

Gastroenterology

Our new rapid dual test for determination of hemoglobin and hemoglobin-haptoglobin complex in stool samples is easy-to-use, fast and provides reliable results



The advantages of using the more sensitive and specific combined test for hemoglobin and hemoglobin-haptoglobin (Hb/Hp) complex for the detection of occult (hidden) blood in stool samples were outlined in the last issue of R-Biopharm^{news}. These tests run using monoclonal and polyclonal antibodies, so it provides specific immunological detection of human hemoglobin and hemoglobin-haptoglobin complex. Furthermore, the tests do not give false-negative or false-positive results by influence of food ingredients.

Studies have shown that the combined hemoglobin plus hemoglobin-haptoglobin complex test achieves nearly 96 % sensitivity for detection of colon carcinomas and up to 80 % sensitivity for adenomas.

Previously, laboratories could only use our two ELISA-based tests – RIDASCREEN® Hemoglobin and RIDASCREEN® Hemoglobin/Haptoglobin Complex – for simultaneous determination of the two parameters. A new innovative combi test now offers an attractive solution also for smaller labs.

New! - and unparalleled, BioNexia® Hb/Hp-Complex rapid test

In contrast to ELISA tests, the immunological BioNexia® rapid test uses a special test tube for collection of defined stool samples. Three drops of the diluted stool sample are placed on the test

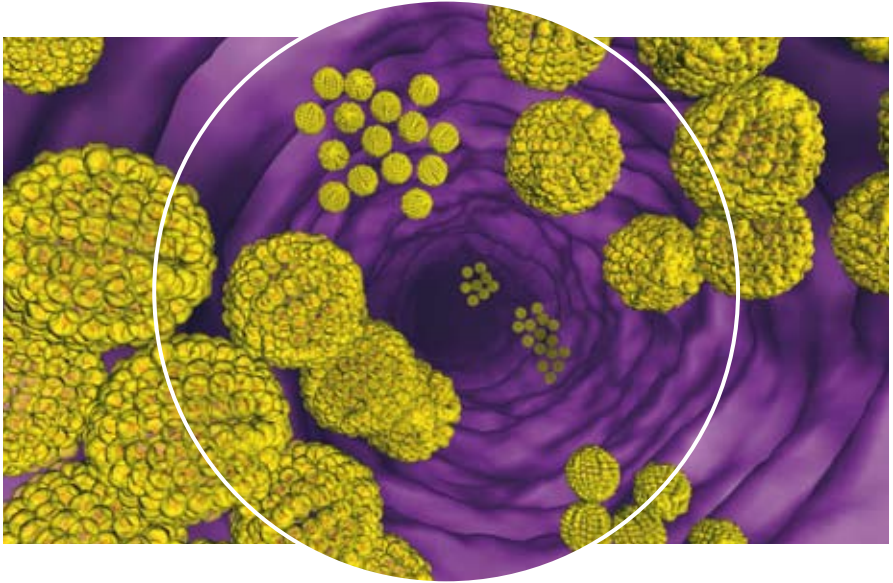
cassette for hemoglobin and hemoglobin/haptoglobin complex, respectively. The qualitative results can be read off the colored bands within 5 to 10 minutes.

Would you like to know more?

Then contact our product manager gastroenterology, Mrs. Gabriele Frost:
Phone: +49 (0) 61 51 - 81 02-632, E-Mail: g.frost@r-biopharm.de

Infectious Diseases – Antigen Tests

Canadian validation study confirms the reliability of RIDASCREEN® Norovirus ELISA



The results of a clinical validation study by researchers from McMaster University (Hamilton, Ontario) were presented in a lecture held at the 74th annual conference of the Canadian Association of Clinical Microbiology and Infectious Diseases (CACMID) in Victoria, British Columbia, in March 2006.



A total of 240 stool samples from adults and children with gastroenteritis were investigated in this study. The fecal specimens were obtained during outbreaks and individual cases of gastroenteritis.

All samples were tested in parallel using RIDASCREEN® Norovirus ELISA as well as RT-PCR (using the JV12 and

JV13 primers described in Vinje et al., 2003), an electron microscope, and another commercial ELISA kit.

The study results were also summarized in a poster presentation, which can be ordered under the contact data given at the end of the article.

From a group of 66 samples which were tested positive by PCR, the RIDASCREEN® Norovirus correctly identified 53 samples compared to 40 by the other commercial ELISA and only 24 by electron microscopy. The sensitivity of the tests was 80.3 % versus 60.6 % and 36.4 %, respectively. Both ELISA systems achieved a specificity of 100 %. The specificity of electron microscopy was only 97.1 % because 5 samples were falsely identified as containing norovirus particles.

Important factors to consider when comparing methods with different analytical sensitivities

The comparison study above fulfilled two important prerequisites that many previous studies comparing PCR and ELISA have not, namely, timely collection of stool samples in the acute

stages of gastroenteritis (diarrhea and vomiting) and use of one and the same homogenous stool suspension for all methods used for norovirus diagnosis.

Both are very important and decisive prerequisites for achieving a good correspondence between a highly sensitive test like the PCR (detection limit: 10 to 100 virus particles per gram stool sample) and an antigen-based test like the ELISA, which has a detection limit of roughly 10^5 virus particles/gram stool sample.

This is especially critical for norovirus testing because maximum fecal excretion is only 10^7 to 10^{10} particles/gram stool in the acute stage.

For comparison: Rotaviruses, on the other hand produce concentrations of 10^{15} particles/gram stool sample during the acute stage.

Normally, within 3 days the amount of norovirus particles drops under 10^5 particles/gram stool. Symptoms of infected persons have usually subsided by that time.

A highly sensitive PCR test would find noroviruses in samples from asymptomatic carriers, in contrast to excellent correlation between positive ELISA results and an existing clinical picture. Without additional quantification, positive PCR results do not make it possible to determine whether the identified pathogen is causing the acute disease or acting as an asymptomatic carrier that is not the cause of disease in patients with active diarrhea symptoms.

If you would like further information or if you have any questions regarding norovirus diagnostics, please contact our project manager, Dr. Georgios Kiourkenidis: Phone: +49 (0) 61 51 - 81 02-96, E-Mail: g.kiourkenidis@r-biopharm.de

PCR has definite advantages when used for post-infection excretion monitoring when this is important for the affected individuals and their environment.

However, during the acute stage of infection when antigen excretion levels are high, ELISA is sufficient and can be used as the method of choice.

In norovirus detection, PCR will more likely find its calling in the identification of infection sources (foods, smear samples, and general searches in the patient's environment) within the scope of optimized hygiene management and less likely in direct testing of stool samples from individuals with acute infections.

If PCR were used to diagnose all diarrhea-related fecal pathogens that must be considered in the scope of differential diagnosis, then the number of double, triple and multiple infection diagnoses would increase dramatically. As a result, the cause of the patient's actual clinical symptoms would remain unclear and unnecessarily complicated. Asymptomatic transient carrier activity and excretion of potentially pathogenic microorganisms as well as their asymptomatic chronic excretion might then impede proper medical decision-making.

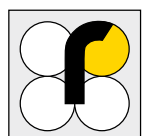
The bottom line is: Use big guns (PCR) for severe and critical cases and small artillery (ELISA) for reliable everyday routine. This is especially true for diagnosis of norovirus infections.



If you are interested

in our products, please contact your local distributor for more information.

r-biopharm



ECCMID 2006

This year's ECCMID (European Conference of Clinical Microbiology and Infectious Diseases) was held in Nice from April 1–4. With a turnout of over 5000 participants, the conference was a huge success. It was attended not only by visitors from Europe, but also by a large number from overseas and Asia. The scientific congress was accompanied by a trade fair with nearly 100 companies from the diagnostic and therapeutic product sectors.

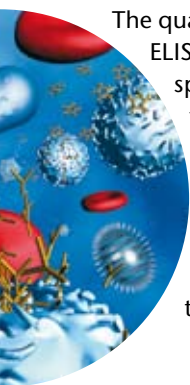
R-Biopharm and its subsidiary in Lyon have been active on the French diagnostic products market since last year. Our associate François Gnemmi took this excellent opportunity to have

many interesting talks with French customers.

Another very popular item was a poster presentation with daily alternating themes like diarrhea related to antibiotics caused by *C. difficile*, norovirus infections and, of course, bird flu. A poster presented by Dr. Péter (Sion), a Swiss *Borrelia* expert, demonstrated the excellent quality of RIDASCREEN® *Borrelia* ELISA tests.

Next year's ECCMID will be hosted in Germany. The conference venue is the ICM in Munich; date: March 31 to April 3, 2007. After all the positive experiences this year, R-Biopharm will also host a stand at next year's conference.

High Sensitivity for Borrelia Diagnosis



The quality of RIDASCREEN® *Borrelia* ELISA was evaluated in a retrospective study using sera from patients with confirmed stage 1-3 *Borrelia* infections. Dr. Olivier Péter (CONSILIA, Laboratoires et Conseils Médicaux SA, Sion, Switzerland) conducted the study.

The sensitivity for erythema migrans patients was 70 % (for the combination of IgG and IgM). With IgG EIA, sera from neuroborreliosis patients (stage 2) reacted with a sensitivity of 98 %. Stage 3 patients (arthritis, ACA) were detected at a rate of 100 %. Dr. Péter displayed the data in a poster presented at this year's ECCMID. We will gladly send a copy of the poster on request.

Trade Fairs and Conferences

04.09. - 06.09.06

R-Biopharm International Distributor Meeting Clinical Diagnostics
Kongresshotel centrovital
Berlin-Spandau

10.10. - 12.10.06

DIHE 2nd Dushanbe International Healthcare Exhibition
Dushanbe, Tajikistan



R-Biopharm^{news} is edited by

R-Biopharm AG, Landwehrstrasse 54,
64293 Darmstadt, Germany
Tel.: +49 61 51 - 81 02-0
Fax: +49 61 51 - 81 02-40

r-biopharm

