

Instructions for use

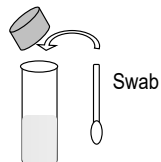
Product name / Trade name

Pyromol-Test

Product Description / Intended Purpose

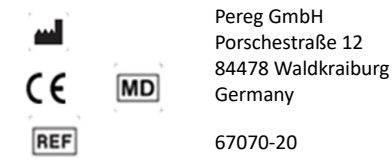
The devices Pyromol-Test are used for detection of protein residue on surgical instruments and surfaces. The devices are used by medical professionals and trained CSSD staff in CSSD departments of Hospitals and medical practices.

Instructions for use



1. Wet surfaces are swabbed with the dry cotton swab. Dry surfaces are swabbed after moistening the swab with a drop of clean water.
2. Swab the sample thoroughly. Focus onto the area where residue is suspected (joints, crevices, visible spots or discolouration). Use the longer swabs available for cannulated instruments.
3. Drop the swab into the vial, close and let stand for 5 minutes. Check the swab for a colour change to blue-green indicating protein residue on the tested surface. If protein residue is present a colour change might be visible after 1minute. A longer waiting time will give a clearer result and a stronger colour.
4. Record the result for quality assurance. 1 µg of protein residue on the swab will develop a small blue-green spot. Large amount of soluble protein can turn the whole test solution to blue-green.

NOTE: In case of jointed surgical instruments blood residue is most common inside joints which cannot be sampled with a swab. For this purpose, TOSI indicators should be used to check the cleaning efficacy of the washer-disinfector.



Performance characteristics

The test kit can detect 1 µg of protein. A dye binding method is used for the detection of protein residue.

In the event of malfunction / performance changes

Only completely clean instruments are safe. Residue shown by Pyromol-Test 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-Test.

Restrictions on combinations

Contact to alkaline substances can give a false positive result. Quaternary ammonium salts (used in some disinfectants) will give a false positive result. Finger prints can contain protein particles and may give a false positive result.

Each test kit consists of:

20 X single use test for detection of protein residue on instruments and surfaces.

- o Pyromol-Test vial
- o Swab

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.

Safe disposal of device

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

Version and date of the issuance of the IFU.

Version: 2.0 Date: 22.07.2025