

Optimized Pathogen Detection: A Compatibility Evaluation of Revvity chemagic™ 360 system and NZYTech qPCR Kits for MRSA and GBS detection

Endorsed Technical File

Introduction:

Automated nucleic acid extraction systems have become essential in molecular diagnostic laboratories to ensure efficient and reliable results in a timely manner. The chemagic™ 360 instrument from Revvity is a compact and flexible system for automated DNA and RNA purification. The system uses well-established M-PVA Magnetic Bead technology to provide high yields of ultra-pure nucleic acids suitable for a wide range of downstream applications. The chemagic™ Pathogen NA gDNA Kit H96 from Revvity is specifically designed for the isolation of DNA and RNA from bacteria and viruses, making it ideal for microbial detection in clinical samples.

Group B Streptococcus (GBS) and Methicillin-resistant Staphylococcus aureus (MRSA) are common bacterial pathogens associated with healthcare-associated infections (HAIs) in newborns, pregnant women, and hospitalized patients. Early detection and accurate diagnosis of these pathogens is critical for effective treatment and prevention of HAIs. NZYTech offers two Real-time PCR kits, the MRSA Multiplex Real-time PCR Kit, IVD, and the Group B Streptococcus Real-time PCR Kit, IVD, for the rapid and precise identification of these bacteria. Here, we demonstrate the compatibility of the chemagic system - chemagic™ 360 instrument plus chemagic™ Pathogen NA gDNA Kit H96 - with NZYTech's qPCR kits for MRSA and GBS detection.

Materials and Methods:

To assess the compatibility of the chemagic™ 360 system with NZYTech' qPCR kits, we conducted a clinical validation study using MRSA and GBS positive and negative clinical samples. The clinical performance of NZYTech' MRSA Multiplex Real-time PCR Kit, IVD (MD04931) was evaluated using 155 nasal swab samples. As for Group B Streptococcus Real-time PCR Kit, IVD (MD04941), 48 vaginal/perianal swab samples were assessed. Nucleic acids were extracted following manufacturer's instructions and the results were compared to a gold standard nucleic acids extraction competitor.



Extraction Kit: chemagic™ Pathogen NA gDNA Kit H96 (IVD-1049)
Instrument: Revvity chemagic™ 360 instrument (2024-0010)
qPCR Kits: MRSA (MD04931) and GBS (MD04941)

Kit Used	MRSA (MD0493)	Kit Used	GBS (MD0494)
PPA	91.07%	PPA	95.8%
NPA	97.98%	NPA	100%
LoD	750 copies/mL	LoD	500 copies/mL

Table 1: Performance of chemagic™ 360 instrument with chemagic™ Pathogen NA gDNA Kit H96 and the NZYTech qPCR Kits for MRSA Detection

Table 2: Performance of chemagic™ 360 instrument with chemagic™ Pathogen NA gDNA Kit H96 and the NZYTech qPCR Kits for GBS Detection

To determine the Limit of Detection (LoD), nucleic acids extracted using the chemagic™ 360 instrument were subjected to testing using NZYTech's qPCR kits for MRSA and GBS detection. The testing experiment involved two different operators and three kit batches, with a total of 48 replicates conducted to ensure the accuracy and reproducibility of the results.

Results:

For MRSA samples, the system chemagic™ Pathogen NA gDNA Kit H96 plus chemagic™ 360 instrument performed well in the clinical validation study, demonstrating a positive percent agreement (PPA) of 91.07% and a negative percent agreement (NPA) of 97.98%. As for GBS samples, the system demonstrated an excellent performance, with a PPA of 95.83% and an NPA of 100%. Regarding LoD determination, data show that when nucleic acids are extracted using chemagic™ 360 system, NZYTech's Group B Streptococcus Real-time PCR Kit, IVD detects 500 copies/mL and that NZYTech's MRSA Multiplex Real-time PCR kit, IVD detects 750 copies/mL.

Conclusion:

The efficient extraction of genomic DNA and pathogen DNA/RNA from clinical swab samples is critical for the accuracy and reliability of real-time PCR assays for GBS and MRSA detection. The results of this study demonstrate that the chemagic™ 360 instrument and chemagic™ Pathogen NA gDNA Kit H96 are compatible with the NZYTech' MRSA Multiplex Real-time PCR Kit, IVD and Group B Streptococcus Real-time PCR Kit, IVD, for the detection of MRSA and GBS respectively. The high level of agreement with the reference method and the low LoD demonstrate the suitability of this solution for accurate and sensitive detection of GBS and MRSA in clinical samples. The use of the chemagic™ Pathogen NA gDNA Kit H96 and the chemagic 360 Instrument can improve the accuracy of diagnosis, reduce turnaround time, and facilitate the implementation of surveillance programs for the prevention of HAIs.

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20% off:
MRSA Multiplex Real-time PCR Kit
(MD04931)
Group B Streptococcus Real-time PCR
Kit (MD04941).

MKT-088_V01/2023

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