergy diagnostic tests supplied by R-Biopharm are based on conventional allergen disc technology. Selected from a range of approximately 700 different allergens, the target allergens are bound to individual cellulose discs and inserted into the wells of the microtiter plates. In the first incubation step, the patient's serum is pipetted into the microtiter plate containing the different allergens.

If any specific IgE antibodies are present in the patient's serum, they will bind with the allergens on the cellulose discs. The remainder of test procedure is analogous to that of a normal ELISA, i.e., the intensity of substrate staining corresponds to the amount of bound antibodies and a quantitative readout is obtained using a standard curve supplied with the kit. R-Biopharm AG has introduced custom microtiter plates with allergen discs assembled according to the individual customer specifications. This gives physicians the option to individually select and test allergens for each patient from the entire range of available allergens.

If you have questions regarding these applications or the equipment setup, please contact your local distributor or the international sales department of R-Biopharm AG, Germany.



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