cube dx
hybCell technology

DATA SHEET

hybcell Bacteria DNA xA for Sepsis Testing

CUBE-DS-15022-V01-E

Fast and efficient method to determine bacterial DNA in human whole blood (or other sample material) applying Cube Dx' compact sequencing and Molzym's MolYsis DNA isolation.

Benefits

- Identification of a panel with a single reaction
- Within 4 hours from whole blood to result - using Molzym's MolYsis
- Fast system startup for 24/7 operation even for single samples
- Fully automated sequencing
- Integrated result calculation and presentation

Usage and Product Description

Cube Dx' hybcell Bacteria DNA xA facilitates the diagnosis of bloodstream infections by identifying major sepsis-causing bacteria in human DNA extracted from whole blood.

The assay is based on three steps: DNA preparation from whole blood, 16S PCR and a sequencing step. Sample preparation is done with the MolYsis DNA isolation kit (www.molzym.com). Testing starts with amplifying 16S rDNA of bacterial genomes of the prepared DNA in a PCR reaction, at the same time fluorescence-labelling single strands. Subsequently Cube Dx' compact sequencing is applied: PCR amplicons bind to immobilized probes on the hybcell surface and - in case of 3´-complementarity - are extended due to polymerase activity. Extended probes remain associated at high temperatures while duplexes without extension are washed away during a washing step. Finally the hybcell is scanned and analyzed by hyborg software. Distinction between PCR amplicons and thus species discrimination is achieved by signal pattern recognition. A compact report is generated automatically.

hybcell protocol:	hybcell Bacteria DNA xA - A23 - V001	Sample ID
hybcell ID:	1613A230068	
Sample ID:	St.aureus	
hybcell created:	Service, 6/10/2014 3:27:38 PM	hybcell ID
hybcell processed:	Service, 4/15/2014 4:46:34 PM	

Control criteria

Control	Quality
Surface Control	VALID
Background Control	VALID
Primer Extension Control	VALID

Criteria

Name	Quality
Bacteria pan	positive
Bacillus subtilis	negative
Gram positive bacteria	
Enterococcus	
Enterococcus faecalis	negative
Enterococcus faecium	negative
Streptococcaceae	
Strep. agalactiae/dysagalactiae	negative
Streptococcus anginosus	negative
Streptococcus pneumoniae	negative
Streptococcus pyogenes	negative
Staphylococcaceae	
Staphylococcus aureus	positive
CoNS	
Staphylococcus epidermidis	negative
Staphylococcus haemolyticus	negative
Staph spp.	negative
Gram negativ bacteria	
Acinetobacter baumannii	negative
Escherichia coli	negative
Klebsiella oxytoca	negative
Klebsiella pneumoniae	negative
Enterobacter aerogenes	negative
Enterobacter cloacae	negative
Proteus mirabilis	negative
Pseudomonas aeruginosa	negative

Reported results.

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Sample volume: 5 µL (eluate of MolYsis kit)

Analysis system: hyborg Dx RED

Test duration: DNA preparation 120 minutes (from whole blood), PCR 90 minutes, compact sequencing 30 minutes.

hybcell Core.

Throughput: First sample approx. 4 hours (any following sample takes additional 30 minutes)

Kit contents: material for 12 tests

Shipping and storage: hybcells can be shipped and stored at room temperature (8 to 25 °C) with a shelf life of 24 months. Some components have to be shipped frozen and must be stored at -15 to -25 °C (for maximum 24 months).

Order number: HC0410-12

Specification

Limit of Detection: 0,5 pg/µL DNA (Bacillus subtilis standard-DNA; Nr. S-200-050 Molzym GmbH)

Tested DNA references			Correctly classified		
Genus	**Species**	**Reference no. DSMZ**	**Bacteria**	**Genus**	**Species**
Bacteria pan					
Bacillus subtilis		S-200-050 (Molzym)			
Staphylococcus	*aureus*	DSM 20714	✓	✓	✓
	epidermidis	DSM 20044	✓	✓	✓
	haemolyticus	DSM 20263	✓	✓	✓
	warneri	DSM 20316	✓	✓	-
Streptococcus	*anginosus*	DSM 20563	✓	✓	✓
	agalactiae, dysgalactiae	DSM 2134, DSM 20662	✓	✓	✓
	pneumoniae	DSM 20566	✓	✓	✓
	pyogenes	DSM 20565	✓	✓	✓
Enterobacter	*aerogenes*	DSM 30053	✓	✓	✓
	cloacae	DSM 30054	✓	✓	✓
Escherichia	*coli*	DSM 30083	✓	✓	✓
Klebsiella	*oxytoca*	DSM 5175	✓	✓	✓
	pneumoniae	DSM 30104	✓	✓	✓
Proteus	*mirabilis*	DSM 4479	✓	✓	✓
Pseudomonas	*aeruginosa*	DSM 50071	✓	✓	✓
Enterococcus	*faecalis*	DSM 20478	✓	✓	✓
	faecium	DSM 20477	✓	✓	✓
Acinetobacter	*baumannii*	DSM 30007	✓	✓	✓

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