AAC. 7b Policy on Quality Program ensures quality of test results through internal quality control

1. Purpose

To ensure that Inodaya Hospital Laboratory provides accurate, precise, reliable, and reproducible test results through an effective **Internal Quality Control (IQC) Program** in all laboratory sections.

2. Scope

This policy applies to all testing areas within Inodaya Hospital Laboratory, including:

- Biochemistry
- Hematology
- Immunoassay
- Clinical pathology
- Microbiology (where applicable)

3. Policy Statement

Inodaya Hospital is committed to maintaining the highest standards of laboratory performance. Internal Quality Control (IQC) shall be performed **daily, per shift, or per run**, depending on the test system, to ensure reliable patient results.
No patient report shall be released unless IQC results meet acceptable limits.

4. Responsibilities

Prepared by:	Verified By:	Approved by:
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Pathologist	Medical Director	Accreditation Coordinator

Laboratory Director / Pathologist

- Approves IQC policies, QC plans, and corrective actions.
- Reviews QC reports weekly and monthly.

Technical Supervisor / Section In-charge

- Ensures daily implementation of IQC.
- Monitors QC logs, flags failures, and initiates corrective actions.

Laboratory Technologists

- Perform tests only when QC is acceptable.
- Document all QC activities and corrective actions.

5. Description of the Internal Quality Control Program

5.1 Types of Internal QC

- **Normal and abnormal/multi-level controls** for analyzers
- **Positive and negative controls** for immunology/microbiology assays
- **Lot-to-lot verification** of reagents and controls
- **Instrument calibration and calibration verification**

5.2 Frequency of IQC

- **Daily** for routine analyzers

- **Per batch/run** for ELISA, coagulation, microbiology
- **After maintenance, calibration, or reagent change**
- **When clinical results appear inconsistent**

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6. IQC Procedure

6.1.1 Verify Environment and Equipment Readiness

Before preparing or running QC materials:

1. Ensure analyzer is switched on and fully initialized.
2. Check instrument maintenance logs to confirm:
   - Daily start-up maintenance completed
   - Photometers, sensors, tubing, sampling probes are functioning
   - Reagents and calibrators loaded correctly
3. Confirm environmental conditions:
   - Room temperature at 20–25°C (as analyzer specifies)
   - Humidity within acceptable limits
4. Verify UPS and power supply are stable.

6.1.2 Check QC Materials and Storage Conditions

1. Retrieve QC vials from the refrigerator or freezer **only when needed**.
2. Check the following before use:
   - Manufacturer's name & lot number
   - Expiry date

- Recommended storage temperature (2–8°C or frozen at –20°C depending on QC type)
- Whether the vial is opened or unopened
- Remaining volume

3. Inspect for any deterioration signs:
   - Discoloration
   - Precipitate
   - Leakage or damaged vial
4. QC vials must always be stored in dedicated QC racks—**not with patient samples**.

6.1.3 Bring Controls to Room Temperature

1. Allow QC vials to stand at **room temperature (20–25°C)** for **10–30 minutes** as recommended by the manufacturer.
2. Do not heat directly or expose to sunlight.
3. Gently mix controls (for liquid controls) by:
   - **Slow inversion** 8–10 times
   - Do **not** shake vigorously to avoid foam and air bubbles.
4. For lyophilized (powder) controls, proceed to **reconstitution**.

6.1.4 Reconstitution of Lyophilized Controls (If applicable)

1. Wash hands and wear gloves.
2. Check manufacturer instructions (insert sheet).
3. Add the exact volume of **distilled/deionized water** using a calibrated pipette.
4. Allow to stand for the specified time (usually **10–15 minutes**) to fully dissolve.
5. Gently swirl until homogenous—**never shake**.
6. Label the vial with:
   - Date of reconstitution

- Time
- Expiry period after reconstitution (e.g., 7 days)
- Technician initials

6.1.5 Labeling and Identification

Every QC vial must include:

- QC level (Level 1 – Normal, Level 2 – Abnormal, Level 3 – High/Low depending on analyte)
- Lot number
- Date of opening/reconstitution
- Expiry after opening
- Section name (Biochemistry/Hematology/Coagulation)

Use color-coded stickers if possible.

6.1.6 Load or Register QC in Analyzer / LIS

1. Register QC materials in the analyzer's QC program menu.
2. Select proper QC lot number from stored library or manually enter it.
3. Input QC range (target value and acceptable limits) from manufacturer's insert sheet:
   - Mean
   - Standard deviation (SD)
   - 2SD/3SD limits
4. Assign QC to specific test panels (biochemical tests, CBC parameters, clotting assays, etc.).

6.1.7 Perform Pre-Run Analyzer Checks

Before running QC:

1. Verify reagent packs have sufficient volume.
2. Check reagent expiry and calibration validity.
3. Confirm that cuvettes or reaction cells are clean or auto-clean cycles are completed.
4. Run water blank or system check if recommended.

6.1.8 Prepare QC Worklist (if applicable)

1. Select the number of QC levels to run (usually **2 levels**, sometimes **3**).
2. Set up run order:
   - **Level 1 → Level 2 → Level 3** (or per machine protocol)
3. For hematologyanalyzers:
   - Standard sequence: **Low → Normal → High**
4. Document the planned QC run in the **Daily QC Log Book**.

6.1.9 Ensure Bio-Safety Measures

1. Wear gloves, mask, coat, and, when needed, face shield.
2. Handle QC materials as **potentially infectious**, especially serum-based controls.
3. Dispose of waste according to biohazard guidelines.

→ Test patient samples and release results normally.

7. Action for Out-of-Control (OOC) Results

- **Stop patient testing immediately.**
- **Do not release any patient reports** until QC problem is resolved.
- **Repeat the QC run** using the same vial/level.

If QC fails again, **check QC vial for issues**:

- expiry date
- improper storage
- contamination / discoloration
- incorrect reconstitution
- insufficient mixing

- If QC material is defective, **replace QC vial** and repeat QC.

If QC still fails, **check analyzer status**:

- daily maintenance completed
- probe, cuvette, reaction chamber clean
- temperature stability
- any analyzer error messages

- Perform**required maintenance/cleaning** and repeat QC.

- If QC still fails, **check reagent conditions**:
  - expiry date
  - proper storage
  - sufficient reagent volume
  - bubbles / contamination
- Replace reagent pack if required and **repeat QC**.
- If QC still fails, **check calibration status**:
  - calibration due?
  - previous calibration errors?
  - Perform **full calibration**, then run QC again.
  - If QC remains OOC, **open a new QC lot/vial** and run QC again.
  - If QC still does not pass, **perform cross-check** on another analyzer (if available).
- Compare results to identify whether the issue is:
  - instrument-related
  - QC material-related
  - reagent-related

If problem persists, **inform technical supervisor/pathologist immediately**.

- **Contact manufacturer/service engineer** for further troubleshooting.
- Record all findings and actions taken in the **OOC Corrective Action Log**.

- After corrective action, **run QC again at all levels** (Level 1, Level 2, Level 3 if applicable).
- Confirm QC results fall within **acceptable limits / Westgard rules**.
- Once QC is satisfactory, **authorize analyzer for patient testing**.
- Resume patient testing.
- Release patient results only after **supervisor approval**.
- Review trends weekly and discuss repeated OOC events in **monthly QC meeting**.
- Implement preventive measures to avoid recurrence (staff retraining, improved storage, periodic maintenance, etc.).

WESTGARD RULES SUMMARY

Rule	Symbol	What It Means	Type of Error	Action
1–2s (Warning Rule)	1_2s	One QC exceeds **±2 SD**	Warning only	Check next QC result
1–3s	1_3s	One QC exceeds **±3 SD**	Random/Systematic	Stop testing, investigate
2–2s	2_2s	Two consecutive QCs exceed **same +2 SD or –2 SD**	Systematic	Troubleshoot immediately
R–4s	R_4s	Difference between two QC levels is **4 SD**	Random	Check pipetting, mixing, analyzer

Rule	Symbol	What It Means	Type of Error	Action
4–1s	4_1s	Four consecutive QCs exceed **±1 SD** on same side	Systematic (shift/trend)	Check reagents, calibration
10x	10x	Ten consecutive QCs on **same side of mean**	Systematic (bias)	Recalibrate analyzer