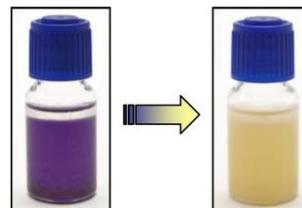


Total Viable Count



CBT-A01

1.1. Package

Vials ready for analysis and bottles of sterile demineralized water.

1.2. Use

The MBS method can be used for selective detection and enumeration of microorganisms which may be present in the agro-food, water and on the surfaces of processed raw materials.
 The product is a reagent for the detection of aerobic or microaerophilic mesophilic microorganisms able to grow on complete media.
 The product can be used only inside the vials provided by Royal Biotech.

1.3. Principals

The MBS method measures the enzyme catalytic activity oxidoreductase of primary metabolism, allowing you to establish a clear correspondence between the enzyme activity detected and the microbial load present in the sample.
 The method is based on the observation of a color change in the suspension formed in the bottle when inserted into the sample to be analyzed: the suspension changes color (turns) if there are microorganisms, the greater the amount of microorganisms, the faster the change of color.

1.4. Features

The MBS method has been validated in accord with the criteria defined by the standard ISO 16140:2003 "Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods", using as reference the method ISO 4833:2003 "Microbiology of food and animal feeding stuffs – Horizontal method for enumeration of microorganism – Colony count technique at 30 °C".
 An accuracy analysis showed a very high correlation between the two methods, in addition the MBS method is extremely reproducible, with values of variance and standard deviation better than the reference. The linearity of the MBS method as compared to bacterial contamination is excellent, with a sensitivity to the analyte remaining consistent with values of CFU/ml < 1 to contamination in the order of 10⁶ CFU/ml. Even the inclusiveness of the method is very satisfactory, since it does not occur with either false negatives or false positives.

1.5. Composition

- Nutrients: Mainly proteins, glucides and lipids, to sustain the growth of bacteria.
- Selective agents: To inhibit the growth of all the bacteria with the exclusion of those that should be detected.
- Reductants: Organic compounds able to transfer electrons to the bacterial respiratory chain without being oxidized by molecular oxygen.
- Redox dyes: Organic compounds that change their colour as a function of the redox state of the medium
- Oil: Inert liquid petroleum jelly to avoid oxygen transfer inside the vial from gaseous phase to liquid phase.
- Sterilant: Chemical compound used for sterilizing the vials after analysis.

1.6. Quality control

| POSITIVE CONTROLS | | NEGATIVE CONTROLS | |
|--|-----------------------|---|-------------------------|
| Reference strain | Limit of Sensibility | Reference strain | Limit of Sensibility |
| <i>E. coli</i> ATCC 25922 | 1 CFU/g | <i>Clostridium perfringens</i> ATCC 13124 | > 10 ⁶ CFU/g |
| <i>Enterobacter cloacae</i> ATCC 13047 | 1 CFU/g | | |
| <i>Enterobacter sakazakii</i> ATCC 51329 | 1 CFU/g | | |
| <i>Salmonella thyphimurium</i> ATCC 14028 | 1 CFU/g | | |
| <i>Pseudomonas aeruginosa</i> ATCC 27853 | 1 CFU/g | | |
| <i>Listeria innocua</i> ATCC 33090 | 1 CFU/g | | |
| <i>Listeria monocytogenes</i> ATCC 7644 | 1 CFU/g | | |
| <i>Aspergillus niger</i> ATCC 964 | 10 ² CFU/g | | |
| <i>Saccharomyces cerevisiae</i> ATCC 18824 | 10 ² CFU/g | | |
| <i>Enterococcus faecalis</i> ATCC 29212 | 1 CFU/g | | |

1.7. Validity and conservation

In the original packaging, the product has a validity of 12 months when stored at 5 °C and 6 months when stored at 20 °C and protected from direct light.

1.8. Waste management

After sterilization and inactivation of chemical components, obtained by pressing the gas cap, the analysis bottle can be safely disposed of as a "sanitary waste non-hazardous" in accord with the DM of 25/5/89, the waste may be disposed of in the same way as the drugs which have expired.

1.9. Warnings and precautions

The product is classified as hazardous under current legislation; it is recommended to consult the MSDS before its use.

