

CERTIFICATE OF ANALYSIS POSITIVE CONTROL KIT

 PRODUCT CODE: SI 190.911
 NAME: POSITIVE CONTROL KIT

 BATCH N.:
 PCK21004
 EXPIRY DATE: 17/06/2022

 MANUFACTURING DATE:
 26/04/2021

RECONSTITUTING AND DILUTING SOLUTIONS

Eugonic broth

Batch N.: FLA20005

Expire date: 16/11/2022

| | Physical | Decontamination at | econtamination at Growth | |
|----------|--------------|--------------------|--------------------------|-------------|
| | parameters * | 37 °C after 72 h | inter batch | intra batch |
| Expected | Compliant | No growth | CV%≤35% | CV%≤35% |
| Found | ОК | ОК | 2 1 ,8 % | <5% |

* Volume, transparency, colour

LYOPHILIZED MICROORGANISM

| | | Growth inter batch (CV% ≤35%) | Physical check** |
|-------------------------|----------|----------------------------------|------------------|
| Batch N.: 20002 | Expected | Compliant | Compliant |
| Expire date: 17/06/2022 | Found | ОК | ОК |

** Aspect

STORAGE CONDITIONS: 2 ÷ 8 °C

Date of Approval: 29/04/2021

Pividori Denis: Manufacturing Manager

Date of Release: 29/04/2021

We certify that the lot in object has been manufactured and tested according with ALIFAX manufacturing and quality control procedures and specifications. These requirements have been established according to the European Directive 98/79/EC. We confirm that the above referenced product conformed to the specifications and then it is released

Release authorized by Quality Assurance

ALIFAX S.r.l.

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