New Rapid test for Rotavirus and Adenovirus detection: bioNexia® Rota-Adeno

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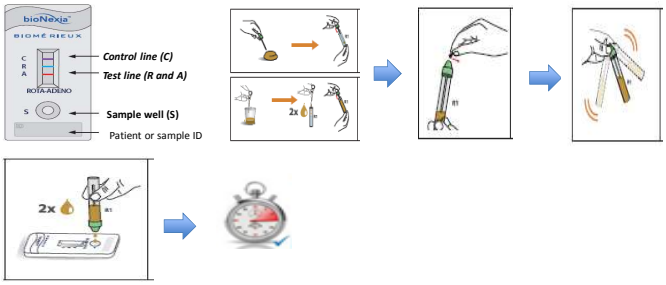
INTRODUCTION

Acute gastroenteritis (AGE) is one of the most common diseases in humans and continues to be a cause of high morbidity and mortality in children worldwide. Rapid detection can support the implementation of infection control procedures to help prevent the spread of the disease and limit the impact.

bioNexia® Rota-Adeno is a qualitative rapid test for detection and differentiation of Rotavirus and Adenovirus in human stool specimens which has been recently launched by bioMerieux company.

The test is intended to be used by healthcare professionals in laboratories as well as for Near-Patient-Testing



The aim of this study was to evaluate the performance of bioNexia® Rota-Adeno versus a real-time Reverse Transcription Polymerase Chain Reaction (RT-PCR) and/or versus another immunochromatographic test (ICT)

MATERIAL AND METHOD

•A multi-center study was carried out in 3 clinical laboratories in Europe (Leeds Teaching Hospital – United Kingdom, CHRU of Brest – France and Erasmus Medical Center – The Netherlands) using stool samples collected from patients showing gastroenteritis symptoms.

	Site 1 - Leeds			Site 2 - Brest			Site 3 - Rotterdam			All sites		
	+	-	Total	+	-	Total	+	-	Total	+	-	Total
Rotavirus	0	20	20	76	45	121	6	55	61	82	120	202
AdenoVirus	0	20	20	9	112	121	22	39	61	31	171	202

•**The evaluation of Rotavirus performance** of the bioNexia® Rota-Adeno test (bioMérieux) was carried out by comparison to a Rotavirus RT-PCR test (RIDAGENE® Viral Stool Panel II – R-Biopharm) using 200 stool samples, after exclusion of invalid results by RT-PCR.

The sites used the following material and protocol:

	1 - Leeds	2 - Brest	3 - Rotterdam
Sample pre-treatment**	Yes	Yes	Yes
Extraction system	QIAsymphony	easyMag	MagNA Pure 96
Extraction kit**	Same as routine	Same as routine	Same as routine
Amplification system	ABI 7500	LightCycler 480 II	LightCycler 480 II
Amplification protocol	Described in RIDAGENE Viral Stool Panel II IFU		

•**The evaluation of Rotavirus performance** of the bioNexia® Rota-Adeno test (bioMérieux) was also carried out by comparison to another ICT (RidaQuick® Rotavirus / Adenovirus Combi – R-Biopharm) using 202 stool samples.

•**The evaluation of Adenovirus performance** of the bioNexia® Rota-Adeno test was conducted by comparison to another ICT (Ridaquick® Rotavirus / Adenovirus Combi – R-Biopharm) using 202 stool samples.

RESULTS

1. Performance for Rotavirus detection

• bioNexia® Rota-Adeno versus RT-PCR

		RT-PCR - RIDAGENE Viral Stool Panel II											
		Site 1 - Leeds			Site 2 - Brest			Site 3 - Rotterdam			All sites		
		+	-	Total	+	-	Total	+	-	Total	+	-	Total
bioNexia® Rota-Adeno	+	0	0	0	75	3	78	5	0	5	80	3	83
	-	0	20	20	3	38	41	6	50	56	9	108	117
Total		0	20	20	78	41	119	11	50	61	89	111	200

Performances	Site 1 - Leeds	Site 2 - Brest	Site 3 - Rotterdam	All sites
Positive agreement	Not applicable	96,15 [89,17 – 99,20]	45,45 [16,75 – 76,62]	**89,89** [81,89 – 94,59]
Negative agreement	100,00 [83,16 – 100,00]	92,68 [80,08 – 98,46]	100,00 [92,89 – 100,00]	**97,30** [92,35 – 99,08]
Overall agreement	100,00 [83,16 – 100,00]	94,96 [89,35 – 98,13]	90,16 [79,81 – 96,30]	**94,00** [89,81 – 96,53]

Among 200 samples analyzed, 12 samples were discordant:
- 9 samples positive with RT-PCR were negative with bioNexia® Rota-Adeno. These samples were retested with bioNexia® Rota-Adeno for information purpose only and were still negative.
- 3 samples negative with RT-PCR were positive with bioNexia® Rota-Adeno.

• bioNexia® Rota-Adeno versus RidaQuick®

		RidaQuick Rotavirus / Adenovirus Combi											
		Site 1 - Leeds			Site 2 - Brest			Site 3 - Rotterdam			All sites		
		+	-	Total	+	-	Total	+	-	Total	+	-	Total
bioNexia® Rota-Adeno	+	0	0	0	75	3	78	5	0	5	80	3	83
	-	0	20	20	1	42	43	1	55	56	2	117	119
Total		0	20	20	76	45	121	6	55	61	82	120	202

Performances	Site 1 - Leeds	Site 2 - Brest	Site 3 - Rotterdam	All sites
Positive agreement	Not applicable	98,68 [92,89 – 99,97]	83,33 [43,65 – 96,99]	**97,56** [91,47 – 99,70]
Negative agreement	100,00 [83,16 – 100,00]	93,33 [81,73 – 98,60]	100,00 [93,47 – 100,00]	**97,50** [92,87 – 99,48]
Overall agreement	100,00 [83,16 – 100,00]	96,69 [91,75 – 99,09]	98,36 [91,28 – 99,71]	**97,52** [94,32 – 99,19]

Among 202 samples analyzed, 5 samples were discordant:
- 2 samples positive with the other rapid test were negative with bioNexia® Rota-Adeno. These samples were negative with RT-PCR too.
- 3 samples negative with RT-PCR and with the other rapid test were positive with bioNexia® Rota-Adeno.

2. Performance for Adenovirus detection

• bioNexia® Rota-Adeno versus RidaQuick®

		RidaQuick Rotavirus / Adenovirus Combi											
		Site 1 - Leeds			Site 2 - Brest			Site 3 - Rotterdam			All sites		
		+	-	Total	+	-	Total	+	-	Total	+	-	Total
bioNexia® Rota-Adeno	+	0	0	0	8	0	8	17	0	17	25	0	25
	-	0	20	20	1	112	113	5	39	44	6	171	177
Total		0	20	20	9	112	121	22	39	61	31	171	202

Performances	Site 1 - Leeds	Site 2 - Brest	Site 3 - Rotterdam	All sites
Positive agreement	Not applicable	88,89 [56,50 – 98,01]	77,27 [56,56 – 89,88]	**80,65** [63,72 – 90,81]
Negative agreement	100,00 [83,16 – 100,00]	100,00 [96,68 – 100,00]	100,00 [90,97 – 100,00]	**100,00** [97,80 – 100,00]
Overall agreement	100,00 [83,16 – 100,00]	99,17 [95,47 – 99,85]	91,80 [82,21 – 96,45]	**97,03** [93,67 – 98,63]

Among 202 samples analyzed, 6 samples were discordant (positive with the other rapid test and negative with bioNexia® Rota-Adeno):
- 5 samples were Adenovirus serotypes 1, 2, 3, 5 or 21.
- 1 sample was not serotyped.

CONCLUSION

For Rotavirus, the bioNexia® Rota-Adeno test showed very satisfactory agreement versus the RT-PCR and excellent agreement versus the other ICT.
For Adenovirus, the bioNexia® Rota-Adeno test showed satisfactory agreement versus the other ICT. From a usability standpoint, the test was considered easy-to-use, with all the material required to perform the test included in the kit.