

**New!**

Lead article

## **RIDASCREEN<sup>®</sup> Calprotectin – Marker of inflammation in chronic bowel disease**

Dr. Andrea Lennerz



- Differentiation of inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS)
- Monitoring of response to treatment in IBD-therapy

In Germany, it currently takes an average of 2 to 5 years to reliably diagnose patients with chronic inflammatory bowel disorders such as Crohn's disease. Measurement of the fecal calprotectin (FC) concentration is a fast and reliable way to determine the presence or absence of intestinal inflammation. The fecal calprotectin concentration is an excellent

parameter for discriminating between chronic inflammatory bowel disease (IBD) and functional bowel disease of unclear etiology.

Both groups of diseases commonly produce unspecific gastrointestinal symptoms such as recurrent stomach ache and diarrhea. Colonoscopy was generally used to establish

continued on page 2



### Further topics:

**p.2** RIDA<sup>®</sup>GENE EHEC/EPEC – specific and direct detection of life-threatening EHEC bacteria in less than 2 hours  
*Dr. Andreas Simons*

**p.3** RIDA<sup>®</sup>GENE Rotavirus/Adenovirus Duplex: Real-time Duplex PCR for direct determination and differentiation of rotavirus and adenovirus in stool samples  
*Dr. Andreas Simons*

RIDA<sup>®</sup>GENE Norovirus quality validated by independent QCMD panel in 2010  
*Dr. Andreas Simons*

**p.4** Improved possibilities for diagnosis of drug allergies  
*Joachim Zehender*

Fairs and Conferences

the diagnosis in the past. Now, however, fecal calprotectin tests can be used. Normal FC concentrations (less than 50 mg/kg) exclude inflammatory bowel disease with high probability. Conversely, a positive FC test indicates the presence of inflammatory bowel disease and contributes to its early diagnosis and effective treatment. Fecal calprotectin is an ideal follow-up marker for patients with chronic inflammatory bowel diseases such as Crohn's disease and ulcerative colitis. Quantitative analysis of fecal calprotectin provides a direct method of assessing the results of IBD treatment. Any increase in FC concentration in IBD patients in remission is a more reliable indicator of disease relapse than previous standard markers of inflammation such as C reactive protein and erythrocyte sedimentation rate.\*

With RIDASCREEN® Calprotectin, R-Biopharm AG can now offer an ELISA assay for quantitative determination of fecal calprotectin. RIDASCREEN® Calprotectin

produces highly accurate and reliable FC concentration measurements not only in the cut-off range (50 mg/kg), but also across the entire measuring range. Unlike other assay formats where several standards have to be run with the samples to generate a standard curve, RIDASCREEN® Calprotectin features one-point calibration, which increases the number of patient samples per microplate significantly. This is a great economic advantage because RIDASCREEN® Calprotectin allows you to make an economic diagnosis, even with a small sample throughput.

Chronic inflammatory bowel diseases are common and affect more than 300,000 people in Germany. Unspecific symptoms of irritable bowel syndrome such as diarrhea and stomach aches account for approximately 50 % of all visits to gastroenterologists.

\* Schoepfer A et al. Am J Gastroenterol 2010; 105: 162-169.  
Quall et al. Inflamm Bowel Dis 2009; 15(5): 756-759.

## RIDA®GENE EHEC/EPEC



### Multiplex real-time PCR rapid assays enables specific and direct detection of life-threatening EHEC bacteria in less than 2 hours

Currently, we are seeing an increased frequency of confirmed and suspected cases of infection with the intestinal pathogen known as enterohemorrhagic *Escherichia coli* (EHEC). An unusual feature of this epidemic is the large number of adults with severe EHEC infection and complications. Some of the patients develop hemolytic-uremic syndrome (HUS), which can lead to kidney failure and even death.

R-Biopharm AG has developed a multiplex real-time PCR assay for the rapid and specific detection of EHEC bacteria. Previous assays

required 24 to 36 hours of cultivation for diagnosis of infection with enterohemorrhagic *E. coli*. The new RIDA®GENE EHEC/EPEC assay is able to demonstrate the presence of EHEC pathogens in less than 2 hours. This real-time PCR assay is compatible with commonly used real-time PCR cyclers such as the LightCycler®480II, SmartCycler®, ABI7500, Rotor-Gene Q and Mx series. The multiplex real-time PCR system detects EHEC-specific pathogenicity-genes (*stx1/stx2* and *eae*). Therefore, a negative test result allows to exclude STEC/EHEC infection.

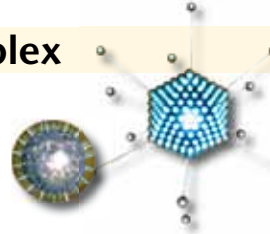


### Advantages of RIDA®GENE EHEC/EPEC for you:

- Direct detection in stool and culture samples
- Test results available in less than 2 hours
- Multiplex real-time PCR
- Detection of pathogenicity-genes *stx1/stx2*, *eae* and *ipaH*



# RIDA® GENE Rotavirus/Adenovirus Duplex



## Real-time Duplex PCR for direct determination and differentiation of rotavirus and adenovirus in stool samples

With the introduction of the RIDA® GENE Rotavirus/Adenovirus Duplex real-time PCR assay, R-Biopharm AG has expanded its portfolio of products for detection of the pathogens most commonly associated with viral gastroenteritis.

Acute gastroenteritis is one of the leading causes of morbidity and mortality worldwide. Enteric viruses are the most frequent causes of gastroenteritis, particularly in children. Noroviruses, Rotaviruses and Adenoviruses (serotypes 40, 41 and 31) are the most common viral causes of diarrhea. The RIDA® GENE Rotavirus/Adenovirus Duplex real-time PCR assay is specific for the NSP3 gene of Rotavirus and the hexon gene of

Adenovirus. It is compatible with commonly used real-time PCR cyclers, such as the LightCycler® 480II, SmartCycler® and ABI7500 systems. Test results are available in less than 2 hours, from extraction to determination of the pathogen. Because of their standardized PCR format, the RIDA® GENE Rotavirus/Adenovirus Duplex real-time PCR can be run simultaneously with the RIDA® GENE Norovirus PCR on a real-time PCR system. All of the required real-time PCR components are included in the kit, ready for use. Each kit contains sufficient reagents for 100 assays. The analytical sensitivity of the RIDA® GENE Rotavirus/Adenovirus Duplex assay is  $\leq 5$  RNA or DNA copies, respectively, per reaction.

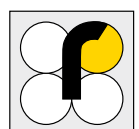
# RIDA® GENE Norovirus quality validated by independent QCMD panel in 2010



## With RIDA® GENE Norovirus, R-Biopharm AG successfully participated in the Quality Control for Molecular Diagnostics' (QCMD) international external quality assessment (EQA) program for Norovirus in 2010

QCMD is an independent international proficiency testing organization for quality assessment of molecular diagnostics. A QCMD EQA panel consists of a series of samples compiled to assess various aspects of assay performance. Certain samples in the panel are designated "core proficiency samples". These are samples which can be expected in clinical cases in terms of viral load and diversity and should therefore be detected by routine diagnostic tests. Therefore, laboratories are expected to correctly analyze and report all "core proficiency samples". The remaining samples allow for assessment of the limits of detection of an assay, which could be relevant in specific circumstances (e.g. detection of a virus in samples collected after the acute stages of infection). The 2010 EQA panel for detection of Norovirus consists of six samples containing various concentrations of Norovirus. Two of these samples are negative for Norovirus and the remaining four contain

RNA transcripts of Norovirus DNA plasmids. These samples include various Norovirus target genes from different circulating Norovirus strains. R-Biopharm AG reported 7 out of 7 (100.0 %) core proficiency samples correctly. 77.6 % of all participating laboratories reported correct results for all core proficiency samples. The results of the ring trial/proficiency test are available on request from R-Biopharm AG.



# Improved possibilities for diagnosis of drug allergies

The **histamine release test (HRT)** provides improved possibilities for cellular allergy diagnosis that now make it possible to achieve a much more sensitive diagnosis of drug allergies



Measurement of histamine release from the patient's basophil leukocytes after provocation with the drug suspected of triggering an allergic reaction allows to determine whether the patient has a type 1 allergy to the medication in question.

Previous exposure to a drug long in the past can result in a false-negative specific IgE test result, putting the patient at a high risk of anaphylactic shock. Functional cellular allergy diagnosis in whole blood samples is based on the bridging of two cell-bound IgE antibodies on the cellular membrane of basophil leukocytes by the allergen and measurement of the subsequent histamine release. Because cell-bound antibodies remain in serum much longer than free IgE antibodies, this strategy results in a significant improvement of

diagnostic accuracy. A positive reaction of basophil leukocytes in the patient's sample is a strong evidence that the patient will react with allergic symptoms to this particular drug.

The ability to analyze drugs that are not yet, already available as commercial test reagents gives allergologists new options for customized allergy testing. Consequently, this test system has a much wider range of applications than specific IgE tests, particularly in view of the fact that the use of customized allergens is hardly possible with specific IgE tests.

The histamine release test therefore provides a useful additional diagnostic option for patients with questionable allergy test results for drugs as well as insect venoms and food allergens.

## If you are interested in our products,

please contact your local distributor

### Fairs and Conferences



24.07. – 28.07.2011	<b>AACC</b> Atlanta, Georgia, USA
07.09. – 09.09.2011	<b>West African Health</b> <b>6th International Medical Exhibition &amp; Conference</b> Lagos, Nigeria
07.09. – 10.09.2011	<b>6th German Allergy Congress</b> Wiesbaden, Germany
14.09. – 17.09.2011	<b>Visceral Medicine 2011</b> Leipzig, Germany
14.09. – 16.09.2011	<b>Medical Fair Thailand</b> Bangkok, Thailand
05.11. – 07.11.2011	<b>10th Chinese Laboratory Medicine Conference</b> Taipei, Taiwan
16.11. – 19.11.2011	<b>Medica</b> Düsseldorf, Germany

R-Biopharm<sup>news</sup> is edited by

R-Biopharm AG  
An der neuen Bergstraße 17  
64297 Darmstadt, Germany  
Reg.-Nr.: Amtsgericht Darmstadt, HRB 8321  
Phone: +49 (0) 61 51 - 81 02-0  
Fax: +49 (0) 61 51 - 81 02-40  
www.r-biopharm.com

r-biopharm

