



# unYvero



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# UNYVERO SOLUTION – A VERSATILE PLATFORM



UNYVERO L4 LYSATOR   UNYVERO C8 COCKPIT   UNYVERO A50 ANALYZER

Most of today’s molecular testing systems are very complex, requiring special environments as well as trained operators, limiting their availability to central or specialized laboratories. This process is not acceptable for diagnostic testing of severe acute infections as in most cases the results are not delivered in the required time frame of only a few hours. Curetis solves this problem by offering the fully automated and integrated Unyvero System.

Curetis has shown feasibility or even pre-clinically evaluated the testing of more than 100 different pathogens (bacteria, fungi and viruses) and antibiotic resistance genes in various sample types targeting different clinical applications. The first application of the Unyvero platform is Hospitalized Pneumonia followed by Implant & Tissue Infections and other infection diseases in the near future.



## UNYVERO SYSTEM

THE CURETIS UNYVERO SYSTEM IS BASED ON A  
VERSATILE HARDWARE PLATFORM –  
THE UNYVERO LYSATOR AND THE UNYVERO ANALYZER -  
HANDLING DISEASE SPECIFIC CARTRIDGES FOR  
THE ANALYSIS OF VARIOUS DISEASE MARKER PANELS.

# UNYVERO SOLUTION COMPONENTS – COVERING THE ENTIRE WORKFLOW



The Unyvero System translates a complex laboratory process into an easy-to-use format. The analytical process requires merely the addition of the unprocessed patient sample and enzymes for DNA amplification. All other reagents are preloaded into a self-contained, contamination safe cartridge. After the patient sample

and the Master Mix are inserted into the cartridge, the cartridge is loaded into the analyzer and processed fully automatically. The Unyvero System generates complete diagnostic information in 4 – 5 hours, without any further operator interaction.

**THE UNYVERO SOLUTION FEATURES A  
»SAMPLE TO ANSWERS« APPROACH AND  
CONSISTS OF:**

- > the Unyvero L4 Lysator for sample lysis
- > the application specific Unyvero Cartridge
- > the Unyvero A50 Analyzer handling the Unyvero Cartridge
- > the Unyvero C8 Cockpit for intuitive user interaction
- > and the optional Unyvero Server Software for integration into the hospital's information systems

# CURETIS` UNIQUE TECHNOLOGIES

The patented Unyvero sample preparation technology uses a combination of different chemicals, a novel mechanical actuation and thermal lysis. Because of its universal applicability it can use a single protocol for sample preparation for many different sample types. This means consistent workflow and an almost completely automated sample analysis, thus reducing potential handling errors.

One of Curetis` core competencies is the design of reliable bio-assays in self-contained cartridges to enable sensitive multiplexed testing. First, the system isolates and purifies the DNA, followed by a specific multiplex PCR amplification step. A low-density array based on an optical readout of the fluorescently labeled DNA amplicons performs the final

DNA detection and has been optimized for hybridization times of a few minutes.

Thereby Curetis` cartridge technology can detect more than 100 different analytes in a single cartridge within a few hours.

Ease-of-use requirements are addressed by the complete integration of all test processes into the closed Unyvero Cartridge for one-time use. All analytical steps for sample preparation, DNA extraction and purification, amplification and specific detection are executed inside of this cartridge which is preloaded with all (despite the enzymes) necessary reagents. All molecular testing steps are performed automatically without manual interaction.

## INFECTIOUS DISEASE ASSAY



**1. COVERAGE**  
Detects 90% of infectious disease causing pathogens and clinically most relevant antibiotic resistances

**> 100 ANALYTES POSSIBLE**



**2. DIVERSITY**  
Enables testing of clinically relevant, different native sample types

**SPUTA, BAL, TRACHEAL ASPIRATES, STOOL, TISSUE, URINE AND OTHERS**



**3. SPEED**  
Delivers clinically relevant answers in time

**4 – 5 H**

## PRE-REQUISITES

- > **WORKS WITH VARIOUS NATIVE SAMPLES AND POSITIVE BLOOD CULTURE BOTTLES**
- > **NEEDS SAMPLE PREPARATION WITH HIGH DNA YIELD**
- > **ALLOWS MULTIPLEX PCR OF MORE THAN 100 ANALYTES**
- > **REQUIRES SPECIFIC DETECTION**



## UNYVERO L4 LYSATOR – HANDLES ANY SAMPLE

The Unyvero L4 Lysator performs the sample lysis of up to four samples in parallel and convinces with reliable results for diverse sample types.

It even handles complex samples like viscous sputa, thus ensuring high DNA yield after extraction.

It accepts a wide range of sample types because of a proprietary sample processing method (patents pending) including sputum, broncho-alveolar lavage (BAL), tracheal aspirates, swabs, catheters, sonication / synovial fluids, stool, urine, positive blood cultures, and others. For higher throughput settings up to two L4 Lysators can be attached to a single Cockpit enabling the simultaneous preparation of 8 samples.



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## UNYVERO L4 LYSATOR



## UNYVERO A50 ANALYZER – DETECTS MORE THAN 100 ANALYTES PER SLOT

The Unyvero A50 Analyzer automatically processes the Unyvero Cartridge and consists of mechanical, electronic and optical elements to control all sample processing and analysis steps, which happen inside the sealed cartridge.

The Unyvero A50 Analyzer is a module capable of processing two cartridges independently with full random-access capabilities. Depending on required throughput needs, the user can stack up to eight A50 Analyzers allowing for up to 16 cartridges being processed simultaneously.

For robustness and safety reasons the Unyvero Analyzer does not contain any reagent or waste – all reagents and waste are contained in the disposable cartridge and will be disposed together with the used cartridge.



Made in Germany



# UNYVERO C8 COCKPIT – FEATURES »PLUG & PLAY« USE

The Unyvero Lysator and the Analyzer are controlled by the Unyvero C8 Cockpit with an integrated touch screen. The high-contrast 17-inch full color touch screen for data entry and display has a built-in barcode scanner to identify samples, patients or users.

The C8 Cockpit guides from first user interaction to starting of the fully automated process. The software manages automatic result generation and storage and supports the user in checking lot numbers and expiry dates.

An optimal integrated information management software enables easy data transfer, archiving, maintenance and quality control processes optimizing the routine laboratory workflow.



A built-in barcode scanner

## UNYVERO C8 COCKPIT





## UNYVERO CARTRIDGE – BACKBONE FOR VARIOUS CLINICAL APPLICATIONS

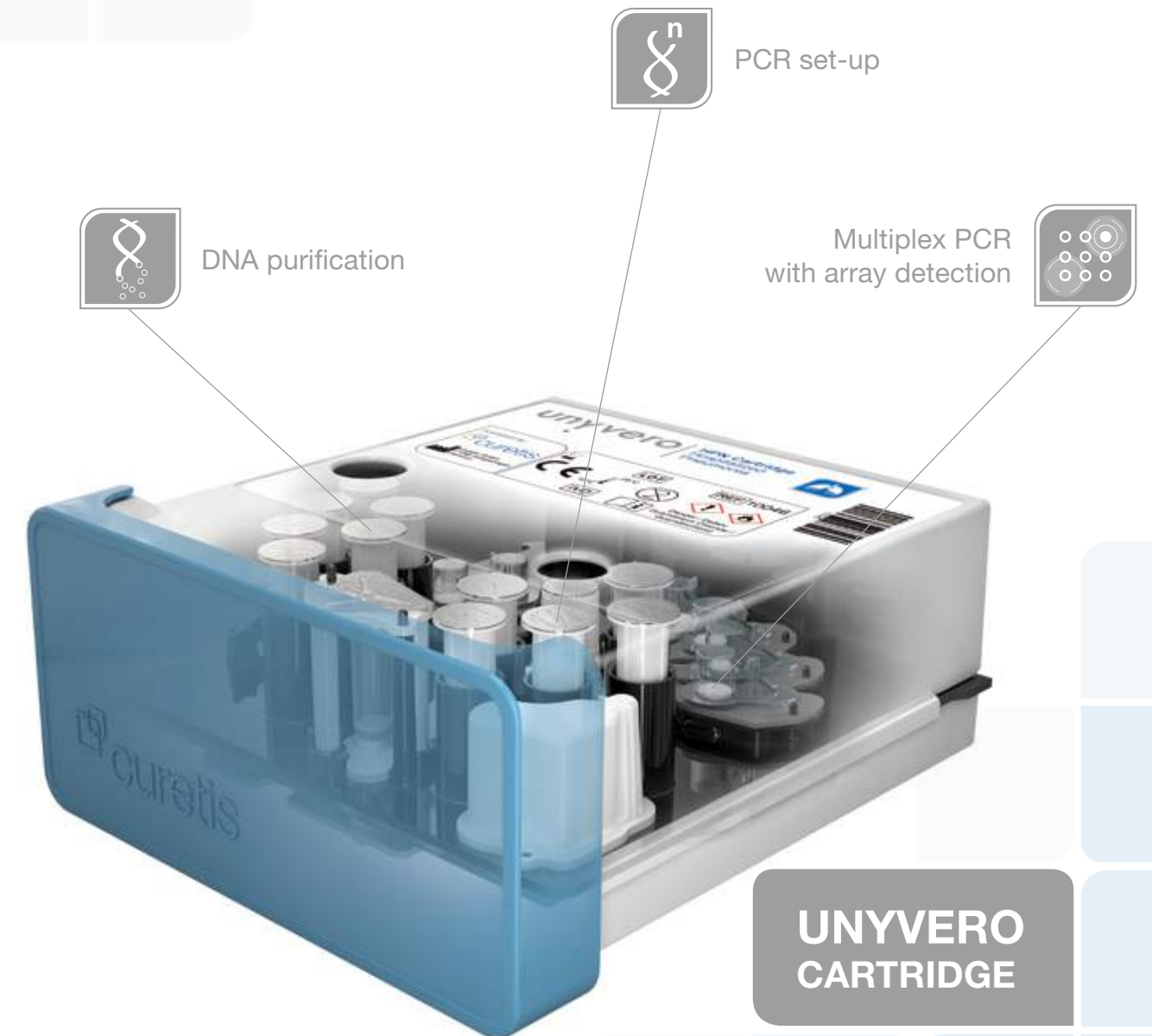
The unique disposable Unyvero Cartridge is disease specific, allows for detection of multiple analytes and integrates all sample analysis steps to execute a complete test: DNA purification, PCR set-up, multiplex end-point PCR and amplification as well as detection by arrays.

Therefore the closed Unyvero Cartridge is equipped with integrated reagent containers, a DNA purification column, eight PCR chambers and an according number of arrays. The cartridge is pre-filled with buffers for DNA clean up, reagents and fluorescence-labeled primers for PCR amplification, respectively for array hybridization of the PCR product.

After sample lysis, the user assembles the cartridge by simply inserting the Unyvero Sample Tube and the Unyvero Master Mix Tube - no further hands-on steps are necessary.

Once assembled, the cartridge is a physically closed system – avoiding any possibility of spilling sample fluids or reagents, and minimizing contamination risks. The disposable cartridge is compatible with standard waste disposal procedures of hospitals and laboratories.

For quality management purposes an internal control (a synthetic gene, without any homology to known sequences) is processed on the cartridge together with the patient sample. This approach enables the control of the entire workflow.



# UNYVERO SOLUTION – SIMPLIFIED WORKFLOW

The intuitive simple workflow is consistent across all clinical applications and sample types, thus drastically reducing invalid tests due to operator errors.

**STEP 1**  
TRANSFER OF SAMPLES  
AND LYSIS



**Working time** ▶ **~ 60 seconds:**

1. The patient sample is transferred to the Unyvero Sample Tube, then sealed in with the Unyvero Sample Tube Cap and lysed for 30 minutes in the Unyvero Lysator.

**STEP 2**  
ASSEMBLING THE  
UNYVERO CARTRIDGE



**~ 30 seconds:**

2. After 30 minutes, the Unyvero Sample Tube can be removed from the Lysator and inserted together with the Unyvero Master Mix Tube into the corresponding Unyvero Cartridge.

**STEP 3**  
SCANNING AND INSERTING  
THE UNYVERO CARTRIDGE



**~ 20 seconds:**

3. The cartridge is now scanned and inserted into the Unyvero Analyzer. Up to two cartridges per analyzer can be analyzed simultaneously.

**STEP 4**  
FOUR TO FIVE-HOUR  
ANALYSIS PROCESS



**It takes just a few minutes for subsequent analysis of the results:**

4. The Unyvero analysis now runs for four to five hours. The results are then displayed on the screen or can be exported as a PDF.

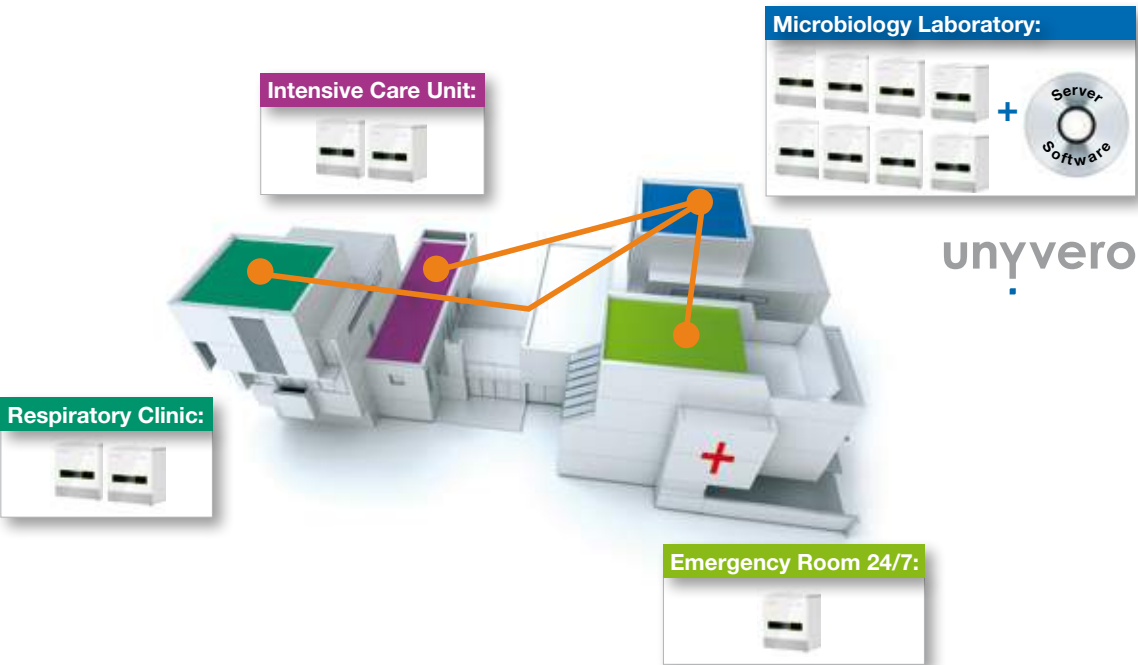
UNYVERO SOFTWARE –  
INTUITIVE – EASE OF USE



After just four to five hours, the Unyvero test results are displayed in four windows on the touchscreen of the Unyvero Cockpit.

A stand-alone solution consists of one Unyvero Cockpit with at least one Unyvero Lysator and one Unyvero Analyzer not connected to any hospital network and will be managed by the Unyvero OS software. Software Plug-Ins customize this general software to use with the disease-specific Unyvero Cartridges.

UNYVERO SOLUTION – ENABLING  
24H / 7D MOLECULAR TESTING



The Unyvero Server Software enables the combination of installations at different locations (e.g. laboratory, ward or ER). All instruments can then be managed centrally, including confirmation of findings by a physician, data storage and archiving, as well as quality control or reporting of epidemiological data.

The Unyvero Solution delivers fast and reliable results for a broad panel of pathogens and antibiotic resistance markers.

## UNYVERO AT A GLANCE

### THE UNYVERO SOLUTION

- > detects broad panels of pathogens and antibiotic resistances from a single sample in one run
- > enables testing of many clinically relevant native samples
- > delivers clinically relevant information in 4 – 5 hours, to aid an informed therapy decision as early as possible
- > enables point of need testing
- > provides high productivity through
  - minimizing operator time to a few minutes with full walk-away automation based on a simple and consistent workflow for any clinical application
  - low implementation requirements and low total cost of ownership, as no staff with molecular biology skills nor special infrastructure is needed
  - configurations that meet individual customer needs, satisfying throughput demands ranging from a few samples to almost a hundred tests per day
  - optimizing the routine hospital workflow by sophisticated information management

# unyvero



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