



**Tarangan Community Hospital**  
Clinical Laboratory • Clinical Microscopy & Serology

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

## Abbott Bioline hCG Urine & Serum Pregnancy Test Rapid Bench Card

Cat. No. 30FK10 • Analytical Sensitivity: 25 mIU/mL • Specimen: Urine (preferred) or Serum\*

\* Confirm serum use against the Cat. 30FK10 insert in the laboratory.

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

**1 Expiry Check:** Verify the pouch expiry date **before opening the pouch**; do not use expired kits.

**2 Equilibration:** Allow sealed foil pouch and urine or serum specimen to reach **room temperature (15–30 °C)** for 15–30 minutes before opening. First-morning urine is preferred for peak  $\beta$ -hCG concentration. SOP 5.4

**15–30 min**

**3 Pouch Check & Labeling:** Tear open foil pouch; inspect desiccant (discard). Place cassette flat on a clean, horizontal surface. Label plastic frame with **2 unique patient identifiers**. Do not touch membrane. SOP 5.5.2–3

**4 Specimen Inoculation:** Draw clear urine or serum into the supplied disposable dropper. Hold dropper **strictly vertical (90°)** and dispense exactly **3 drops (approximately 100  $\mu$ L)** into round sample well (S). Avoid bubbles. SOP 5.5.4

**3 drops (100  $\mu$ L)**

**5 Timer Activation:** Start digital stopwatch immediately after dispensing the 3rd drop. Keep cassette flat and undisturbed. Observe purple chromatographic dye front migrating across the reading window. SOP 5.5.5–6

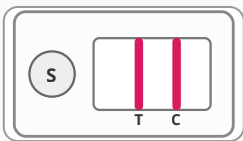
**6 Analytical Result Reading:** Read and interpret visual band patterns at **exactly 3 minutes** under bright, direct white illumination. SOP 5.5.7

**3 min**

**7 STOP / STRICT CUTOFF** **Maximum Reading Window: DO NOT read or interpret results after 10 minutes.** As the nitrocellulose membrane dries, non-specific protein binding and evaporation lines cause false-positive artifacts. SOP 5.5.8

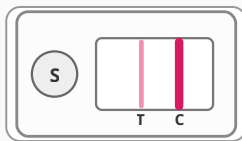
**STOP > 10 min**

### POSITIVE



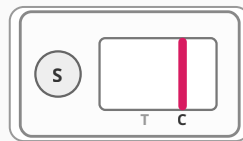
Two distinct red/pink bands (C and T lines visible)

### FAINT POSITIVE



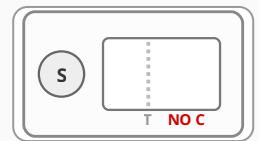
Any visible T line, even faint, indicates hCG  $\geq$  25 mIU/mL

### NEGATIVE



Control line C only; T zone completely clear white

### INVALID



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

### CLINICAL CAUTIONS & QUALITY CONTROL (SOP 5.7 & 5.8)

- **Internal Control (C):** A distinct colored C line must appear on every cassette. Never report an invalid test as negative.
- **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).
- **Very Early Gestation:** In early pregnancy, hCG may be  $< 25$  mIU/mL. If clinically suspected, repeat with first-morning urine in 48–72 hours or test serum per SOP-S-005.
- **Dilute Urine:** Low specific gravity ( $< 1.005$ ) may yield false negatives; request a concentrated first-morning collection.
- **Hook Effect (Molar Pregnancy):** Extreme hCG ( $> 500,000$  mIU/mL) causes false negative. If gestational trophoblastic disease suspected, dilute urine 1:10 and 1:100 in saline.

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