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Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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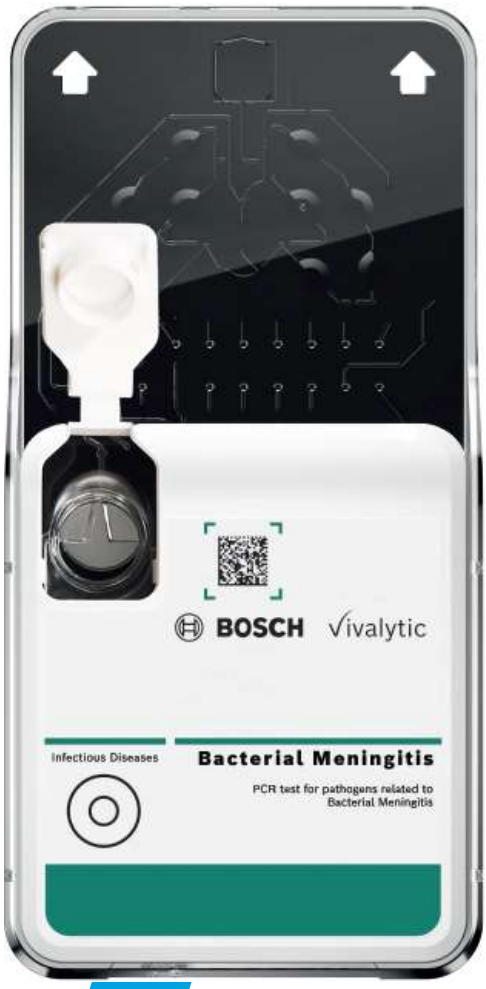
BOSCH



For Research Use Only

vivalytic

Bacterial Meningitis

PCR test for detection of pathogens related to Bacterial Meningitis

Instructions for Use (RUO)

F09G301123

For Research Use Only.
Not intended for diagnostic use.

Package Contents
Each package contains 15 Vivalytic Bacterial Meningitis RUO test cartridges. The Bosch Vivalytic Bacterial Meningitis RUO test is a qualitative PCR-based assay for simultaneous detection of 6 pathogens related to bacterial meningitis in cerebrospinal fluid (CSF) samples.
The Vivalytic Bacterial Meningitis RUO test is configured for use with a Vivalytic *one* analyser.

Detectable Pathogens

Pathogen List	
Neisseria meningitidis	*Escherichia coli*
Streptococcus pneumoniae	*Listeria monocytogenes*
Haemophilus influenzae	*Streptococcus agalactiae*

Safety Information
These Instructions for Use contain test specific information only. For additional warnings and instructions refer to the Instructions for Use provided with your Vivalytic *one* analyser (chapter device safety information). Only use Vivalytic cartridges and accessories approved for the Vivalytic *one* analyser. Take care to avoid any contamination when handling patient samples and cartridges. When sample was spilled on the cartridge, do not use the cartridge, and dispose it.

WARNING

- Always follow good laboratory practice to ensure the proper performance of this test.
- Make sure to wear appropriate personal protective equipment (PPE).
- Do not use a cartridge if the sealed pouch or the cartridge itself is visibly damaged.
- Do not touch or scratch the detection area of the cartridge.
- Do not reuse a cartridge.
- Do not use expired cartridges. The expiration date can be found on the packaging and the cartridge label.
- Do not wait longer than 15 minutes after opening the cartridge pouch to begin the test. This maintains hygiene and avoids performance loss due to humidity. Prolonged exposure to humidity has a negative impact on test performance.
- Do not shake a cartridge that contains a sample.
- Do not turn the cartridge upside down.
- Place the cartridge on a clean surface and flat surface only.
- Do not use sample types, media and volumes that are not approved for the test application.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Handle potentially infectious samples and cartridges according to national laboratory standards and dispose samples and cartridges according to regional and laboratory standards.
- Be compliant with the national safety regulations and practices.

Note: Further information can be found in the material safety data sheet (MSDS)of the product. Please contact the customer support of your local distributor.

Additional Equipment & Consumables Required but not Provided:

- Bosch Vivalytic *one* analyser (reference number F09G300115)
- Pipette (100 - 1000 µl)
- Sterile filter pipette tips (1000 µl)

Test Principle

Vivalytic Bacterial Meningitis is a qualitative real-time PCR based test.

Storage und Usage Conditions

Product is stable until the expiry date if stored at + 15 °C to + 25 °C. Storage and usage conditions can be taken either from the cartridge, pouch, or box label. The cartridge must be used at + 15 °C to + 25 °C, relative humidity < 65 %, and within 15 minutes upon pouch opening. This maintains hygiene and avoids performance loss due to humidity. Prolonged exposure to humidity has a negative impact on test performance.

Reagents

All reagents necessary for the sample processing are integrated into the cartridge. The processing includes cell lysis, nucleic acid extraction, DNA amplification, and detection.
Reagents within the cartridge include PCR bead, processing buffer, washing buffer, and elution buffer. The PCR bead contains the DNA polymerase, primers, and probes. Processing buffer facilitates extraction of nucleic acids during the extraction process. Washing buffer is a formulation of different salts and solvents to remove impurities e. g. proteins during the extraction process. Elution buffer is a low-salt buffer and contains the purified nucleic acids at the end of the extraction process.

Sample Types / Medium

The test is intended to detect nucleic acids of the above-described pathogens in native cerebrospinal fluid samples (CSF).
Collect samples according to standard clinical procedures. The test detects nucleic acids from intact cells. Thus, samples should be processed immediately after sample collection. In case the sample is not processed immediately, it should be stored at 2-8 °C and be analysed within 1 hour.

Sample Preparation

Fill in 300 µl of CSF sample in the sample input of the cartridge by using a pipette with filter pipette tip and close the cartridge lid. Insert the cartridge in the Vivalytic *one* analyser.
Do not use viscous samples that are difficult to pipette. Do not dilute the sample nor mix it with any buffer solution. Avoid to pipette air bubbles.

Test Result (For Research Use Only)

After automatic processing of the sample with the Vivalytic *one* analyser the test result is shown on the screen.

The sample is classified either as positive for one or more pathogens, negative or invalid or as a combination of the aforementioned. In case of a positive detection of one or more targets the test is considered valid even if the respective Internal Control of this target group is negative.
Detection of the Internal Control in negative samples shows a successful DNA purification and amplification procedure and excludes an inhibition of the PCR reaction.

Interpretation of results is shown in the table below:

Interpretation of results				
Target/s Group 1[a]	Target/s Group 2[b]	Internal Control 1	Internal Control 2	Results
+	-	+/-	+	Assay is valid and sample is considered positive for one or more target/s.
-	+	+	+/-	Assay is valid and sample is considered positive for one or more target/s.
-	-	+	+	Assay is valid and sample is considered negative for all targets.
-	-	+	-	Assay is valid and sample is considered negative for all targets in Group 1[a]. Group 2[b] targets are considered invalid.[c]
-	-	-	+	Assay is valid and sample is considered negative for all targets in Group 2[b]. Group 1[a] targets are considered invalid.[c]
-	-	-	-	Assay is invalid.[c]

[a] Pathogens in Group A: *Neisseria meningitidis*, *Streptococcus pneumoniae, Haemophilus influenzae*
[b] Pathogens in Group B: *Escherichia coli, Listeria monocytogenes, Streptococcus agalactiae*
[c] Retesting is recommended.

PCR – Curve and C_q Value

Real-time PCR curves (software-modified) are shown and classified as positive or negative by the software. In case of positive curves, the respective C_q value is displayed. Inconclusive results are marked by the software (⚠). Retesting is advised.

Invalid or Failed Tests

A test is rated as invalid if neither target DNA nor Internal Control is detected. Possible reasons for an invalid run might be inhibiting substances in the sample (e.g., blood components), interferences with inserted air bubbles, viscous sample material, turning over the cartridge, or insufficient sample volume.

Pay attention to use the correct sample type, sample volume, correct sample insertion and storage of the cartridges prior to the test run. If required, repeat the analysis with a new sample in a new cartridge.

In case of a failed test, first check for correct operating conditions of the Vivalytic *one* analyser (refer to Vivalytic *one* analyser's Instructions for Use). Restart the Vivalytic *one* analyser. If the problem persists, contact the customer support of your local distributor.

Test Termination (Early Finish)

The user has no option to finish the test earlier.

Test Report

In the printed test report, pathogens, results, control and information on user, sample and Vivalytic one analyser are listed with a signature field.

Limitations

The results of the Vivalytic Bacterial Meningitis RUO test are intended for Research Use Only and are not suitable for diagnostic procedures.

- A negative result does not exclude pathogens being present in the sample at a level below assay sensitivity, as non-intact cells or a pathogen that is not covered by this assay.
- There is a risk of false negative or false positive results due to improperly collected, transported, or handled samples.
- In borderline cases atypical PCR characteristics (e.g., flat curve with low or high C_q-value) can occur. Inconclusive results are marked by the software (⚠). Retesting is advised.
- A positive result does not necessarily mean that pathogens are present.
- Vivalytic Bacterial Meningitis RUO is a qualitative real-time PCR test and does not provide a quantitative result.

Symbols

	Manufacturer	SN	Serial number
	Date of manufacture		Temperature limit
	Expiry date		Do not use if package is damaged
LOT	Lot number		For single use only
REF	Reference number		Consult Instructions for Use
Σ	Contains <n> tests		
0 300µl	Pipette the indicated sample volume in the sample input of the cartridge as marked by the black triangle.		

Table 1 – Document History	
Revision 1.0	Initial document (For Research Use Only)
Revision 2.0	Changes: Safety information – removal of cartridge cleaning recommendations for spilled samples Sample storage recommendations – added hint, that assay detects intact cells, storage recommendations adapted Sample preparation – “no dilution of samples” added Additional equipment – added recommendation to use “filter” tips Interpretation of results – corrections of group naming to be aligned with software Limitations – added reason for negative results due to non-intact cells; adapted limitation of positive results Adaption of wording

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For more information see
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