Product: The EndoCheck- Hemoglobin

Product Type: EDH: Detection of Hemoglobin Residue

Reorder Number: EDH-110, EDH-200, EDH-270, EDH-350, EDH-420, EDH-470

Description: The EndoCheck-Hemoglobin is a test kit for detection of blood residue in flexible scopes.

Performance Characteristics: After swabbing the biopsy channel of the scope and the swab is in the vial with the activating agent, a color change to Blue-Green indicates blood is present.

Color Change: The yellow color change after activation is a normal reaction and does not indicate residue. To Blue-Green for positive results. Blue-Green on the swab and/or the activating agent color changes to Blue-Green, represents blood is present.

Measuring Range: The test kit can detect 0.1 ug of blood by showing a slight blue-green spot. 1 ug of blood in the test will give a dark blue color

Physical Characteristics:
- EDH-110 Swab/Tubing ASM: swab size 1.1mm, tubing length 200cm
- EDH-200 Swab/Tubing ASM: swab size 2.0mm, tubing length 230cm
- EDH-270 Swab/Tubing ASM: swab size 2.7mm, tubing length 230cm
- EDH-350 Swab/Tubing ASM: swab size 3.5mm, tubing length 230cm
- EDH-420 Swab/Tubing ASM: swab size 4.2mm, tubing length 230cm
- EDH-470 Swab/Tubing ASM: swab size 4.7mm, tubing length 230cm

Endovial (EndoCheck) [indicator vial with transparent cap and activator vial with green cap)

Selling Unit - 1 Case includes:
- 12 - single use tests: each test containing 1 Swab/Tubing ASM and 1 EndoCheck Vial
- 1 card stock vial holder (4.5" L x 3" W x 1.375" H)
- 1 scissor
- 12 sterile waters
- 1 Instructions for Use

Packaged in 1 white card stock box (9" H x 8" W x 2.5" D)

Environmental Limitations:
- Storage: 2ºC - 30ºC (35.6ºF - 86.0ºF) bring to room temperature before using.
- Shelf Life: The expiry date is printed on the product packaging label.

FDA 510(k) Release to Market Date: N/A