

**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:** 2°C - 30°C (35.6°F - 86.0°F) 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