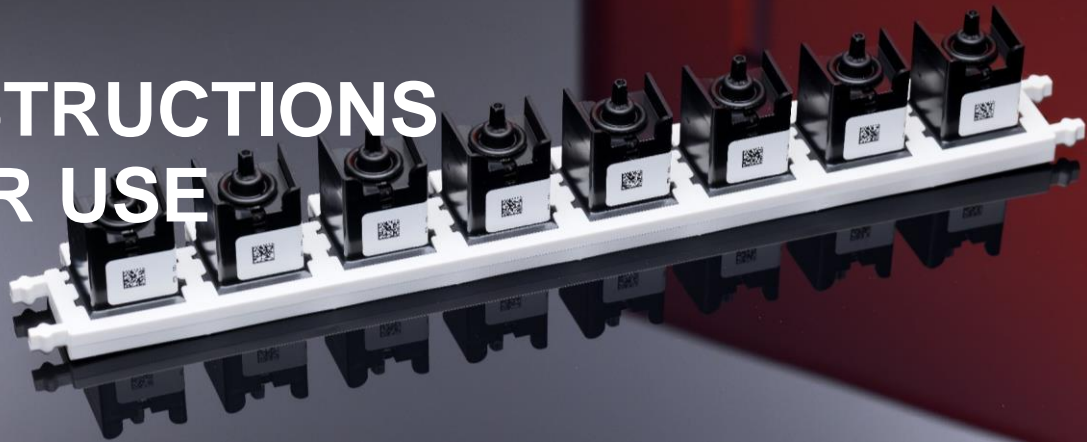


INSTRUCTIONS FOR USE



EPC_instructions for use_E_2023_01_11
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RUO

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| | | |
|-------------------------------------|-------------|----------------------|
| <i>EPC S. aureus 10000</i> | REF | <i>HC0473-10</i> |
| | GTIN | <i>9120127730275</i> |
| <i>EPC C. albicans 10000</i> | REF | <i>HC0475-10</i> |
| | GTIN | <i>9120127730282</i> |

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
















Content

| | | |
|-----|---|---|
| 1. | EXPLANATION OF SYMBOLS | 3 |
| 2. | INTRODUCTION AND INTENDED USE..... | 4 |
| 3. | TECHNICAL DESCRIPTION | 4 |
| 4. | PRODUCT COMPONENTS | 5 |
| 5. | STORAGE AND SHELF LIFE..... | 5 |
| 6. | REQUIRED EQUIPMENT | 5 |
| 7. | TEST PROCEDURE | 6 |
| 8. | PERFORMANCE DATA..... | 7 |
| 9. | MEASURES IN CASE OF CHANGES IN ANALYTICAL PERFORMANCE | 8 |
| 10. | DISPOSAL | 8 |
| 11. | TROUBLESHOOTING | 8 |



1. Explanation of symbols

| Symbol | Explanation |
|---|---|
| RUO | Research Use Only |
|  | Manufacturer. |
|  | Date of manufacture. |
|  | Lot/batch number. |
|  | Catalog number. |
|  | Serial number. |
|  | Keep away from rain/humidity. |
|  | Keep away from sunlight. |
|  | Only use it once. Do not reuse. |
|  | Don't use it if the 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 the 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. |



2. 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 the 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 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, separate 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 have been trained in the use of the used products.**

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

3. Technical description

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

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

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

Spoilt products may result in negative results for the test.



4. Product components

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

- EPC *S. aureus* 10000 (order number HC0473-10, GTIN 9120127730275): 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 the quality of fungal testing, the following specific products are required:

- EPC *C. albicans* 10000 (order number HC0473-10, GTIN 9120127730282): 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!

5. 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) is 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 destroy the product and are strictly forbidden.

6. Required equipment

The following equipment is required for handling the product:

| Required Accessories / Infrastructure | | REF |
|---|----------------------------|---------|
| Freezer (-20°C) | | |
| Pipettes: <ul style="list-style-type: none"> ▪ 20 – 200 µL | GILSON1: PIPETMAN P200N | F144565 |
| Sterile filter tips, DNA-free: <ul style="list-style-type: none"> ▪ 200/300 µL | PEQLAB: 300 µL Biotix | |

Required accessories.

1 <http://www.gilson.com>



7. Test procedure

Note, that using the EPC requires the 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 workbench.

The following steps apply:

1. Pipette 20µL of the EPC (one vial) into the container of a negative patient sample.

For GINA 500:

- Pipette 500µl of the blood sample into the EPC tube and pipette up and down to mix.
- Transfer the sample-EPC mixture into the LE buffer.

For LINA:

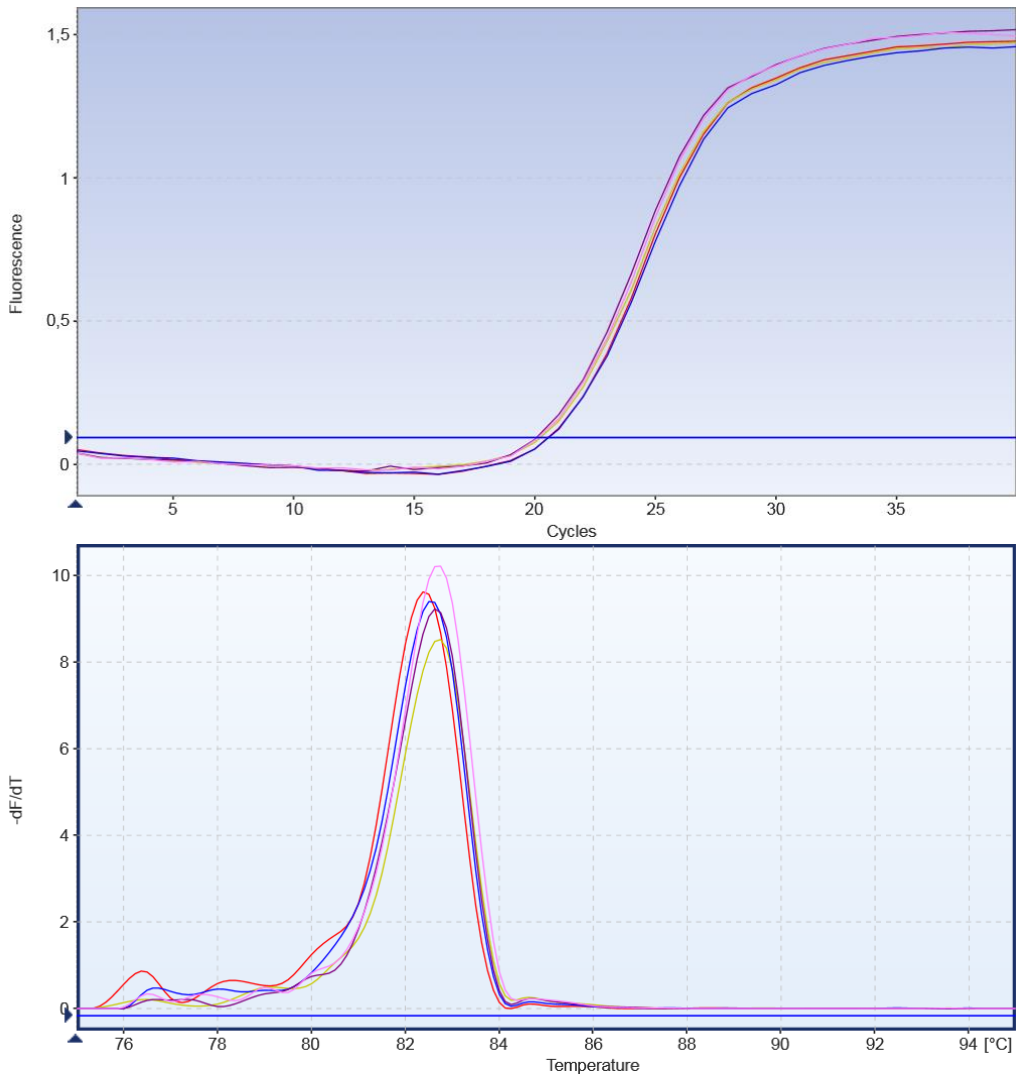
- Pipette 20µl of the EPC into the LINA tube

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.



8. Performance data

Repeatability was tested with 5 different EDTA whole blood samples for each EPC. EPC (20 μ L) 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* 10000 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):

| | <i>S. aureus</i> 10000 | <i>C. albicans</i> 10000 |
|---------------------------------------|------------------------|--------------------------|
| Average: | 20,3 | 26,2 |
| Standard Deviation: | 0,2 | 0,7 |
| Coefficient of Variation (CV): | 1,1 | 2,6 |



9. Measures in case of changes in analytical performance

To verify the functionality of the EPCs, run several tests and check the outcome. If the outcome is not as expected, use EPCs from another lot and repeat the tests.

10. Disposal

EPC tubes contain potentially infectious material and must be disposed of according to your organization's rules for the disposal of infectious material.

11. 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

For additional information about device and software usage see the hyborg Dx RED2 manual.

