National Standard Operating Procedure of Internal Quality Control (IQC)

First Edition/2026

Sultanate of Oman

Ministry of Health

Directorate General of Health Services and Programs

Department of Health Services Development

Diagnostic Services Development Section

Document Title	**National Standard Operating Procedure of Internal Quality Control (IQC)**
Document Type	Standard Operating Procedure
Directorate/Institution	Directorate General of Health Services and Programs
Targeted Group	Medical Laboratories
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Designation	Task Force for Unifying Haematology Laboratory Documents
Release Date	August 2026
Review Frequency	Every Five Years

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August 2026	**Date**	August 2026

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Acknowledgment:

We would like to thank and appreciate the effort of the Hematology Laboratories Task Force members that have written the first version of this document, as well as the individuals and teams that have contributed to the revision. Participated and contributed personnel are:

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Acronyms:

IQC	Internal Quality Control
SD	Standard Deviation
CV%	Coefficient of Variation
LJ	Levey–Jennings
TA_E	Total Allowable Error
CLIA	Clinical Laboratory Amendments
CMLSO	Chief Medical Laboratory Scientific Officer

1. **Purpose**

   This SOP outlines standardized procedures for implementing, monitoring, and evaluating Internal Quality Control (IQC) across laboratory analyzers to ensure accuracy, reliability, and consistency of patient results by monitoring analytical performance against prescribed boundaries.

2. **Scope**

   This procedure applies to all laboratory staff performing IQC in Hematology, and related analytical sections under the Ministry of Health and collaborative health institutions.

3. **Definitions**

   - **Quality Control (QC):** is a process for assessing the accuracy and reliability of a test system using materials with known values.
   - **Levey–Jennings (LJ) Chart:** is a graph used to monitor QC values over time.
   - **Westgard Rules:** Statistical rules for QC acceptance or rejection.
   - **Random Error:** Unpredictable deviations (e.g., bubbles, pipetting errors) often detected by 1_3s or R4s rules.
   - **Systematic Error:** A consistent bias in the system (e.g., reagent lot changes, calibration drift) often detected by 2_2s, 4_1s or 10x rules.
   - **$\bar{X}$b (Moving Average):** A statistical process where the average of sequential patient results is continuously calculated to detect systematic shifts.
   - **Truncation Limits:** Pre-set limits used to exclude abnormal patient values that may bias the moving average.
   - **Control Limits:** Pre-established acceptable limits for the moving average line.

4. **Procedure**

   4.1. Internal Quality Control

   4.1.1. Quality Control Materials

   - Use <u>at least</u> two levels of commercially available control material (Low, Normal and High) for each analytical run.
   - Establish laboratory-specific target means and SD (Lab QC Ranges) by:
     - Perform a minimum of **20 runs** for new QC lots to calculate mean, SD, and CV%.

- Ensure calculated mean and SD fall within manufacturer's acceptable range.
- Document and program new ranges into analyzers.

4.1.2. Quality Control Run and Review

4.1.2.1 Daily QC Review

- Run QC at least once per shift or per manufacturer requirements.
- Plot results automatically or manually on LJ charts.
- Review values against established mean ± SD.

4.1.2.2 Weekly Review

- Supervisor reviews LJ charts for trends, shifts, or rule violations.
- Evaluate systematic and random errors using Westgard rules.

4.1.2.3 Monthly Review

- Supervisor and Quality Officer review:
  - QC performance trends.
  - CV% compared with accepted limits.
  - Completed corrective action forms.

4.1.3. Interpretation of QC Results

4.1.3.1 Acceptable Run

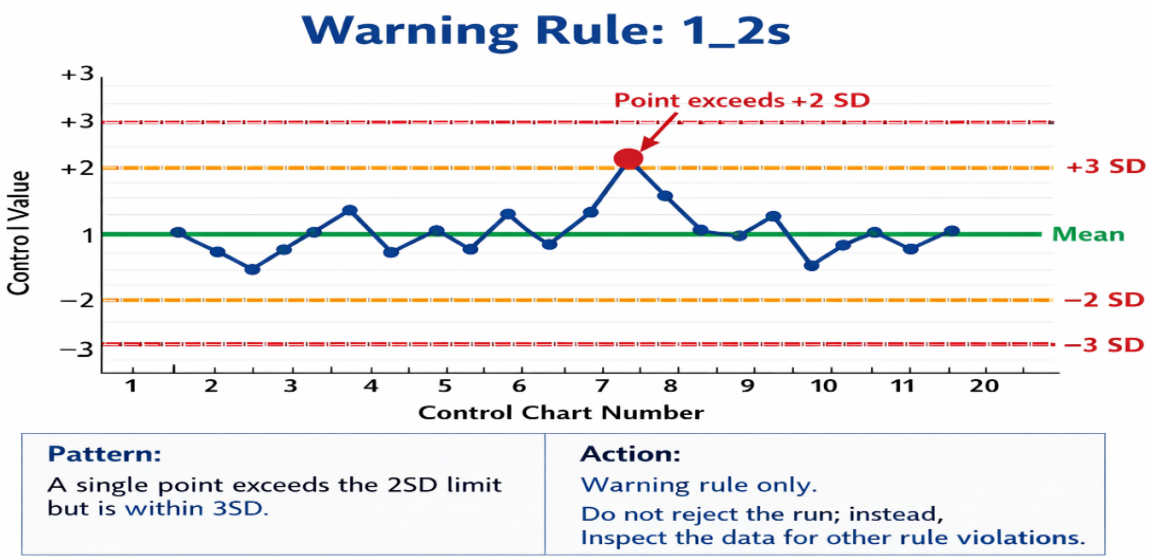
CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186. Is used as a guideline for acceptable performance for **Analytical Quality Requirements**.

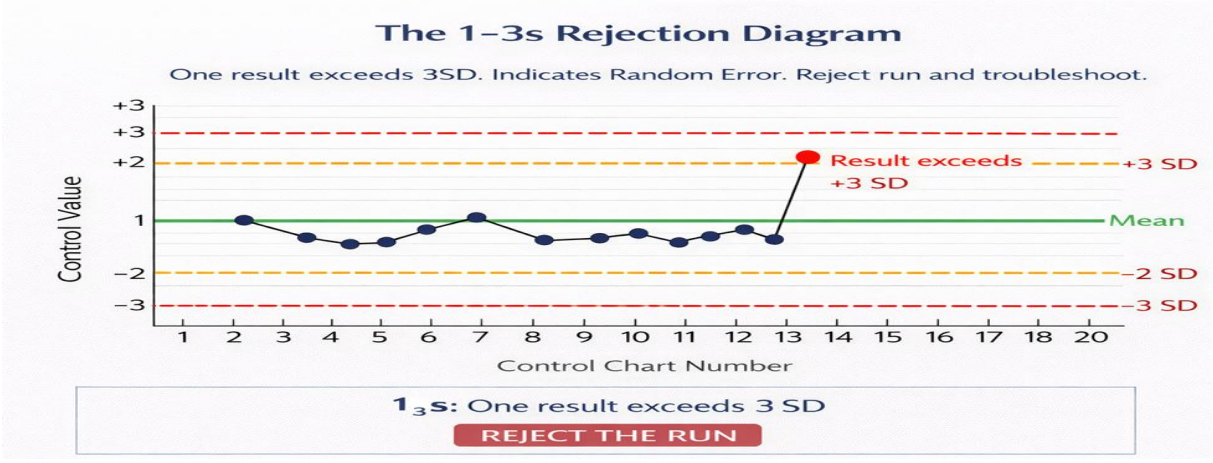
Diagram 1: A QC run is acceptable when all results fall within the established limits and no Westgard rejection rule is violated.

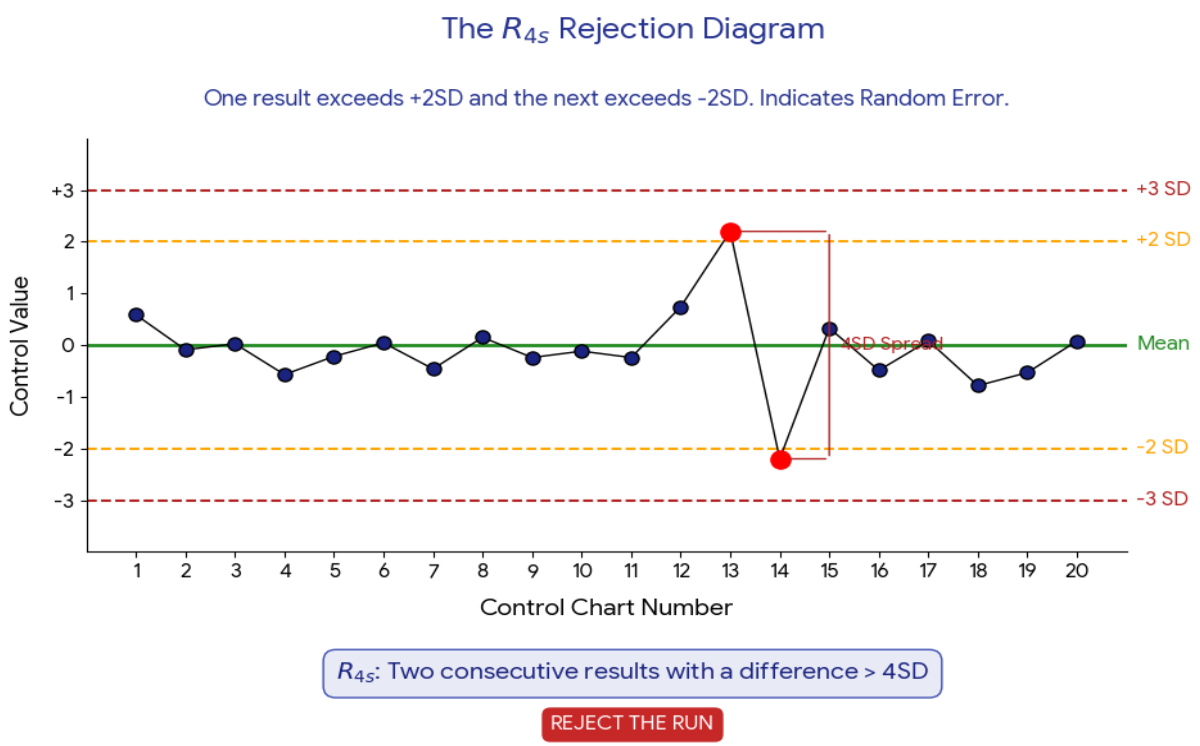
Westgard Rules Applied & Rejection Criteria

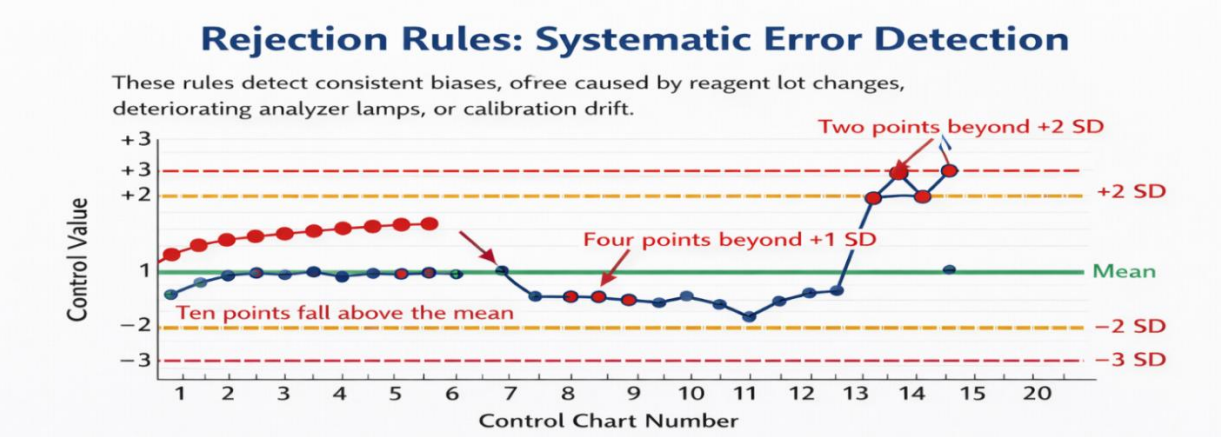
The following multi-rule scheme shall be used to interpret QC data:

Rule	Type	Interpretation & Action
1-2s	**Warning**	**Diagram 2**: One result exceeds 2SD. Inspect data for other rule violations; if none, accept run.
Definition	The 1–2s rule is triggered when a single QC result falls outside the mean ±2 SD range. This is considered a warning rule and does not indicate that the system is out of control, but it signals the need for increased attention.	
Interpretation	If no additional QC rules are violated, the event is usually due to normal random variation. Patient results may be released.	
Corrective Action	No immediate corrective action is required. However, the warning suggests a possible developing issue. It is advisable to review routine maintenance, verify proper QC material handling, and ensure correct sampling technique.	

Rule	Type	Interpretation & Action
		
1-3s	Rejection	**Diagram 3:** One result exceeds 3SD. Indicates **Random Error**. Reject run and troubleshoot.
Definition	The 1–3s rule is violated when a single QC result exceeds the mean ±3 SD limits. This is a *rejection rule* and is highly sensitive to random error.	
Interpretation	A 1–3s violation indicates significant random error and that the analytical system is *out of control*. Patient results must not be reported and should be repeated only after the issue is corrected	
Corrective Action	Repeat the affected QC level using proper technique. ➢ If the repeat QC falls within the ±2 SD range, the issue is most likely due to random error. ➢ If the repeat QC remains outside ±2 SD, further investigation is required. Possible causes include: ▪ Incorrect or inappropriate SD limits	

Rule	Type	Interpretation & Action
		▪ Improper storage of QC materials ▪ Incorrect handling or preparation of QC material ▪ QC batch deterioration—consider changing the lot ▪ Insufficient instrument maintenance or potential malfunction
		
R4S	Rejection	**Diagram 4:** Difference between two controls in a run exceeds 4SD (e.g., one +2SD, one -2SD). Indicates **Random Error**.
Definition		The R–4s rule is violated when two consecutive QC results differ by more than 4 SD—typically one exceeding the +2 SD limit and the adjacent result exceeding the –2 SD limit (or vice versa). This is a *rejection rule* and is highly sensitive to detecting random error.
Interpretation		A violation indicates significant random error and that the analytical system is *out of control*. Patient results must not be released until the issue has been identified and corrected.
Corrective Action		Follow the same troubleshooting approach used for the 1–3s rule, including repeating QC, reviewing technique, and investigating possible sources of random error (QC integrity, pipetting issues, maintenance status, etc.).

Rule	Type	Interpretation & Action
		
2-2s	Rejection	**Diagram 5**: Two consecutive results exceed same +2SD or -2SD. Indicates **Systematic Error**. Reject run.
41s	Rejection	**Diagram 5**: Four consecutive results exceed +1SD or -1SD. Indicates **Systematic Error** / Shift.
10x	Rejection	**Diagram 5**: Ten consecutive results fall on the same side of the mean. Indicates **Systematic Bias**.
Definition	A violation of any of these rules represents a **rejection condition** and often indicates an early developing **shift** or **trend** in the method.	
Interpretation	A systematic error is present, and the analytical system is out of control. Patient results must not be released and should be repeated only after the issue has been identified and resolved	
Corrective Action	Investigate and correct potential sources of systematic error, including: • Incorrect or inappropriate SD limits	

Rule	Type	Interpretation & Action
		• Improper QC handling or preparation technique • QC material degradation or the need to change the QC lot • Improper storage conditions for QC materials • Issues arising from incomplete or insufficient instrument maintenance Repeat QC after each intervention to confirm the system has returned to control before processing patient samples.
		

4.1.4. Corrective Action

When a rejection rule is triggered, follow these steps:

1. **Do not report patient results.**
2. **Identify Error Type:** Use the table above to determine if the error is Random or Systematic.
3. **Troubleshoot:** Check for recent reagent changes, maintenance, or environmental issues (temperature/humidity), or analyzer hardware part failure.
4. **Action:** Rerun QC. If it fails again, use a fresh vial or recalibrate the instrument.
5. **Documentation:** Record the failure and corrective action in the QC log.

4.1.4.1. For Random Errors

- Inspect QC samples and reagents for bubbles or improper mixing.
- Prime analyzer if required.
- Re-run QC after stabilizing to room temperature.

4.1.4.2. For Systematic Errors

- Check lot numbers, expiry, and stability of QC material.
- Inspect calibrator, reagent integrity, and instrument condition.
- Review maintenance logs and recent part replacements.
- All actions must be documented using the **Corrective Action Log (FM/LAB/QC/___).**

4.1.5. Patient Result Management During QC Failure

- Do not report patient results until QC is corrected.
- Re-run affected samples (within 1–2 hours' pre-failure) and calculate delta %.
- If a second analyzer is available, run 5 samples in parallel.
- Accept results only if within total allowable error (TA_E).

4.1.6. Documentation and Record Keeping

- Daily QC worksheets.
- LJ charts (printed monthly).
- QC summary reports.
- Corrective action logs.
- QC range establishment records.

The retention period must comply with MOH laboratory quality regulations.

4.2. Temporary Use of Retained Patient Samples for IQC

When commercial Internal Quality Control (IQC) materials or certified reference materials are unavailable, the laboratory may implement a temporary precision-check procedure using retained patient samples. This process is authorized **ONLY** under the **approval of the CMLSO and Section Head and must not replace standard IQC.** The purpose of this procedure is to verify analyzer precision during periods when standard QC materials are unavailable due to supply delays or stock shortage.

4.2.1. Sample Selection Criteria

- **Eligible samples must meet the following criteria:**
  - Fresh whole blood samples analyzed within the past **2 hours**.
  - Sufficient volume to allow repeat testing for **24 hours**.
  - Free from clots, hemolysis, lipemia, or abnormal morphology affecting counts.
  - Represent normal or near-normal ranges to ensure stable monitoring.

- Labelled using the *Retained Patient IQC* form (FM/HAEM/ROUT/012).

- **Number of retained samples required:**
  - **Three** retained patient samples (RP1, RP2, RP3), each tested across up to **three analyzers** (A, B, and C) if available.

4.2.2. Procedure for Retained Patient IQC

Testing Schedule - Repeat measurement of each retained sample at:

- 10:00
- 13:00
- 19:00
- 24:00

Results must be recorded across available analyzers.

4.2.3. Acceptability Criteria

Precision is evaluated by calculating the **percent difference** between repeated measurements over time:

Interpretation based on delta percentage Formula:

Δ% = (Repeat – Initial) / Initial × 100

- Monitored measurable Parameters & Allowable Variance %
  - Hb: 7%
  - WBC: 15%
  - PLT: 25%
  - MCV: 6%
  - RBC: 6%

Results **exceeding allowable variance** indicate loss of precision and require immediate investigation

4.2.4. Interpretation & Corrective Actions

- **Acceptable precision:** Analyzer continues in service.
- **Unacceptable precision:** Immediate investigation required:

  If repeated measurements exceed allowable limits:

  1. Stop reporting patient results.
  2. Verify sample integrity and repeat.
  3. Inspect analyzer for:
     - Calibration drift

- Reagent issues (expiry, bubbles, contamination)
- Background checks
- Maintenance issues

4. Compare results across multiple analyzers (A, B, C).
5. Document findings on the corrective action log.
6. Withdraw analyzer from service if issue persists
7. Notify:
   - Section Supervisor
   - CMLSO & HOD
   - Quality Officer

4.2.5. Document Control Requirements

- All retained patient IQC forms must be filled completely and signed.
- Forms must be archived according to MOH retention policy.
- This temporary strategy must be discontinued once normal IQC material is available.
- A report must be submitted to the HOD summarizing:
  - Duration of retained sample IQC use
  - Analyzer performance
  - Any corrective actions taken

4.2.6. Limitations

- Retained patient samples **cannot** assess **accuracy**, only **precision**.
- Cannot be used for analyzer calibration, reagent validation, or lot verification.
- Must not exceed **24 hours'** usage from initial draw time.
- Retained patient samples Method should not exceed one week.

4.3. Moving Average Program ($\bar{X}$b)

The Moving Average Program ($\bar{X}$b), also known as the Moving Patient Average, is used as a continuous, patient-based quality control tool to monitor analyzer stability and detect gradual shifts or trends between routine QC runs.

The purpose of this procedure is to establish a standardized procedure for implementing and monitoring the $\bar{X}$b moving average program as an additional quality assurance measure for hematology parameters, and it is applicable to hematology analyzers

equipped with moving average functionality for parameters such as Hb, WBC, RBC, PLT, and MCV.

4.3.1. Procedure

1. **Initial Setup:**
   - Determine appropriate truncation limits for each parameter based on historical patient data.
   - Configure analyzer or middleware with these limits.
   - Establish baseline mean and acceptable limits using at least 500–1000 patient results where possible.
2. **Daily Monitoring:**
   - Technologist reviews X̄b charts at the beginning, middle, and end of each shift.
   - Observe for sudden shifts, drifts, or trends beyond the control limits.
3. **Interpretation of X̄b Patterns:**
   - **Stable values within limits:** Analyzer performance is acceptable.
   - **Shift upward or downward:** Suggests systematic error or calibration drift.
   - **Increasing scatter:** Indicates potential random error or reagent deterioration.
4. **Triggers for Investigation:**
   - X̄b crosses warning or rejection limits.
   - Sustained upward or downward movement over time.
   - Abrupt change following maintenance, part replacement, or reagent lot change.

4.3.2. Corrective Actions

- Verify QC performance using standard internal QC or retained patient QC if applicable.
- Inspect analyzer for:
  - Maintenance issues
  - Reagent lot shifts
  - Calibration drift
  - Blockages, bubbles, or contamination
- Re-run selected patient samples for verification.

- Document findings and corrective actions.

4.3.3. Documentation Requirements

- Daily $\bar{X}$b review logs.
- Investigation reports for any deviations.
- Comparison of patient-based QC trends with standard QC performance.

4.3.4. Limitations

- Not suitable for low-volume analyzers due to insufficient patient numbers.
- Sensitive to changes in patient population (e.g., ICU-only days).
- Must not replace routine QC.

5. Responsibilities

- **Laboratory Technologist**
  - Run daily IQC as per schedule.
  - Review QC results and LJ charts.
  - Apply Westgard rules and document acceptance/rejection decisions.
  - Initiate corrective actions for QC failures.
- **Section Supervisor**
  - Review weekly and monthly QC performance.
  - Verify corrective actions and trends.
  - Ensure appropriate ranges are established for each QC lot.
- **Quality Officer**
  - Oversee QC documentation compliance.
  - Validate monthly QC summaries and performance indicators.

6. Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2031

7. References

- ISO 15189: Medical Laboratories – Quality and Competence
- CLIA Guidelines
- Westgard QC Rules
- IBMS Guidelines
- Manufacturer QC Instructions
- Westgard, J.O. (2024). *Basic QC Practices*. Westgard QC Website.
- Royal Hospital, Hematology Department Internal Quality Control Program

8. Annexes

- **Annex 1:** Total Allowable Error Table (TA_E)
- **Annex 2:** Accepted CV% Limits
- **Annex 3:** QC Corrective Action Form
- **Annex 4:** Retained Patient IQC Log

Annex 1: Total Allowable Error Table (TA_E)

Test code	Test Name	Total allowable error	Source
RBC	Erythrocytes count	+/- 6.0%	1 CLIA, 2 WLSH, 3 NYS, 6 AAB
HBG	Hemoglobin	+/- 7.0%	1 CLIA, 2 WLSH, 3 NYS, 6 AAB
HCT	Hematocrit	+/- 6.0%	1 CLIA, 2 WLSH, 3 NYS, 6 AAB
MCV	Mean corpuscular volume	2.3%	5BV
MCH	Mean corpuscular hemoglobin	2.7%	5BV
MCHC	Mean corpuscular hemoglobin concentration	2.2%	5BV
MPV	Mean Platelets volume	5.8%	5BV
RDW	Red cell distribution wide	4.6%	5BV
PLT	Platelets count	+/- 25%	1 CLIA, 2 WLSH, 3 NYS, 6 AAB
WBC	Leukocyte count	+/- 15%	1 CLIA

Neut	Neutrophil	+/- 22.4%	5BV
Lymph	Lymphocytes	+/- 16%	5BV
Mono	Monocytes	+/- 27.9%	5BV
Eos	Eosinophils	37.1%	5BV
Baso	Basophils	38.5%	5BV
RETIC	Reticulocytes count	16.8%	5BV
HbA2	Hemoglobin A2	7.15%	Article
HbF	Hemoglobin F	7.15%	Article

Table 1.0 Total allowable error to this document (Ref: Data innovation allowable total error-westgard)

Annex 2: Accepted CV% Limits

Test code	Test Name	Accepted CV% for QC material	Accepted CV% for whole blood sample
WBC	White Blood Cell count	Low level ≤6.0 Normal level ≤5.73 High level ≤2.7	≤2.7
RBC	Red Blood Cell count	≤1.60	≤1.5
HBG	Hemoglobin	≤1.43	≤1.0
HCT	Hematocrit	≤1.35	
MCV	Mean Corpuscular Volume	≤0.70	≤1.0
MCH	Mean Corpuscular Hemoglobin	≤0.70	
PLT	Platelets count	Low level ≤4.5 Normal level ≤4.6 High level ≤4.0	≤4.0
MPV	Mean Platelet Volume	≤2.15	≤5.0
RETIC	Reticulocytes count	≤5.5	≤15

Table 2.0 Accepted CV% for QC material and whole blood (ref: verification and quality control of routine hematology analyzer J.Y.VIS. A Hushiman john Ltd, int.Jnl.Lab.Hem 2016)

Annex 3: Quality Control Corrective Action Form

1. Incident Details

- **Date of Occurrence: _____ Time: _____**
- **Instrument Name/ID: _____**
- **Parameter/Analyte: _____**
- **Control Level:** □ Level 1 (Low) □ Level 2 (Normal) □ Level 3 (High)
- **Lot Number: _____ Exp. Date: _____**

2. Problem Identification

Westgard Rule Violated (Check one):

- [ ] **1_{3}s** (Random Error - Value exceeds 3SD)
- [ ] **2_{2}s** (Systematic Error - 2 consecutive points exceed same 2SD)
- [ ] **R4s** (Random Error - Range across levels exceeds 4SD)
- [ ] **4_{1}s** (Systematic Error - 4 consecutive points exceed same 1SD)
- [ ] **10x** (Systematic Error - 10 consecutive points on one side of mean)

Observation/Shift/Trend:

_____

_____

3. Troubleshooting Checklist (Check all that apply)

- [ ] Reagent levels checked (Expired/Low/Bubbles)
- [ ] Control material checked (New vial used/Improperly thawed)
- [ ] Probe/Tubing checked for clogs or leaks
- [ ] Daily maintenance performed prior to run
- [ ] Calibration status verified
- [ ] Environmental factors (Room temperature/Humidity within range)

4. Corrective Action Taken

- [ ] **Immediate Action:**

  _____

  _____
- [ ] **Rerun Result: _____ Status:** □ Acceptable □ Failed (Escalate)
- [ ] **Recalibration performed?** □ Yes □ No
- [ ] **Service engineer called?** □ Yes □ No (Ref #: _____)

5. Impact on Patient Samples

- [ ] No patient results were released.
- [ ] Patient results were held; rerun after QC was corrected.
- [ ] Results released prior to QC failure detection; retrospective review required (See Remark).

Remarks:

_____

_____

6. Review and Authorization

- **Performed by (Technologist): _____ Signature: _____Date:_____**
- **Reviewed by (Supervisor): _____ Signature: _____Date:_____**
- **Final Approval (CMLSO/HOD): _____ Signature: _____ Date:_____**

Instructions for Completion:

1. **Stop Testing:** Immediately stop reporting patient results for the affected parameter.
2. **Identify:** Use the Westgard rules provided in the SOP to categorize the error.
3. **Investigate:** Do not just repeat the control; check the instrument and reagents first to identify the "Root Cause."
4. **Verify:** Only resume patient testing once two consecutive QC runs (or as per protocol) are within acceptable limits.
5. **File:** Attach the failed LJ plot and the successful rerun plot to this form

Annex 4: Retained Patient IQC Log

Date		Analyser A					Analyser B					Comment/ Initial
Sp #		Hb	WBC	PLT	MVC	RBC	Hb	WBC	PLT	MVC	RBC	
Retained Patient 1												
Allowable Variance		7%	15%	25%	6%	6%	7%	15%	25%	6%	6%	
Allowable limits +/-												
Time 10:00												
Time 13:00												
Time 19:00												
Time 24:00												

Date		Analyser A					Analyser B					Comment/ Initial
Sp #		Hb	WBC	PLT	MVC	RBC	Hb	WBC	PLT	MVC	RBC	
Retained Patient 2												
Allowable Variance		7%	15%	25%	6%	6%	7%	15%	25%	6%	6%	
Allowable limits +/-												
Time 10:00												
Time 13:00												
Time 19:00												
Time 24:00												

Date		Analyser A					Analyser B					Comment/ Initial
Sp #		Hb	WBC	PLT	MVC	RBC	Hb	WBC	PLT	MVC	RBC	
Retained Patient 3												
Allowable Variance		7%	15%	25%	6%	6%	7%	15%	25%	6%	6%	
Allowable limits +/-												
Time 10:00												
Time 13:00												
Time 19:00												
Time 24:00												