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# Curetis AG

## Technology Fact Sheet

### Overview

Curetis develops advanced molecular diagnostics for infectious diseases. The company's products are based on comprehensive know-how in biotechnology, medical technology, diagnostics and engineering.

Curetis' unique Unyvero™ System provides clinicians with reliable information on pathogens in life-threatening infectious diseases within hours - results that require several days if obtained by standard microbial culture.

At the core of the Unyvero™ System is a disposable cartridge which is available for the diagnosis of specific disease indications. It contains all reagents and materials for the processing of patient samples and the subsequent PCR-based analysis to identify bacterial, fungal or viral pathogens and their antibiotic resistance marker spectrum in a single, fully automated run. It includes a high performance automated sample preparation technology that can handle a wide range of clinical sample types and an analyzer that performs all analytic steps automatically without any operator interaction.

Curetis covers the entire chain from research, platform and content development and clinical validation to the volume manufacturing of disposables. This requires in-depth molecular biology knowledge as well as state-of-the-art, high precision plastics-manufacturing and assembly in a clean-room environment.

### Background

To date, the identification of pathogens and their antibiotic resistances requires skilled personnel, a complex infrastructure and may take up to several days. As a consequence, clinicians often cannot make informed therapy decisions in life-threatening diseases, and patients often do not receive adequate treatment in time.

The Unyvero™ System is designed to provide pathogen identification and antibiotic resistance marker information within hours without the need for expert staff. It integrates all necessary pre-analytical and analytical steps into one solution optimized for reliability, speed and cost.

### Unyvero™ System

The Unyvero™ System comprises three devices and a set of disposables:

- **Lysator L4** for the preparation of up to 4 raw (i.e. native) patient samples in parallel
- **Analyzer A50** for the processing of up to 2 cartridges in parallel
- **Cockpit C8** for the control of up to 8 Analyzers
- Disposable **Unyvero™ Cartridge**, **Unyvero™ Sample Tube** and **Unyvero™ Master Mix Tube**

The **Unyvero™ Lysator** is able to process diverse patient samples, e.g. all types of body fluids as well as sputum, aspirates, lavage samples, and protected brush specimens. It is based on a proprietary combination of different reagents, mechanical actuation, and thermal lysis to improve sample homogenization and lysis performance. The user only has to transfer a native patient sample into the **Unyvero™ Sample Tube** prefilled with specific reagents. Subsequently, the tube is handled by the Lysator. This ensures consistent work flow and reduces potential handling errors.

After lysis, the **Unyvero™ Sample Tube** with the processed sample and the **Unyvero™ Master Mix Tube** are inserted into the **Unyvero™ Cartridge**, which integrates all sample analysis steps to execute a complete test, comprising nucleic acid purification, PCR set-up, multiplex end-point PCR and amplicon detection by hybridization to oligo probes spotted on membrane arrays. The cartridge is pre-filled with buffers for DNA clean up as well as reagents and fluorescence-labeled primers for PCR amplification and array hybridization of the PCR product. For quality control purposes, it also processes a synthetic gene alongside each patient sample. As a physically closed system, the cartridge avoids spilling of sample fluids or reagents and minimizes contamination risks. After use, it

### Quick Facts

#### Unyvero™ System

Lysator L4  
Analyzer A50  
Cockpit C8

Disposable cartridge  
Master Mix Tube  
Sample Tube

#### Cartridge Applications

P50 Pneumonia

#### In preparation:

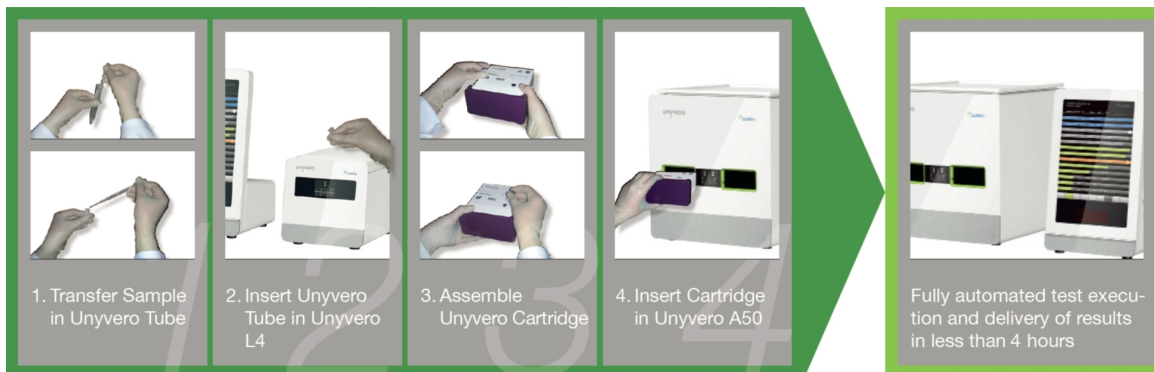
Surgical site infections  
Blood stream infections  
Tuberculosis

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is compatible with standard waste disposal procedures of hospitals and laboratories.

The **Analyzer** automatically performs the handling of the **Unyvero™ Cartridge**, including genomic DNA purification, multiplex nucleic acid amplification with end-point PCR and the detection of the target sequences after hybridization on a special array.

Lysator and Analyzer are controlled by the **Unyvero™ Cockpit**, which also guides the user through the work flow. An integrated bar-code reader enables quick patient information entry and traceability throughout the entire work flow. The software manages automatic results generation and storage and supports users with detection of lot numbers and checking of expiry dates. Each test can be started by full random-access with a simple finger-tip and results are automatically processed and displayed without requiring any further interaction.



Workflow of the Unyvero™ System

### Unyvero™ P50 Cartridge

The first Unyvero™ Cartridge, Unyvero™ P50, focuses on pathogen as well as antibiotic resistance testing for pneumonia. Each cartridge handles one patient sample and analyzes 39 DNA targets simultaneously. Results are available within less than 4 hours.

The pathogen panel has been selected for clinical relevance based on clinical guidelines and has been reviewed by clinical experts in Europe and the USA. Resistance genes were chosen by frequency and clinical significance.

	beta-lactames	ESBL	ampC	carbapenems	methicillin	macrolides	lincosamides	sulfonamides	quinolones	MDR
<i>Acinetobacter baumannii</i>	•			•				•		•
<i>Chlamydomphila pneumoniae</i>										
<i>Enterobacter</i> sp. ( <i>E. aerogenes</i> , <i>E. asburiae</i> , <i>E. cloacae</i> group)	•	•	•					•		•
<i>Escherichia coli</i>	•	•	•					•		•
<i>Haemophilus influenzae</i>	•									
<i>Klebsiella oxytoca</i>	•	•	•					•		•
<i>Klebsiella pneumoniae</i>	•	•	•					•		•
<i>Legionella pneumophila</i>										
<i>Moraxella catarrhalis</i>										
<i>Morganella morganii</i>	•		•					•		•
<i>Pneumocystis jirovecii</i>										
<i>Proteus</i> sp. ( <i>P. mirabilis</i> , <i>P. penneri</i> , <i>P. vulgaris</i> )	•	•	•							•
<i>Pseudomonas aeruginosa</i>	•							•		•
<i>Serratia marcescens</i>	•	•	•					•		•
<i>Staphylococcus aureus</i>					•	•	•			
<i>Stenotrophomonas maltophilia</i>										
<i>Streptococcus pneumoniae</i>							•	•		

Curetis P50 Pneumonia Panel covers 17 pathogens and 22 of their clinically most relevant resistance markers

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