| **510635GMP,**  **510636GMP** | **Sterility Testing by Direct Inoculation** | **Inventory Control** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Supplier Catalogue Number** | **Oracle Part Number** | **Inventory Control** | **Release**  **Specification** | **In House/ secondary**  **BOM** |
| Material type | Name | **Y/N** | **Y/N** | **Y/N** |
| **Media** | **THIO Broth** | **44001** | **A0000328** | **Y** | **Y** | **Y**  **(KPBT4412)** |
| **Media** | **TSB (Tryptone Soya Broth)** | **44011** | **A0000329** | **Y** | **Y** | **Y (KPBT4412)** |
| **Media** | **TSA (Tryptone Soya Agar)** | **104130** | **A0001753** | **Y** | **Y** | **Y (KPBT4412)** |
| **Media** | **MEA (Malt Extract Agar)** | **104300** | **A0002144** | **Y** | **Y** | **Y (KPBT4412)** |
| **Diluent** | **Sterile Distilled Water** | **15230071** | **100000774** | **Y** | **Y** | **N** |
| **Positive Control** | ***S. aureus* ATCC 6538** | **Q7016C** | **A0000762** | **Y** | **Y** | **Y (BPBT1657)** |
| **Positive Control** | ***B. subtilis* ATCC 6633** | **Q1221C** | **A0000757** | **Y** | **Y** | **Y (BPBT1657)** |
| **Positive Control** | ***C. sporogenes* ATCC 19404 or 11437** | **Q1700C/Q1703C** | **A0000759/760** | **Y** | **Y** | **Y (BPBT1657)** |
| **Positive Control** | ***Ps. aeruginosa* ATCC 9027** | **Q5210C** | **A0000761** | **Y** | **Y** | **Y (BPBT1657)** |
| **Positive Control** | ***A. brasiliensis* ATCC 16404** | **Q1100C** | **A0000756** | **Y** | **Y** | **Y (BPBT1657)** |
| **Positive Control** | ***C. albicans* ATCC 10231** | **Q1503C** | **A0000758** | **Y** | **Y** | **Y (BPBT1657)** |
| **Reagent** | **Anaerobic sachets** | **BRS024/AN0025A** | **A0000666** | **Y** | **N** | **N/A** |

**Approvals**

**Prepared By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approval (Ops) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approval (QA) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Document Revision History**

|  |  |  |
| --- | --- | --- |
| **Revision Number** | **Details** | **Effective Date** |
| R00 | Replaces BOM510635GMP and BOM510636GMP.REV 01  Inclusion of media for inocula check  Update of A niger to A brasiliensis  Inclusion of alternative C Sporogenes | Date of approval |