



Tarangnan Community Hospital
Clinical Laboratory • Serology Section

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Parent document: SOP-S-002, Sections 5.3–5.7 |
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Applies to: Medical Technologists and Laboratory Aides | **Effective date:** MM-DD-YYYY | **Supersedes:** None

HBsAg Rapid Qualitative Immunoassay & Confirmatory Referral Bench Card

Two Authorized TCH Methods • Duplicate Retesting of Reactives • SPH / SACCL Confirmatory Send-Out Protocol

BIOSAFETY: Wear gloves; discard droppers/cassettes into biohazard/sharps waste; decontaminate spills per waste SOP.

1 **Equilibration & Inspection:** Bring refrigerated serum and foil pouch to **room temperature (15–30 °C)** for 15–30 min. Check desiccant: for STANDARD Q, **Yellow = Valid; Green = Discard**. Label cassette with 2 patient identifiers. SOP 5.2/5.4

⌚ 15–30 min

2 **Method-Specific Specimen Loading:**

- **Method A (AllTest/Trimera REF IHBSG-402):** Dispense exactly **3 drops (~75 µL)** serum into well (S). No chase buffer.
- **Method B (SD BIOSENSOR STANDARD Q REF QHBS01G):** Dispense exactly **100 µL** serum (black line of dropper or pipette) into well (S). No chase buffer. SOP 5.3/5.4/5.5

3 **Timing & Incubation:** Start dedicated digital timer immediately upon sample loading. Keep cassette horizontal and undisturbed on bench. SOP 5.3/5.4

4 **Method-Specific Reading Windows:**

- **Method A:** Read results between **15 and 30 minutes**.
- **Method B:** Read result at **15–30 minutes; do not read after 30 minutes**. SOP 5.3/5.4/5.5

⌚ 15–30 min

5 **STOP / STRICT CUTOFF** **Maximum Reading Limit: DO NOT interpret results after 30 minutes for either method.** Evaporation artifacts and non-specific binding cause false-positive lines. SOP 5.3/5.4/5.5

⌚ STOP > 30 min

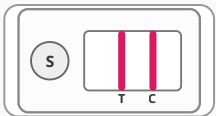
6 **Duplicate Retest of Reactives:** Any initial reactive or faint T line **MUST be retested in duplicate** using fresh cassettes from the original patient tube. If either retest is reactive, confirm reactive screening status. SOP 5.7.2

7 **SPH / SACCL Confirmatory Referral:** Report preliminary screening result: "*Reactive (Initial Screening Only — Referred for Confirmation)*". Aliquot **1.0–1.5 mL clear serum**, store at 2–8 °C, package in triple packaging with cool packs, and dispatch to **Samar Provincial Hospital (SPH)** or **SACCL** per LAB-QM-PRE-002. Notify clinician and report under RA 11332. SOP 5.7.2

EXTERNAL QUALITY CONTROL (ISO 15189:2022 §7.3.7)

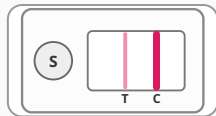
Run kit positive/negative controls with each new lot/shipment or at the SOP-defined frequency; log lot number and expiry (ISO 15189:2022 §7.3.7).

REACTIVE (Positive)



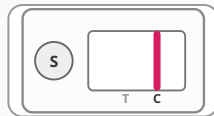
Both C & T lines visible. Perform duplicate retest.

FAINT REACTIVE



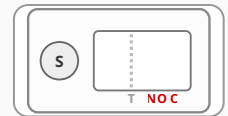
Any visible T line is Reactive. Retest in duplicate.

NON-REACTIVE



C line only. Report Non-Reactive with standard disclaimer.

INVALID



No C line. Test VOID. Discard and repeat with new device.

METHOD SEPARATION TABLE (SOP 5.5)

Parameter	Method A (AllTest)	Method B (STANDARD Q)
Catalog No.	REF IHBSG-402	REF QHBS01G
Serum Vol.	3 drops (~75 µL)	100 µL (black line)
Buffer	None for serum	None for serum
Desiccant	Visual check	Yellow = Valid; Green = Discard
Read Time	15 to 30 min	15 to 30 min (do not read after 30 min)
Max Cutoff	Do not read > 30 min	Do not read > 30 min

CONFIRMATORY REFERRAL CHECKLIST (SOP 5.7.2)

- **Referral Facility:** Samar Provincial Hospital (SPH) or SACCL.
- **Specimen Aliquot:** Minimum 1.0–1.5 mL clear serum.
- **Storage & Cold Chain:** 2 to 8 °C in triple packaging with ice packs per LAB-QM-PRE-002.
- **Documentation:** External Referral Logbook + Transmittal Form.
- **Statutory Notification:** Report reactive hepatitis under RA 11332.

Prepared by: Chief Medical Technologist
Signature / Date: _____

Reviewed by: Pathologist
Signature / Date: _____

Approved by: Hospital Director
Signature / Date: _____