SET-UP OF A NEW RAPID IMMUNOCHROMATOGRAPHIC DIAGNOSTIC FOR ROTAVIRUS DETECTION

D. Van Beers[1], M. De Foor[1], R. Viehoff[2], D. Col[2], M. Venuti[2] and Th. Leclipteux[3]

[1] : Hôpital Universitaire St-Pierre, rue Haute, 298, B-1000 Brussels, Belgium
[2] : Institut d'Hygiène et de Bactériologie, Blvrd Sainctelette, 55, B-7000 Mons, Belgium
[3] : Coris BioConcept, 199 rue Marcel Lecomte, B-5100 Wepion, Belgium

INTRODUCTION

Human gastroenteritis is a multifactoriel disease, cause of illness in young children worldwide. It can be caused by viruses, bacteria and even protozoan organisms.
Human Rotavirus is the main etiologic agent involved in children diarrhoea. It was previoulsy detected by techniques such as electron microscopy, Elisa, and SDS-PAGE. Since several years, new genetic techniques have also rise up which are PAGE detection of rotavirus double-stranded RNA or RT/PCR.
Nevertheless, all these procedure are time consuming and/or sometimes not suitable for physicians or one shot analysis. The growing demand of quick tests has led to the development of new rapid and inexpansive tests. The latex technology has been extensively used for this purpose. However, it is less sensitive than ELISA needs more or less skill for results interpretation and cannot be archived.

Coris BioConcept has developped a new rapid test based on the new immunochromatographic technology giving rise to sensitivity, specificity rapidity and which allows storage of results in ISO 9000 regulated laboratories.

EXPERIMENTAL PROTOCOL

468 faecal samples have been processed with two commercial tests.
A Rotavirus Elisa Test (EliWell Rotavirus, CER, Marloie, Belgium) has been performed in St-Pierre Hospital, Brussels and a rapid latex agglutination test (Virotect-Rota, Omega, United Kingdom) has been used in the Institut d'Hygiène et de Bactériologie, Mons, accordingly to manufacturer instructions to defined positive and negative samples. Doubtfull samples have been processed twice. The three protocols have been timed for the 468 samples to adress the time needed per analysis.
Immunochromatographic test has been processed as the following : each sample was diluted in 0.5 ml of dilution buffer and let to settle down for 1 or 2 minutes. Strips have then been incubated in the faecal solution for 5 minutes and red immediately by three different observers. After drying, strips have been stick for storage.

To evaluate the detectability parameter, positive control culture has been sequentially diluted in respective dilution buffer. Results have been regarded as positive as far as a signal was still observed.
Crossreactivity has been assessed by testing positive samples *with Cryptosporidium parvumn* , Adenovirus group and Adenovirus strain 40/41 specific.

RESULTS

1/ Sensitivity and Specificity Parameters

		EliWell ELISA		
		Positive	Negative	
Latex Test	Positive	60	6	66
	Negative	8	394	402
		68	400	468

Latex specificity : 98.5 % **Latex sensitivity : 88 %**

		EliWell ELISA		
		Positive	Negative	
RotaStrip test	Positive	71	9	80
	Negative	2	386	388
		73	395	468

RotaStrip specificity : 97.7 % **RotaStrip Sensitivity : 97.2 %**

2/ Detectability

Positive Rotavirus Control culture was diluted 1 in 2 up to 1/256

Titre 1/x	ELISA	Rota-Strip	Latex
1	+	+	+
2	+	+	+
4	+	+	+
8	+	+	+
16	+	+	+/-
32	+	+	-
64	+	+	-
128	+	-	-
256	+/-	-	-

CONCLUSION

Results show that the RotaStrip is very specific and more sensitive than the control Latex test. Moreover, detectability parameter is better with the RotaStrip. Each test strip could be dried and stored in order to be in accordance with several ISO 9000 accredited laboratories. This test is very simple to use and do not require any skill results interpretation. In term of time consumption, the 468 samples have been processed within less than 5 hours which is less than 40 seconds per sample. By the way, it could be used for one shot analysis as well as for larger samples series.

199, rue Marcel Lecomte, b-5100 Wepion, BELGIUM
http://www.corisbc.com / coris@corisbc.com