

Stool Diagnostics – Antigen Detection

New – RIDASCREEN® Norovirus 3rd Generation ELISA Simple and reliable!

Noroviruses are responsible for a large share of acute viral diarrheal diseases worldwide.

They are transmitted through smear infections or via the air way through vomiting, as well as from contaminated food and water. The high contagiousity of this pathogen is highlighted by the increased occurrence of norovirus diseases in community facilities. Often preschools and hospitals are affected, but also hotels and cruise ships. Norovirus infection is particularly dangerous for children and the elderly.

The disease is characterized by a sudden onset of vomiting and diarrhea.

In the interests of public health monitoring, mandatory reporting in accordance with the Law for the Prevention of Infection (Infektionsschutzgesetz, IfSG) has been in place in Germany since 2001. Furthermore, the avoidance of such outbreaks is the task of hygiene management in community facilities, in order to prevent more widespread consequences for health and the economy. This requires the introduction of the necessary hygiene measures, as well as the reliable identification of those affected to avoid further propagation.

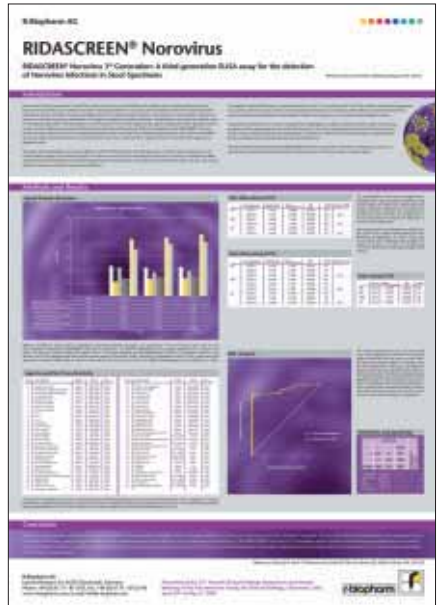
Today the detection of noroviruses is performed by ELISA or PCR. Not only are high demands placed on the sensitivity and specificity when evaluating a method, but also increasingly on its practicability in routine operation. Last but not least, the costs play an enormous role in the choice of a method.

With the RIDASCREEN® Norovirus 3rd Generation ELISA this has been taken into account. The combination of cross-reactive monoclonal antibodies for the first time allows the detection of all common norovirus variants. These antibodies are directed towards various epitopes of the virus, which allows simultaneous detection of the different genotypes.

The clinical performance features of the RIDASCREEN® Norovirus 3rd Generation

ELISA were determined in a clinical study with 183 retrospective samples from the winter season 2004/2005 and 2006. RT-PCR served as a standard for ascertaining the diagnostic sensitivity of 83% and the specificity (100%). No cross-reactivity with other pathogens of the intestinal tract could be detected.

All the data were presented this year as a poster at the 23rd Annual Clinical Virology Symposium in Clearwater, USA.



We would be pleased to send you this poster as a PDF or as an A3 color print. Please contact Tel: 0 61 51 - 81 02-0 or e-mail: info@r-biopharm.de

The new RIDASCREEN® Norovirus 3rd Generation ELISA combines the following properties:

- Optimized sensitivity and specificity
- Reliable detection in the case of outbreaks and individual cases
- Very simple and fast to perform
- Cost-effective



2. Interdisciplinary EHEC Workshop in Wildbad Kreuth, Germany, 9 – 11 May



The Bavarian Health and Food Safety Authority (LGL) once again welcomed EHEC (Enterohemorrhagic Escherichia coli) specialists from Germany, Austria and Switzerland. Together with the German Society for Hygiene and Microbiology (DGHM), the German Veterinary Medicine Society (DVG), the Austrian Reference Center for EHEC and the National Center for Enteropathogenic Bacteria (NENT) in Luzern, Switzerland, once again after July 2004 the LGL organized a workshop on the subject of EHEC, a bacterium causing dangerous colorectal diseases.

Experts from the fields of human and veterinary medicine met up in Wildbad Kreuth to discuss epidemiologic aspects, detection techniques in food and the latest results from EHEC research. The LGL's Academy for Health, Nutrition and Consumer Protection (AGEV) chaired the workshop.

In some top class presentations, this year's meeting underlined the enormous significance of the indeed very heterogeneous pathovars (especially EHEC and STEC) of the genus Escherichia coli and showed how multifaceted its pathogenicity can be.

One result was that the pathogenicity markers are definitely not static and are therefore not typical for certain serotypes for long periods.

The presentations were accompanied by an extensive poster exhibition covering many interesting themes concerning all aspects of EHEC and STEC.

This included a poster from the German Federal Institute for Risk Assessment (BfR) in Berlin, in which the broad reactivity of the RIDASCREEN® Verotoxin ELISA for detecting the various Shiga-toxin variants, totalling 43 Stx1 and Stx2 forming strains, was impressively presented.

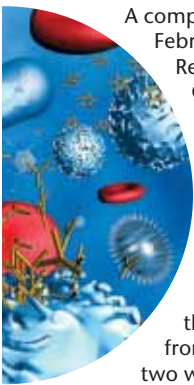


The poster is available as a PDF on request, as well as the associated current publication "Comparative evaluation of the RIDASCREEN® Verotoxin enzyme immunoassay for detection of Shiga-toxin producing strains of Escherichia coli (STEC) from food and other sources" (Beutin et al.; Journal of Applied Microbiology 102 (2007) 630 – 639).

Further information on the EHEC Workshop and the abstract booklet may be viewed and downloaded on the LGL website. (www.lgl.bayern.de).

Serology – Antibody Detection

The RIDASCREEN® Mycoplasma pneumoniae IgM EIA shows outstanding sensitivity for acute infections.



A comparative study was conducted in February 2007 in Budweis, Czech Republic, with five ELISAs and a CFT on a collective of clinically defined patient serums.

The serums were taken from the patients at the time of a local outbreak of Mycoplasma pneumoniae in January 2007. On account of the epidemic occurrence, it was ensured that the serum samples were taken from the patients within the first two weeks after the appearance of clinical symptoms. Furthermore, one week after the first sample, a second one was taken from all patients.

One result of the study was that the detection of antibodies in the early clinical phase turned out to be negative in some cases, which was to be expected. The analysis of

the first serum with RIDASCREEN® EIA (IgM and IgA combined) showed a sensitivity of 54.8% and was so in the same region as other tests. In the follow-up serum, the IgM EIA then identified 29 out of 31 patients as positive, which equates to a sensitivity of 93.5%. The two samples not identified were also IgM negative in other tests or only weakly reactive.

However, using titer increase and sero-conversion in IgG and/or IgA it was possible to detect an acute infection in both patients so that a total of 31 acutely infected patients were identified.

In contrast to the other tests, RIDASCREEN® EIA showed high specificity and therefore a positive-predictive value of 100% in all immunoglobulin classes. This high specificity was confirmed by our internal analyses of blood donor serums. Some very high values for the prevalence of antibodies against

Mycoplasma pneumoniae in the normal population are to be found in the literature (IgA 35%, IgG 40 – 70%) depending on the test used.

RIDASCREEN® EIA however shows significantly lower values in the analysis of blood donor serums (IgA 4%, IgG 21%, IgM 3%). That this does not mean any sensitivity loss is shown by the study data from Budweis. On the contrary, as a result of the lower reactivity, the significance of a positive

result as an indication of an acute infection is increased considerably.

Especially with pathogens like Mycoplasma pneumoniae, which usually occur as isolated cases and every few years as locally limited outbreaks, this is important.

A high positive predictive value supports the relevance of positive antibody detection in this case.

Gastroenterology

Colorectal cancer screening is always an issue, because not every patient takes advantage of the available screening options.

What has colorectal cancer screening achieved for us over recent years?

A total of 544,000 patients insured with the (German) statutory health insurance funds underwent colonoscopy screening in 2005. Around 4000 (0.6 – 0.8%) colorectal carcinomas were diagnosed at a prognostically favorable stage and for 33,000 (6.6%) advanced-stage adenomas were diagnosed. The prevalence of this result increases with advancing age, whereby men are affected more often on average than women.

So the introduction of screening colonoscopy has meant that the number of colorectal cancer deaths could be reduced by around 2000 per year. Nevertheless a negative trend can also be observed.

Despite widespread calls for colorectal screening, the number of screening colonoscopies fell by 30,000 in 2006. Also ever more younger people are developing colorectal cancer.

Today in Germany every patient over 55 has a screening colonoscopy paid for by the statutory health insurance funds every 10 years.

Statutory health insurance patients have the option of having a Guaiac test performed every 2 years. There are now far more reliable and sensitive immunological detection techniques available, which are not, however, paid by the statutory health insurance funds.

So the screening practice could be even more effective today and the question arises as to what happens to under 55-year-old patients.

Here a sensitive test for blood in the stool is helpful as an early indication, e.g.: haemoglobin (Hb) and haemoglobin/haptoglobin complex (Hb/Hp complex). A positive result means that the patient has too much blood in the stool sample – for whatever reason. Irrespective of the cause, this is a reason for the patient to undergo an intensive examination (e.g. with colonoscopy and gastroscopy).

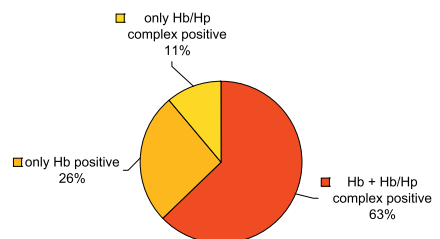


Testing both parameters haemoglobin and the haemoglobin/haptoglobin complex is very much recommended.

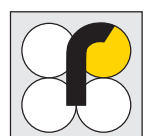
In routine testing of almost 32,000 stool samples, the combined use of the RIDASCREEN® Haemoglobin and RIDASCREEN® Haemoglobin/Haptoglobin Complex ELISA showed the highest detection rate among symptomatic patients.

Overall approx. 15% of the sample collective was found to be positive. Of these overall positives, around 63% showed a positive result congruently for both parameters haemoglobin and the haemoglobin/haptoglobin complex. On the other hand, approx. 11% of the samples were only positive for the Hb/Hp complex, and a remarkable 26% were only positive for haemoglobin.

distribution of overall positives



This makes it clear that a large number of patients with blood in stool would not have been diagnosed performing just one of the two markers.



So take advantage of the certainty with our clinically validated ELISA and rapid tests for blood in stool for highly sensitive colorectal cancer screening.

RIDASCREEN® Haemoglobin and RIDASCREEN® Haemo-/Haptoglobin Complex ELISA

- Economical single-point calibration
- Validated automation solutions individually tailored to your laboratory needs
- Hb and Hb/Hp complex from a single sample extract and dilution solution
- You can perform both ELISAs in parallel on one single microtiter plate
- Reproducible results, constant good, validated quality
- Clinically validated cut-off value for Hb and Hb/Hp complex (2 µg/g stool)
- As required: Low positive control



BioNexia® Hb/Hp-Complex Schnelltest

- Fast and simple to use
- Simultaneous determination of Hb and Hb/Hp complex from one stool suspension
- Clinically validated

R-Biopharm AG is supporting numerous studies for effective colorectal cancer screening.



NEW – RIDASCREEN® α₁-Antitrypsin ELISA – soon available

With this ELISA, another interesting, new gastroenterological stool marker will be available.

α₁-antitrypsin is a protease inhibitor and can be used as a fecal marker for intestinal protein loss and increased permeability in case of non-intact intestinal mucous membrane.

The parameter is very stable in the stool sample as a result of its inhibitor activity and is therefore also excellent for assessing inflammatory bowel diseases. The test is currently undergoing final clinical validation.

If you are interested in our products,
please contact your local distributor.

Fairs and conferences



10.09. – 22.09.2007

ASTANA ZDOROVIE 2007
Astana, Kasachstan
Astana Congress Hall
booth No A59

06.11. – 10.11.2007

JIB 2007
Journées Internationales de Biologie
Paris, France
CNIT Paris La Défense, booth E25

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