

MANUAL



CUBE-MA-18042-V02-E
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July, 2018.

EPC S.aureus 1000

REF HC0472-10

EPC S.aureus 10000

REF HC0473-10

EPC C.albicans 1000

REF HC0474-10

EPC C.albicans 10000

REF HC0475-10

*External Process Controls (EPC) for
quality assurance of molecular infectious disease testing products.*



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
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List of abbreviations

°C.....	<i>Celsius degree</i>	Dx.....	<i>Diagnostics</i>
µL.....	<i>Microliter</i>	ID.....	<i>Identification</i>
Cq.....	<i>Cycle of quantification</i>	IVD.....	<i>In vitro Diagnostic</i>
CE.....	<i>Conformité Européenne (European Conformity)</i>	mL.....	<i>Milliliter</i>
CV.....	<i>Coefficient of variation</i>	qPCR.....	<i>(quantitative) Polymerase Chain Reaction</i>
DNA.....	<i>Desoxyribonucleic acid</i>	UV.....	<i>Ultraviolet</i>



Explanation of symbols

Symbol	Explanation
 	CE mark. In vitro diagnostic medical device.
	Manufacturer.
	Date of manufacture.
	Lot/batch number.
	Catalogue number.
	Serial number.
	Keep away from rain / humidity.
	Keep away from sunlight.
	Only use once. Do not re-use.
	Don't use if package is damaged.
	Do not eat or drink.
	Use by date.
	Temperature limit for storage.
	Sufficient for <n> tests.
R 22	Harmful if swallowed.
S 1/2	Store in a secure location and away from children.
S 18	Open and handle container with caution.
S 20	Do not eat or drink while handling.
S 24/25	Prevent contact with eyes and skin.
S 36/37	Wear appropriate protective gloves and clothing while handling.



Introduction and intended use

Quality assurance concepts for (highly sensitive) molecular pathogen identification from human samples must ensure stable results over time. Therefore well-defined control material should be tested periodically to check and document constant outcome.

EPCs are quantified, inactivated bacterial or fungal cells in different concentrations (frozen). They are intended to safeguard the stability of the molecular pathogen ID processes of human samples over time. Periodic usage of EPCs documents the laboratories ability to detect defined levels of bacterial and fungal DNA.

EPCs come as single use controls in different concentrations to fit to different diagnostic applications.

Running tests with EPCs should be carried out in an environment suitable for molecular biological testing. Dependent on the required sensitivities of the test, this might include DNA-and DNase-free pipets, separated rooms for DNA isolation and amplification/detection and the possibility of UV decontamination. **Running tests with the EPCs should exclusively be performed by qualified personnel, which has been trained in the use of the used products.**

The necessary equipment includes a freezer (-15 to -25 °C).

Technical description

EPCs are quantified, inactivated bacterial or fungal cells in different concentrations (frozen).

The cells are intact but blocked in growth. Therefore, DNA extraction process can be tested with this “sample-like” EPCs, same as with still growing organisms.

Each single tube contains 20µL of the solution with the inactivated cells. The 20µL in the tube are intended to be one sample for the periodic testing of the molecular diagnostic test (single-use reagent).

It is possible that spoilt products may result in negative results for the test.



Product components

To assure quality of bacterial testing, following specific products are required:

- **EPC *S.aureus* 1000** (order number HC0472-10): store at **-15 to -25 °C**
 - 10 x 20µL EPC *S.aureus* 1000
(10 separately packed 0,5mL micro tubes with ~ 1.000 CFU each (in 20µL solution))
- **EPC *S.aureus* 10000** (order number HC0473-10): store at **-15 to -25 °C**
 - 10 x 20µL EPC *S.aureus* 10000
(10 separately packed 0,5mL micro tubes with ~ 10.000 CFU each (in 20µL solution))

To assure quality of fungal testing, following specific products are required:

- **EPC *C.albicans* 1000** (order number HC0472-10): store at **-15 to -25 °C**
 - 10 x 20µL EPC *C.albicans* 1000
(10 separately packed 0,5mL micro tubes with ~ 1.000 CFU each (in 20µL solution))
- **EPC *C.albicans* 10000** (order number HC0473-10): store at **-15 to -25 °C**
 - 10 x 20µL EPC *C.albicans* 10000
(10 separately packed 0,5mL micro tubes with ~ 10.000 CFU each (in 20µL solution))

Pay attention not to mix up components of different lots!

Storage and shelf life

The minimum shelf life of the products is only guaranteed, if the required temperature and humidity conditions are safeguarded during transportation and storage. The expiry dates of the products are depicted on the products' labels.

EPCs are delivered frozen and must be stored at **-15 to -25 °C**.

If any packaging (e.g. any tubes) are damaged / or the minimum shelf life has expired, the product / component must not be used. Components have to be used immediately after opening the vessel. Thawing and freezing again destroys the product and is strictly forbidden.



Required equipment

The following equipment is required for handling the product:

Required Accessories / Infrastructure		REF
Freezer (-20°C)		
Pipettes: ▪ 20 – 200 µL	<u>GILSON</u> ¹ : PIPETMAN P200N	F144565
Sterile filter tips, DNA-free: ▪ 200/300 µL	<u>PEQLAB</u> : 300 µL Biotix	

Required accessories.

Test procedure

Note, that using the EPC requires thawing of reagents. As these may be associated with waiting times, read the entire chapter of the test procedure before starting.

During test preparation and processing a laboratory coat, latex gloves, sleeve guards, hair (and beard) net and a surgical mask should be worn to avoid contamination of the test reagents. Preparation should be done under a DNA work bench.

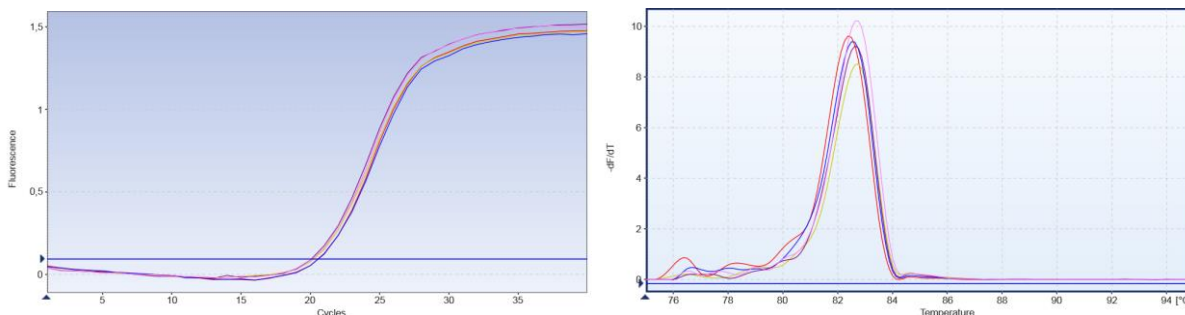
1. Pipette 20µL of the EPC (one vial) into the container of a negative patient sample.
2. Follow the instruction of your test procedure like you would do for a patient sample.
3. Compare the results of the test with the expected result and document the outcome.

¹ <http://www.gilson.com>



Performance data

Repeatability was tested with 5 different EDTA whole blood samples for each EPC. EPC (20µL) was added and the samples were processed according to the GINA 500 protocol (including DNA purification). *PCR-Box Bacteria* or *PCR-Box Fungi* (see example graphs for EPC S.aureus 10.000 below) was run and the results were verified by running *hybcell Pathogens DNA xB*.



The analysis of quantification cycles (Cq) resulted in (all values rounded):

	S.a. 1000	S.a. 10000	C.a. 1000	C.a. 10000
Average:	23,3	20,3	30,9	26,2
Standard Deviation:	1,6	0,2	0,7	0,7
Coefficient of Variation (CV):	6,7	1,1	2,3	2,6

Measures in case of changes in analytical performance

For verification of the functionality of the EPCs, run several tests and compare outcomes with expected outcome. If outcome is not as expected, use EPCs from another lot and repeat the tests.



Disposal

EPC tubes are containing potentially infectious material and have to be disposed according to your organisation's rules for disposal of infectious material.

Troubleshooting

In case of problems with the device or the test, please contact:



Cube Dx GmbH
Westbahnstraße 55, 4300 St. Valentin, Austria
Contact information: www.cubedx.com

