

PRO1 MICRO

Hygiene Monitoring System.

High sensitivity pen system for the detection and quantification of surface proteins and allergens.



Usage

Designed to detect and quantify proteins, allergens and reducing agents with high sensitivity on surfaces and difficult-to-access areas after the cleaning process.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016.

ISO 15883-1: 2006 / HTM 01-01: 2016 / HTM 01-05: 2013.

Characteristics

- The system consists of a reactive solution and a high absorption swab, which allows the collection of samples from different types of surfaces with the same efficiency.
 - Pen diameter: 12.4 mm; Pen length: 161 mm; Swab length: 111.9 mm.
 - Limit of quantification: 1.0 µg of BSA.
 - Sensitivity: 0.3 µg of BSA.
 - Qualitative analysis: Incubate using the Bionova® IC10/20 incubator (temperature: 60± 2 °C; 15 minutes) and interpret visually by using the reference guide available inside the product's box.
 - Quantitative analysis: Using the Bionova® IC10/20FR, Bionova® IC10/20FRLCD or Bionova® MiniPro auto-reader incubators. Read the instructions for use of the device previously.
- Incubation time: using the Bionova® IC10/20FR or the Bionova® IC10/20FRLCD auto-reader incubators: 15 minutes; using the Bionova® MiniPro auto-reader incubators: 10 minutes.
- Incubation range: 60± 2 °C.

Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %.

Storage conditions

T = 2-30 °C, RH = 30-80 %, store in dark place.
Store vertically as indicated on the package.

Transport conditions

Storage conditions should be strictly followed.
Transport in closed and strengthened boxes in order to avoid damages. The transport of this product does not represent a risk for health. Product can be kept at temperature below 30 °C for up to 25 days during transport without modifying its shelf-life (provided that the subsequent storage conditions are respected).

Shelf life

Shelf life 24 months when stored refrigerated (between 2 - 8 °C).
Maximum shelf life at room temperature is 6 months. 1 month of storage at room temperature (up to 30 °C) reduces the expiration date by 4 months.

Packing

Box with 100 units (5 aluminum bags with 20 pens each + 1 swab moisturizer)

Box with 20 units (1 aluminum bag with 20 pens + 1 swab moisturizer)

Aluminum bag with 8 units (8 pens + 1 swab moisturizer) as sample.

Packing information: product code and description, manufacturer information and data on label.

Labelling

On product: product code and description, batch number, manufacture and expiration date and datamatrix code.

On product's box: product code and description, batch number, manufacture and expiration date, bar code and datamatrix code.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information

Read product's instructions for use thoroughly before use.

Precautions

Do not reuse.

Do not open until its use.

Do not touch the swab with your hands. Wear gloves, surgical mask and other hygiene measures.

Do not freeze.

High concentrations of alkaline sanitizers may cause false negative results in some cases. Hydrogen peroxide based disinfectants may cause a false positive color change reaction.