

Instructions for use

Product name / Trade name

Pyromol-E

Available in sizes: 1.0, 1.7, 2.8, 3.8, 5.0 mm

Product Description / Intended Purpose

The devices Pyromol-E are used for detection of protein residue in flexible endoscope channels. The devices are used by medical professionals and trained CSSD staff in CSSD departments of Hospitals and medical practices.

Instructions for use



Picture A

The size of the swab must be compatible to the diameter of the endoscope channel.

1. Moisten the EndoSwab tip with a drop of clean water. Insert the EndoSwab into the channel to be tested and push it all the way through, once only.
2. Cut the EndoSwab 2cm behind the tip with scissors, place into the test vial (picture A), closed and let stand for 5 minutes.
3. A colour change to blue-green on the EndoSwab indicates protein residue.
4. Record the result for quality assurance. 1 µg of protein residue on the EndoSwab will develop a small blue-green spot. Large amount of soluble protein can turn the whole test solution to blue green.



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1.0	77070-06X
1.7	77070-06A
2.8	77070-06B
3.8	77070-06C
5.0	77070-06D

Performance characteristics

- Pyromol E: Detection of protein residue.
- The test kit can detect 1µg of protein

Version and date of the issuance of the IFU.

Version: 2.0 Date: 22.07.2025

In the event of malfunction / performance changes

Only completely clean instruments are safe. Residue shown by Pyromol-E is an indication of an inefficient cleaning process.

Precautions:

- Open package carefully and handle with care.
- Don't eat and drink at work. No smoking. Keep away from food.
- Avoid contact with skin and eyes.
- Store protected from light, heat and chemicals.
- Use eye protection (Chemical splash goggles).
- Wear chemical resistant gloves.
- Inhalation protection in case of vapor or aerosol.
- Don't use twice.
- Use only for the intended purpose.
- Read the instructions carefully before interpreting the results.

Safe combinations with devices / equipment

Only use swabs supplied with Pyromol-E

Restrictions on combinations

Pyromol-E use only for detection of protein residue in endoscope channel, according to the enclosed instructions. Contact to alkaline substances and quaternary ammonium salts (used in some disinfectants) will give a false positive result. However glutaraldehyde or peracetic acid, used for flexible endoscopes, will not interfere with Pyromol-E test. Finger prints can contain protein particles and may give a false positive result.

Each test kit consists of:

6 X single use test for detection of protein residue in flexible endoscope channels

- o Pyromol-E test vial
- o EndoSwab

Special storage and/or handling condition

- Store at +2°C to +25°C
- Store in closed original packaging.
- Store protected from light, heat and chemicals.

Side effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are located.

Significant residual risks:

After use, always check if the swab is still intact. After the test, the endoscope needs to be reprocessed / disinfected again.

Safe disposal of device

Dispose of Pyromol-E in accordance with valid local regulations.