



# CERTIFICATE OF ANALYSIS Nr 258



**Product:** BioCapt® Single-Use Manufactured by Neomed srl **Product Code:** 79001409

**Media:** **SABOURAUD DEXTROSE AGAR + NEUTRALIZERS**  
(Sabouraud Dextrose Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine)

**Lot Nr:** 18D2603 **Date of Manufacturing:** 26 Apr 2018 **Expiry date :** 26 Jan 2019 **Storage Conditions:** 2-25°C up to expire date

**Sterilization:** ≥25 KGy gamma irradiated **Irradiation Certificate Nr:** 3485 **Conforms**

## CHEMICAL / PHYSICAL TESTS:

<b>Appearance:</b> amber coloured, clear to slightly opalescent gel forms in BioCapt device plates	<b>Conforms</b>
<b>pH specification:</b> 5,6 ± 0,2 at 25°C	<b>pH result:</b> 5,5 <b>Conforms</b>
<b>Filling media Volume:</b> 30 ml ± 1ml	<b>Conforms</b>
<b>Media Composition:</b> SDA+Neutralizers– BSE free (see technical data sheet cod 79001409)	<b>Conforms</b>

## MICROBIOLOGICAL TEST CONTROLS:

**Sterility Control - Absence of contamination**  
At the following incubation conditions (performed before gamma irradiation):  
32.5 ± 2.5°C aerobic for 7 days  
22.5 ± 2.5°C aerobic for 7 days **Conforms**

**Fertility - Growth Promotion test** ( performed after gamma irradiation): **Conforms**

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70% ≤ R% ≤ 200%	79,2%	<b>Conforms</b>
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	48-120 h at 22.5 ± 2.5°C	70% ≤ R% ≤ 200%	117,0%	<b>Conforms</b>

**GROWTH PROMOTION TEST** IN ACCORDANCE TO HARMONISED EP – USP PHARMACOPOEIAS CHAPTER, BY QUANTITATIVE SURFACE PLATING METHOD.  
**RECOVERY:** RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES X 100/CFU ENUMERATION ON REFERENCE TESTS.  
**REFERENCE MEDIUM** FOR RECOVERY TESTS: TRYPTIC SOYA AGAR FOR ALL BACTERIA AND SABOURAUD DEXTROSE AGAR FOR YEAST & MOLD SPECIES.  
**ATCC** IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION.

**Lot Status:** Approved

**Lot Approval Date:** 04 Jun 2018

**Quality Control Manager:** Dott.ssa Cinzia Bovio

**Signature:**