



Tarangnan Community Hospital
Clinical Laboratory • Clinical Microscopy

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Applies to: Medical Technologists and Laboratory Aides | **Effective date:** MM-DD-YYYY | **Supersedes:** None

Stool Rapid Tests (RightSign H. pylori Antigen & Immunochemical FOBT) Card

Standardized fecal extraction, rapid lateral-flow testing, medication hold governance, and result reading

BIOSAFETY: Wear gloves; discard used cassettes, droppers, and extraction tubes into biohazard/sharps waste; decontaminate spills per waste SOP.

KIT CHECK & EXTERNAL QC (BOTH PARTS)

- **Expiry & Storage:** Verify kit expiry date and storage condition per kit insert before testing; do not use expired kits.
- **External QC:** Run kit positive/negative controls with each new lot/shipment or at the SOP-defined frequency; log lot number and expiry (ISO 15189:2022 §7.3.7).

PART A: RIGHTSIGN HELICOBACTER PYLORI STOOL ANTIGEN (REF HPG-C61)

- A-1** **Spiral Wand Sampling & Extraction:** Stab applicator wand into stool at **3 to 6 sites** (~50 mg feces in spiral grooves; do NOT scoop). Reinsert wand into extraction tube, tighten cap, shake vigorously for 20 s, and **stand for 2 min.** SOP 5.2.4

Stand 2 min

- A-2** **Cassette Inoculation & Reading:** Break dropper tip. Invert tube vertically over sample well (S) of labeled RightSign cassette. Dispense exactly **2 drops (approximately 80 µL)**. Start timer. **Read at 10 minutes.** SOP 5.2.4

10 min

- A-3** **STOP / STRICT CUTOFF** **H. pylori Maximum Reading Limit: DO NOT read or interpret after 20 minutes.** Late drying causes false-positive artifacts. If fluid fails to migrate within 2 min, centrifuge extraction tube at 1000 × g (confirm the rpm on your centrifuge's conversion chart) for 3 min and retest with a new cassette. SOP 5.2.4

STOP > 20 min

PART B: QUALITATIVE IMMUNOCHEMICAL FECAL OCCULT BLOOD TEST (IFOBT / FIT)

- B-1** **FOBT Wand Sampling & Extraction:** Insert FOBT applicator wand into stool at **3 to 6 random sites** to coat spiral grooves. Insert into FOBT buffer tube, tighten cap, shake vigorously for 20 s, and **stand for 2 min** to settle debris. SOP 5.3.3

Stand 2 min

- B-2** **FOBT Inoculation & Reading:** Break dropper tip. Invert vertically over sample well (S). Dispense **2 to 3 drops (approximately 80–100 µL)** of extracted buffer. Start timer. **Read at 5 to 10 minutes.** SOP 5.3.3

5–10 min

- B-3** **STOP / STRICT CUTOFF** **FOBT Maximum Reading Limit: DO NOT read or interpret after 10 minutes.** Prolonged incubation produces false-positive ghost lines. SOP 5.3.3

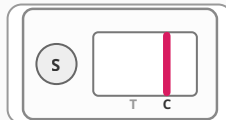
STOP > 10 min

POSITIVE (Reactive)



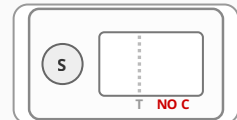
Both C & T lines visible (active H. pylori or human Hb ≥ 50 ng/mL)

NEGATIVE (Non-Reactive)



Control line C only. T line completely absent.

INVALID



Control line C absent. Test VOID. Repeat with fresh cassette.

H. PYLORI MEDICATION CLEARANCE RULES (SOP 5.2.2)

- **PPIs & Bismuth:** Must be off for at least **2 weeks** (omeprazole, pantoprazole, lansoprazole, bismuth subsalicylate). Suppression of bacterial density causes false negatives.
- **Antibiotics:** Must be off for at least **4 weeks** before testing.
- **Test of Cure:** Schedule ≥ 4 weeks after finishing eradication therapy.

IFOBT PRE-ANALYTICAL & CLINICAL GUIDANCE (SOP 5.3.1–2)

- **No Dietary Restrictions (FIT advantage):** Monoclonal anti-human hemoglobin is unaffected by red meat, turnips, or vitamin C (unlike legacy guaiac tests).
- **Medication Hold (per kit insert — verify):** Withhold heavy NSAIDs, aspirin, and alcohol for 48 h before collection; these can irritate the GI tract and cause bleeding the test will detect.
- **Collection Precautions:** Defer collection during active menses (wait 3 days post-menses), with bleeding hemorrhoids, or with hematuria.
- **Lower GI Specific:** Upper GI blood globin is degraded by proteases.
- **Specimen Acceptance:** Clean dry container; no toilet-water or urine contamination; minimum sample per insert; test fresh or refrigerate ≤3 days per insert (verify).

Prepared by: Chief Medical Technologist
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