

\$ 28.4 billion*

* Annual Medical Costs of
Nosocomial Infections to
U.S. Hospitals (CDC, 2009)

Benefits of Prevention

1 737 125 healthcare-associated infections (HAIs) were reported in 2008. The annual direct hospital costs of treating the HAIs in the United States ranges from \$ 28.4 to 33.8 billion. A CDC study published March 2009 used results from published medical and economic literature. The benefits of prevention – depending on its effectiveness of control – range from a low of \$ 5.7 to \$ 6.8 billion for inpatient hospital services. The medical costs of preventable HAIs are comparable to e.g. the costs of stroke (\$ 6.7 billion). Noroviruses are affecting 23 million people annually in the U.S. and infections in hospital

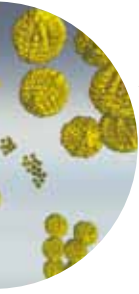
settings are causing numerous outbreaks. Outbreaks could be prevented by immediate infection control actions. Avoiding transport delay, diagnosis delay in combination with a rapid, simple and sensitive test system are critical factors supporting aggressive efforts to prevent transmission in health care settings. Enabling hospitals to act early would stop a significant morbidity of staff and patients and financial costs to institutions. Implementation of infection-control policies when Norovirus is identified could potentially prevent nosocomial outbreaks.

*Lit: Scott RD, U.S. CDC 2009;
Johnston CP et al. Outbreak management and implications of a nosocomial norovirus out- break.
Clin Infect Diseases 2007; 45: 534-540.*

Infection Control Measures: RIDA®QUICK Norovirus near patient test

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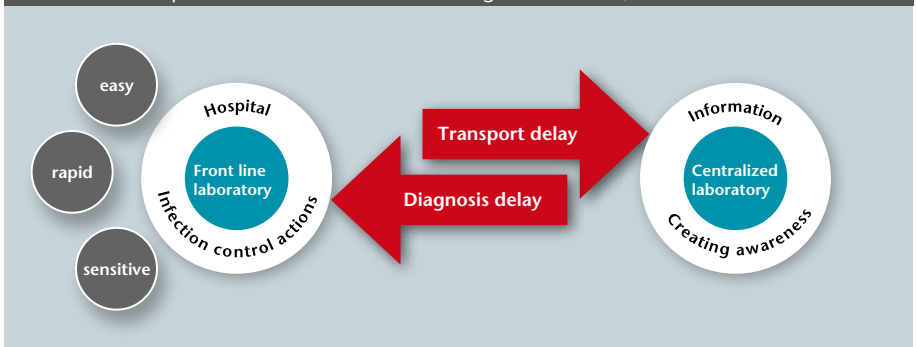


An evaluation was performed of frozen samples and a second prospective study on samples from presumed viral outbreaks. The positive predictive value for disease makes the RIDA®QUICK Norovirus test useful for rapid outbreak diagnosis.

Real time PCR is now in widespread use for diagnosis of outbreaks and sporadic cases of presumed viral gastroenteritis. However, there are inherent delays in diagnosis associated with PCR because of transport to a regional centre. At present minimal PCR is being

performed in small laboratories. In contrast, the disadvantage of EIA-based formats so far described is lack of sensitivity, even leading to false negative outbreaks. The RIDA®QUICK Norovirus kit is a flow through enzyme linked rapid assay.

Figure 1: Speeding up the information and creating awareness of healthcare professionals to empower them to take action is the goal of RIDA®QUICK Norovirus



Methods:

An initial evaluation was performed on 50 frozen PCR positive samples. Based on those results, a further prospective evaluation was performed on samples from presumed viral outbreaks. Fresh samples had to arrive within

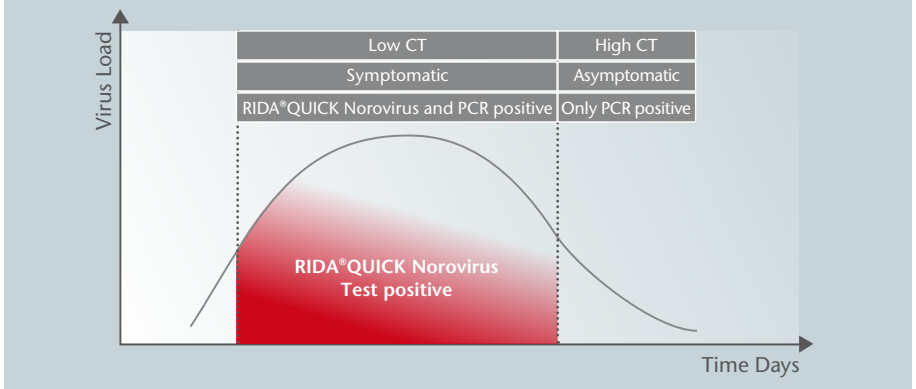
3 days of being taken and had to take the shape of the container. Overall, 157 samples were evaluated over 7 weeks. The test was performed according to the kit insert.

Results:

42 /50 (84%) of the retrospective samples were positive by RIDA®QUICK Norovirus. 53/157 (34%) of the prospective samples were positive by RIDA®QUICK Norovirus (67/157 by PCR). No samples were RIDA®QUICK Norovirus positive PCR negative. Outbreaks were deemed to be positive where a minimum of 3 samples from the outbreak had been received and at least one sample was positive. Of the 24 PCR positive outbreaks (158 samples) contained within the study, all were confirmed as positive by RIDA®QUICK

Norovirus met these criteria mentioned before. At a CT of 16 and below 94% of the PCR positive samples were also RIDA®QUICK Norovirus positive. No sample with a CT of 24 or above was positive by RIDA®QUICK Norovirus. CT means "Cycle Threshold": PCR cycle number at which the fluorescence generated within a reaction well exceeds the threshold. The threshold is arbitrarily defined to reflect the point during the reaction at which a sufficient number of amplicons have accumulated.

Figure 2: Positive predicted value for disease of the RIDA®QUICK Norovirus



Conclusions:

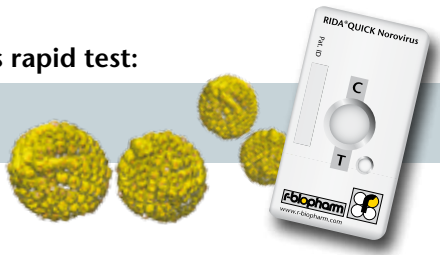
Overall, the sensitivity for individual samples was 81%. Specificity appeared excellent. No outbreaks were missed; in two outbreaks, only one of 2 samples positive by PCR was positive by RIDA®QUICK Norovirus and in another only one out of three PCR positives was RIDA®QUICK Norovirus positive. As samples with a higher CT may be found in asymptomatics, the positive predictive value for disease of the RIDA®QUICK Norovirus is likely to be better than PCR. This test is likely

to be useful adjunct to norovirus outbreak diagnosis and rapid institution of infection control measures.

Results were presented at the ESCMID (European Society of Clinical Microbiology and Infectious Diseases Meeting Istanbul September 2009) and IBMS (Biomedica Science Congress Birmingham October 2009) congresses.

More about RIDA®QUICK Norovirus rapid test:

- www.rapid-diagnostics.info
- www.r-biopharm.com



RIDASCREEN® Astrovirus – New ELISA Version

R-Biopharm AG launched a new version of its established RIDASCREEN® Astrovirus ELISA test in July 2009.



The new version of the test is available under the same article number (Art. No. C1301) and distinguishes itself from its predecessor by virtue of the improved shelf life stability of its reagents and by optimised sensitivity and specificity of the test. This was accomplished through the use of two new conjugates which, when combined, produce a much stronger signal than the predecessor version. This quality improvement requires an additional incubation step to the test procedure,

but the considerable enhancement of robustness of the test and the simultaneous improvement of the signal/background ratio more than compensates for that additional step. R-Biopharm AG will continue to successfully adapt the test procedure to the very successful RIDASCREEN® Norovirus ELISA test format and extend these adaptations to its other ELISA tests for stool analysis. RIDASCREEN® Rotavirus and RIDASCREEN® Adenovirus are the next kits which will follow in adaptation and can be expected on the market in the second quarter of 2010.

Parasite diagnostics

R-Biopharm AG offers a wide range of tests for parasite diagnosis. Which antigen and/or antibody test to choose depends on the type of organism to be detected. Both ELISAs and rapid tests are available.

Depending on which organism is to be identified, it is necessary to use a combination of different tests in different stages of diagnosis.

RIDASCREEN® Entamoeba or RIDA®QUICK Entamoeba (antigen test) and RIDASCREEN® Entamoeba histolytica (antibody test) by R-Biopharm AG, for example, are excellent choices for two-stage diagnosis of Entamoeba infection.

Stage 1: Imaging studies or direct antigen tests form the first stage of diagnosis of suspected Entamoeba infection. Microscopy is the classical method of stool sample analysis. However, the fact that it can lead to false-negative results and cannot distinguish between *Entamoeba dispar* (apathogenic) and *Entamoeba histolytica*

(pathogenic) is an important limitation.

The RIDASCREEN® Entamoeba antigen test features a high level of diagnostic certainty but is also unable to distinguish between *E. dispar* and *E. histolytica*. Imaging is the primary technique for diagnosis of liver abscess.

Stage 2: The second stage of Entamoeba diagnosis is necessitated by the need for clear differentiation between *E. histolytica* and *E. dispar*. If the results of the first stage of testing are positive, the identification of specific antibodies makes it possible to differentiate between *E. histolytica* and *E. dispar* because *E. histolytica* induces antibody production whereas *E. dispar* does not.

