Rapid detection of rotaviruses – are laboratories underestimating infection in infants?

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To the Editor: Acute diarrhoeal diseases are a major public health problem leading to high morbidity in both developed and developing countries, with the additional burden of high mortality in the latter. Worldwide, rotavirus infection is the most common cause of severe diarrhoea in young children,[1] accounting for 20 - 25% of diarrhoeal deaths in any 1 year.[2] It is estimated that rotavirus infection annually causes 111 million episodes of gastroenteritis requiring home care, 25 million clinic visits, 2 million hospitalisations and approximately 600 000 deaths in children under 5 years of age.[3] Rotavirus vaccine development and introduction is a priority in the fight to reduce rotavirus-associated mortality in the developing world. In South Africa, accurate rotavirus surveillance is critical for the rotavirus vaccine trials currently underway in this country. Against this background of morbidity and mortality there is a need for rapid and sensitive rotavirus detection methods in routine diagnostic laboratories, many of which perform rotavirus group antigen detection using either enzyme immunoassay (EIA) or latex agglutination assay (LAA).[4] Dipstick rotavirus immunochromatographic tests (ICT) provide comparable or better sensitivity than LAA.[5,6] These dipstick assays make use of monoclonal antibodies attached to a nitrocellulose solid phase and colloidal gold as indicator.

We set out to compare the sensitivity and specificity of assays used routinely in pathology laboratories for the detection of rotaviruses. LAA and ICT results were compared with the enzyme-linked immunosorbent assay (ELISA) as gold standard. During May and early June 2004 a commercial pathology laboratory based in Johannesburg screened 90 stool specimens for rotavirus using the Diarlex LAA (Orion Diagnostica, Finland). These specimens were re-screened at the Medical Research Council (MRC)/MEDUNSA Diarrhoeal Pathogens Research Unit, University of Limpopo, for rotavirus using the IDEIA ELISA kit (DAKO, Denmark) and the Coris RotaStrip ICT (Coris BioConcept, Belgium).

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Table I shows the results obtained after screening these specimens with the LAA, ICT and ELISA. We noted that of the 90 specimens tested, 83% (75/90) were rotavirus-positive when using the ELISA. The Diarlex LAA showed a very poor sensitivity of 57% (43/75) and a specificity of 93%, while the Coris ICT indicated an improved sensitivity of 88% (66/75) and a specificity of 100% compared with the ELISA.

Table I. Sensitivity and specificity of the Diarlex LAA and the Coris RotaStrip when tested against ELISA

	Dako ELISA		
	Positive	Negative	Total
Diarlex Latex test*			
Positive	43	1	44
Negative	32	14	46
Total	75	15	90
Coris RotaStrip†			
Positive	66	0	66
Negative	9	15	24
Total	75	15	90

*Specificity 93%, sensitivity 57%.
†Specificity 100%, sensitivity 88%.

Pathology laboratories that routinely use LAA kits for rotavirus diagnosis should view the results of this study with concern. While LAA provides a rapid result, requires no specialised equipment and is useful for testing single specimens, the Diarlex LAA appeared to be relatively insensitive when compared with the Coris ICT (57% v. 88%). The Coris ICT is a convenient, cost-effective assay with an equivalent turnaround time that could be adopted for routine, rapid rotavirus detection. It requires no additional equipment and is simple to perform, with easy-to-read results.

It is appropriate that laboratory personnel regularly monitor available kits to find the most sensitive assay. Accurate and rapid diagnosis of (rota)viral infections should reduce unnecessary use of antibiotics in patients infected only with (rota)virus. This would improve treatment – overall costs would be lowered and inappropriate use of antibiotics and resulting antibiotic resistance would be reduced. Rapid rotavirus diagnostic capacity with a quick turnaround time would facilitate containment of infected patients, improving infection control and preventing nosocomial outbreaks.

We suggest that more assay validation should be routinely and regularly performed and that the results of the validation

process should, in turn, be translated into the rapid adoption of assays providing the most sensitive assay results at that time. In addition, protocols to assess the competency of laboratory staff may demonstrate competence but fail to disclose incompetence.[7] We therefore suggest that alternative and new technologies should continue to be investigated for adoption by South African laboratories as they strive to improve their service.

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