

Lead article

Clostridium difficile – A nosocomial pathogen of great concern

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up to **35%**
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up to **8%**
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of Clostridium difficile

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Clostridium difficile – A nosocomial pathogen of great concern

Clostridium difficile-associated diarrhea (CDAD) is one of the most common causes of nosocomial infections in industrialized countries.

Approximately 80 % of all newborns and 3 - 8 % of all adults are asymptomatic carriers of *Clostridium difficile*. In hospitalized patients, the percentage rises to as much as 35 % due to specific risk factors, such as the duration of hospitalization, the age of the patient, the severity of the primary disease, and antibiotic treatment.¹ Up to 71 % of patients that acquire *C. difficile* in the hospital develop symptomatic CDAD.² However, *C. difficile* infection is also being seen in an increasing number of non-antibiotic-treated and non-hospitalized individuals. The symptoms range from mild diarrhea to intestinal infections of variable severity, including pseudomembranous colitis, the most severe form of antibiotic-induced inflammatory bowel disease. Clinically symptomatic cases are caused by toxigenic *C. difficile* strains that produce enterotoxin A and cytotoxin B. *C. difficile* is highly infectious and is transmitted from human to human either directly via the fecal-oral route or indirectly via contaminated surfaces and objects. In recent years, the occurrence of highly virulent *C. difficile* strains such as those caused by ribotypes 027 and 078 has led to a worldwide increase in the number and severity of outbreaks. Health care costs associated with *C. difficile* infection are estimated at around 3 billion euros per year in Europe and roughly 1.1 billion dollars per year in the USA.¹ Early and reliable diagnosis of *C. difficile* infection makes it possible to administer specific treatment to individuals who are already infected and to initiate hygiene measures needed to prevent the




spread of infection. When *Clostridium difficile*-associated diarrhea (CDAD) is suspected, the patient is tested for toxigenic *C. difficile* strains. This is usually done by ELISA or rapid test for detection of *C. difficile* toxins. Molecular biological methods such as PCR are gaining more importance in comparison to the gold standard cytotoxicity assay.

R-Biopharm supplies a rapid test (**RIDA®QUICK Clostridium difficile Toxin A/B**) and an ELISA (**RIDASCREEN® Clostridium difficile Toxin A/B**) as well as various new real-time PCR tests (**RIDA®GENE Clostridium difficile & Toxin A/B**, **RIDA®GENE CD Screen** and **RIDA®GENE Toxin A/B**) for detection of *C. difficile* toxins in stool samples. The RIDA®GENE assays are highly sensitive and specific real-time PCR tests for qualitative detection of *C. difficile* (16s-rDNA) and *C. difficile* toxin A (tcdA) and B (tcdB) genes. The real-time PCR tests come in two versions („V“ and „LC“) that can be run on the commonly used real-time PCR cyclers, such as the LightCycler, SmartCycler or ABI systems. This allows for flexible deployment of the tests in routine diagnostics. The kits contain all components needed for specific detection of *C. difficile* toxins, and an internal amplification control reliably detects potential PCR inhibition.

RIDA®GENE Clostridium difficile HyperTox, a new test for detection of the highly virulent *C. difficile* ribotypes 027 and 078, will be available soon. This new real-time PCR permits early detection and reporting of severe cases of *C. difficile* infection.

1. Kuijper et al., *Clin Microbiol Infect* 2006; 12(6): 2-18.
2. McFarland et al., *N Eng J Med* 1989; 320: 204-210.

R-Biopharm Clostridium difficile tests at a glance:

Product	Description	Tests	Matrix	Art. No.
RIDASCREEN®	Enzyme immunoassay for antigen detection			
Clostridium difficile Toxin A/B	Enzyme immunoassay for simultaneous detection of Clostridium difficile toxins A and B	96	Stool	C0801
RIDA®QUICK	Rapid assay for antigen detection			
Clostridium difficile Toxin A/B	Rapid immunochromatographic test for qualitative detection of Clostridium difficile toxins A and B in stool samples and culture supernatants	25	Stool	N0803
RIDA®GENE	real-time PCR			
Clostridium difficile & Toxin A/B V	Real-time PCR for qualitative detection of Clostridium difficile and C. difficile toxin A and B genes in human stool samples	2 x 100	Stool	PG0805V
Clostridium difficile & Toxin A/B LC	Real-time PCR for qualitative detection of Clostridium difficile and C. difficile toxin A and B genes in human stool samples	2 x 100	Stool	PG0805LC
CD Screen V	Real-time PCR for qualitative detection of Clostridium difficile	100	Stool	PG0815V
CD Screen LC	Real-time PCR for qualitative detection of Clostridium difficile	100	Stool	PG0815LC
CD Toxin A/B V	Real-time PCR for qualitative detection of Clostridium difficile toxin A and B genes	100	Stool	PG0825V
CD Toxin A/B LC	Real-time PCR for qualitative detection of Clostridium difficile toxin A and B genes	100	Stool	PG0825LC
Clostridium difficile HyperTox V*	Real-time PCR for qualitative detection of the highly virulent Clostridium difficile ribotypes 027 and 078 in human stool samples	50	Stool	PG0855V
Clostridium difficile HyperTox LC*	Real-time PCR for qualitative detection of the highly virulent Clostridium difficile ribotypes 027 and 078 in human stool samples	50	Stool	PG0855LC

Can be run on the commonly used real-time PCR cyclers.

* available soon

R-Biopharm AG – Excellence in Norovirus Diagnostics

R-Biopharm AG offers a wide range of test systems for norovirus diagnosis

Noroviruses are the most common cause of acute gastroenteritis worldwide. Outbreaks of norovirus infection in hospitals, community facilities (schools, nursing homes, kindergartens, etc.), cruise ships and hotels make the headlines each year. Because noroviruses are highly infectious, a timely diagnosis and appropriate hygiene measures are crucial to preventing the spread of norovirus infection. Various test

systems for direct detection of noroviruses in stool samples can be used to confirm the suspected diagnosis of norovirus infection. R-Biopharm AG offers a wide range of test systems (rapid test, ELISA and real-time RT-PCR) for direct detection of genogroup I and II noroviruses in stool samples. They are marketed under the trade names **RIDA®QUICK Norovirus**, **RIDASCREEN® Norovirus** and **RIDA®GENE Norovirus**.

RIDA®QUICK Norovirus

is a flow-through enzyme linked immunoassay that enables rapid and simple near-patient-detection of norovirus infection without any special laboratory equipment. The test results are available within 20 minutes.

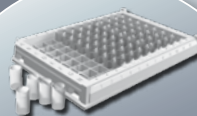


RIDA®QUICK Norovirus

- 20 single pouched cassettes

RIDASCREEN® Norovirus

is a 3rd generation 96-well microtiter plate ELISA with breakable wells. RIDASCREEN® Norovirus can be processed automatically on conventional fully automated microtiter plate systems. Therefore, it is the ideal test system for large sample throughputs. RIDASCREEN® Norovirus received SFDA approval in China in July 2010.

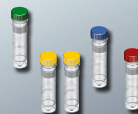


RIDASCREEN® Norovirus

- 96 ELISA format
- single breakable wells

RIDA®GENE Norovirus

is a highly sensitive and specific one-step real-time PCR ideally suited for confirmation of the diagnosis of norovirus infection or for detection of noroviruses in samples with low viral loads. Two versions of RIDA®GENE Norovirus have been available since November 2009: Version V and Version LC. This allows for flexible use of the test in conventional real-time PCR cyclers. The use of an internal amplification control ensures reliable results. A new reagent - RIDA®GENE Norovirus IAC Plus - was introduced in August 2010, making it possible to run Version LC on SmartCyclers.



RIDA®GENE Norovirus

- real-time RT-PCR
- 100 tests

All tests are validated and CE certified.

New Histamine Release Test now available

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Histamine release tests are used to diagnose type I allergies to foods, insect venoms and drugs, providing an additional marker in patients with unclear diagnoses. The old histamine release test had to be performed by specialized laboratories. In recent years, it was replaced by the basophil activation test (BAT), which is based on the determination of basophil CD63 surface expression. One of the reasons for this shift was the difficulty in performing the histamine release test. Nonetheless, CD63 surface expression measurement is also limited to specialized laboratories (mainly university laboratories) because it requires the use of a flow cytometer.

The new histamine release test is a cellular allergy diagnostic test that is open to all allergologists because no special equipment is needed to induce basophil histamine release. The only step that needs to be performed by a specialized laboratory is the later measurement of the released histamine.

The new histamine release test can be used to detect individual allergens in foods, drugs and insect venoms. RefLab will supply a number of allergens in four different concentrations present in the wells of eight-well strips. In addition to these ready-to-use microwell strips, microwell strips without allergens can be used for individual addition of selected allergens.

To perform the test, the required number of eight-well strips containing the allergens to be tested is placed in the strip holder. The sample diluent that comes with the kit and interleukin-3 for activating the histamine release must be added to the patient's blood sample within 24 hours of sample collection. Once diluted accordingly, 25 μ l aliquots of the sample are added to the wells containing different allergen concentrations, and the plate is incubated at 37 °C for 1 hour. After incubation, the plate is washed and dried. Because the released histamine is firmly bound to the glass fiber matrix of the wells, the plate can be sent to a special laboratory for measurement of the released histamine.

With this new test format, whole blood can be used and the microwell plates can be sent to a service laboratory only for the measurement. Therefore, the allergologist does not need any special equipment such as a centrifuge or cytometer.

This is the first histamine release test available in a format that can be performed and billed by all allergologists. The important test gives additional information for many diagnostic applications.



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

Fairs and Conferences



08.11. - 10.11.2010	R-Biopharm AG ASIAN Clinical Product Training , Singapore
17.11. – 20.11.2010	MEDICA 2010 Düsseldorf
02.12. – 03.12.2010	RICAI 2010 (Réunion interdisciplinaire de chimiothérapie anti-infectieuse) Paris, France
06.12. – 10.12.2010	Zdravookhraneniye Moscow, Russia
31.03. – 03.04.2011	LabMed Istanbul Turkey

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