Clinical evaluation of a molecular assay for direct and rapid screening for *Streptococcus agalactiae* in vaginal/rectal samples

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Introduction

Streptococcus agalactiae (GBS) is one of the principal causes of severe neonatal infections.

The current culture based method for detection of GBS has low sensitivity and is time consuming.

This study aimed to evaluate the performance of the GenomEra™ GBS assay (Abbacus Diagnostica, Finland) as a direct and rapid method for detection of GBS in vaginal or rectal samples, by using the culture based method as reference.

Methods

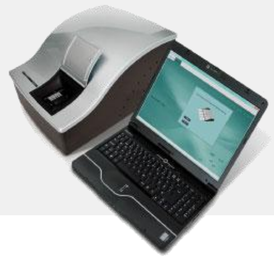
Out of a total 335 vaginal and rectal samples that were analyzed at the laboratory of Clinical bacteriology, 159 samples were selected on the basis of culture results.

Based on the culture results, all GBS positive samples (n=58) as well as 101 negative samples were directly (without prior enrichment) analyzed with the GenomEra™ GBS assay.

GenomEra™GBS assay

The GenomEra platform consists of GenomEra™CDX instrument and assay kits. The instrument is an automated and integrated multiblock thermocyckler and timeresolved fluorometer.

60µl of swab sample was vortexed in a Zirconium tube in order to disrupt cells. 35µl of the disrupted cell solution was transferred to the test chip preloaded with all reagents necessary for performing DNA aplification and detection of the GBS specific ***cfb* gene**. Detection or non detection of the ***cfb* gene** was reported as positive or negative, respectively.



Culture based metod

BG plate at digital reading

Results

The PCR assay had a turnaround time of 1 hour with a sensitivity and specificity of 93.10% and 93.07%, respectively.

The negative and positive predictive value (NPV resp. PPV) was 95.92% and 88.52%, respectively.

Agreement between the GenomEra™ GBS assay and the culture result

		Culture		
		Positive	Negative	Total
GenomEra™ GBS assay	Positive	54[a]	7[c]	61
	Negative	4[b]	94	98
	Total	58	101	159
		Sensitivity 93.10% (54/58)	**Specificity 93.07%** (94/101)	
		PPV=88.52% (54/61)	**NPV =95.92%** (94/98)	

[a]True positive. [b] False negative. [c]False positive

Conclusion

Our results indicate that this PCR assay provides a new and efficient screening test of GBS for prevention of neonatal infections and unnecessary use of intrapartum antibiotic prophylaxis.

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