

## GENERAL INFORMATION

Category : Sterile sampling kits

Family : Sani-S'wipe

Lifespan: 18 months

## TECHNICAL DESCRIPTION

This kit consists of a sterile bag with an integrated closure system and a biocide-free cloth for sampling various surfaces.



## SPECIFIC INFORMATION

### CONTAINER

|                       |                                      |
|-----------------------|--------------------------------------|
| Type of container :   | Bag                                  |
| Material :            | Thermoplastic laminate               |
| Color :               | Transparent                          |
| Dimension :           | 190 x 292mm / 7.5 X 11.5 po          |
| Thickness :           | 3.5 mil.in / 0.0889 mm / 88.9 micron |
| Total volume :        | 2100 ml / 70 oz                      |
| Functional volume :   | 1200 ml / 41 oz                      |
| Printing type :       | Form                                 |
| Opening system :      | Laser scoring line                   |
| Closing system :      | Attachment with 2 round wires        |
| Sterile :             | Yes                                  |
| End of product life : | Garbage                              |

### INSERTION

|                  |  |
|------------------|--|
| Insertion type : | Blue Cloth   |
| Description :    | Non-woven textile composed of cellulose and polyester. Color: pale blue. Folded in 4. Dimensions 9" x 9" (22.9 cm x 22.9 cm). Size (total area): 81 sq. in. (522.5 cm <sup>2</sup> ). Free from biocides |
| Biodegradable :  | Garbage  |

### INSERTION

|                  |  |
|------------------|--|
| Insertion type : |  |
| Description :    |  |
| Biodegradable :  |  |

### SOLUTION

|                    |                                |
|--------------------|--------------------------------|
| Name :             | Neutralizing Buffer (NB)       |
| Type of solution : | Transport medium, neutralizing |
| pH :               | 7.2±0.2                        |

### OTHER

## AVAILABLE DOCUMENTS

|                          |                           |
|--------------------------|---------------------------|
| Data Sheet               | Certificate of Compliance |
| Certificate of Analysis  | Safety Data Sheet (SDS)   |
| Certificate of Sterility | Pyrogen Declaration       |
| DNase/RNase              |                           |

## PACKAGING INFORMATION

|                                      |  |
|--------------------------------------|--|
| Outer box dimension :<br>(W x D x H) | 9.50 X 14.13 X 16.25                         |
| Box weight :                         | 9.45 LB / 4.29 KG                            |
| Conditioning :                       | 100 (1 x 100)                                |
| Storage condition :                  | Upon receipt, store<br>between 2 °C and 8 °C |

Reach out to us for additional resources, if applicable to this product.

## DECLARATION

|              |  |
|--------------|--|
| CFIA         | LABPLAS sampling bags are a solution that may be used in the CFIA Preventive Control Plan (PCP) for the seven principles of the HACCP system. The PCP is a Canadian federal initiative, under the Safe Food for Canadians Regulations (SFCR).  |
| EU           | The materials used to manufacture LABPLAS sampling bags meet, where applicable, the Eu No10/2011 standards for food contact with respect to particle migration.  |
| DNase-free   | This product is DNase-free. Sensitivity of 10-7 Kunitz units/µL  |
| RNase-free   | This product is RNase-free. Sensitivity of 10-9 Kunitz units/µL.   |
| FDA          | The plastic film used in the manufacture of the LABPLAS sampling bag meets the requirements of the Food and Drug Administration Regulation [ 21 CFR 177.1520 (b), (c)2.1, (c)3.1a, (c)3.2a, and 170.39, 174.5 (a), 178.2010 (b), 178.3297 (c), and 178.3860], provided that the sampling bag is not in contact with an alcoholic product and that the conditions of use comply with section C to G of table 2 of 21 CFR 176.170 (c). |
| FDA          | The plastic film used in the manufacture of LABPLAS sampling bags complies with 21 CFR 177.1520 [(c) 3.2c] of the Food and Drug Administration. Its use is limited to temperatures below 212 F according to Table 2 of 21 CFR 176.170 (c).   |
| FDA          | The plastic film used in the manufacture of the LABPLAS sampling bag meets the requirements of 21 CFR 177.1520 of the Food and Drug Administration.  |
| Biocide-free | Biocide-free material  |
| Pyrogens     | This product is non-pyrogenic at the endotoxin limit of 2.15 EU/device. Non-pyrogenicity is supported by endotoxin testing of randomly selected samples using the Limulus amoebocyte lysate (LAL) gel assay according USP-NF <85> and <161> guidelines.  |
| Sterile      | Sterility is provided by irradiation. The sterilization dose ensuring a sterility assurance level (SAL) of 10-3 has been established according to ISO 11137.   |

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