

PRO1 VT

Validation Kit

System for efficacy validation of the PRO1 MICRO Hygiene Monitoring System.



Usage

Designed for efficacy validation of Chemdye® PRO1 MICRO Hygiene Monitoring System when use with Bionova® MiniPro, IC10/20FR or IC10/20FRLCD Auto-Reader Incubators. The PRO1 MICRO allows to quantify with high sensitivity proteins, allergens and reducing agents on different surfaces and difficult 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 has a Negative and a Positive Control.

The Negative Control consists of a vial with a protein-free solution (green cap).

The Positive Control consists of a vial with a defined amount of standard protein (blue cap).

Vial's diameter: 12.0 mm; Vial's length: 47.0 mm.

Quantitative analysis: Using Bionova® IC10/20FR, IC10/20FRLCD or MiniPro Auto-reader incubators. Read the instructions for use of the device previously.

Incubation time: using Bionova® IC10/20FR or Bionova® IC10/20FRLCD: 15 minutes. Using Bionova® MiniPro: 10 minutes.

Incubation range: (60± 2) °C.

Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

T = 2-30 °C, RH 30-80 %, store in dark place.

Transportation conditions

Storage conditions should be strictly followed.

Transport in closed and strengthened boxes in order to avoid damages. Transportation 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 transportation without modifying its shelf-life (provided that the subsequent storage conditions are respected).

Shelf-life

2 years when stored refrigerated (2-8°C) and 6 months when stored at room temperature (up to 30°C).

Packing

Box with 10 Negative Controls (green cap) and 10 Positive Controls (blue cap).

Packing information: product code and description, process for intended use, presentation, storage conditions, manufacturer information and data on label.

Labeling

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

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information

Read product's instructions for use thoroughly before using.

Description of identified and/or predictable risks which could represent a risk for the product

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.