

Instructions for use

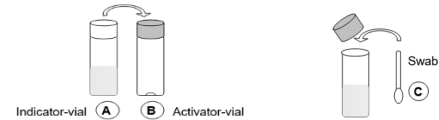
Product name / Trade name

HemoCheck-S

Product Description / Intended Purpose

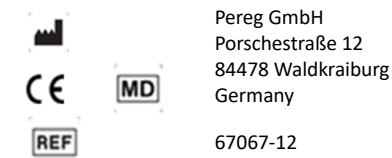
The devices HemoCheck-S are used for detection of blood residue on surgical instruments and surfaces. The devices are used by medical professionals and trained CSSD staff in CSSD departments of hospitals and medical practices.

Instructions for use



1. In case of refrigerated storage condition, let the test warm up to room temperature before use. Wet surfaces are swabbed with the dry cotton swab. Dry surfaces are swabbed by moistening the swab with a drop of clean water. Do not use chlorinated 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. Open one indicator vial (A transparent cap) and transfer the liquid into one activator-vial (B green cap).
4. Place the sample-swab (C) into the vial (head down into the liquid) and shake at least 5 times.
5. Check the swab for an instant colour change to blue-green, which will indicate blood residue on the tested surface. In the presence of large amount of blood, the whole indicator solution will change to dark blue. Record the result immediately as later colour change must be rejected. The yellow colour change after activation is a normal reaction and does not indicate blood residue.

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.



Version and date of the issuance of the IFU.

Version: 2.0 Date: 22.07.2025

Performance characteristics

- The test kit can detect 0,1 µg of blood by showing a slight blue-green spot. 1 µg of blood in the test will already give a dark blue color.
- Due to the high content of peroxidases in blood an enzymatic reaction is used for detection of blood residue.

In the event of malfunction / performance changes

Only completely clean instruments are safe. Blood residue shown by HemoCheck-S 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

Use only swabs supplied with HemoCheck-S.

Restrictions on combinations

Contact to oxidizing agents like chlorine or hypochlorite will give a false positive result. Blood residue bleached with peracetic acid or hydrogen peroxide cannot be detected. In this case the test cannot be used to detect blood residue.

Each test kit consists of:

12 X single use test for detection of blood residue on instruments and surfaces.

- Indicator vial (transparent cap)
- Activator vial (green cap)
- 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 HemoCheck-S in accordance with valid local regulations.