# QUALITY ASSURANCE IN HEMATOLOGY

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# WHAT IS QUALITY?

**Totality of features and characteristics** of a product or service that bear on its ***ability to satisfy stated or implied needs***

**Or**

**Reliability of the Result (Product/service) in a given condition**

**Or**

**Performance versus needs / expectations**

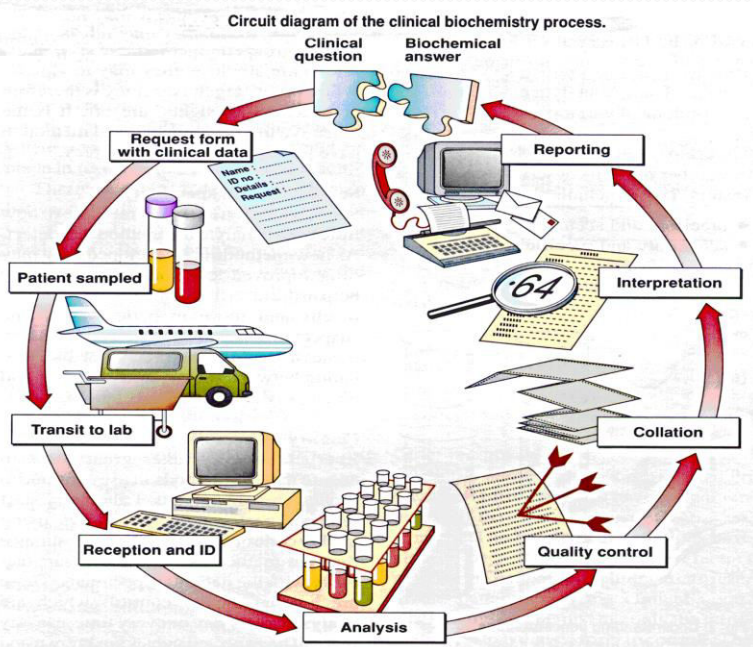
# All systems & measurements are subject to errors!


**All experimental uncertainty is due to either random or systematic errors**

Error - Difference between the observed value and the true value of the quantity being measured

# Potential errors that can affect the quality of the laboratory results.

- Pre-analytical errors
  - Before the sample reaches the laboratory
- Analytical errors
  - During the analysis of the sample
- Post-analytical errors
  - Occurring after the analysis



# Quality Assurance (QA)

- **All aspects** of laboratory activities Not restricted to the development and retention of quality control charts but includes **(Choice of methods**, **training of personnel**, **handling of specimens, reporting results)**

- To **ensure that information generated by laboratory is correct**. (Confidence / Certainty / Promise)

# Laboratory Quality Assurance Program

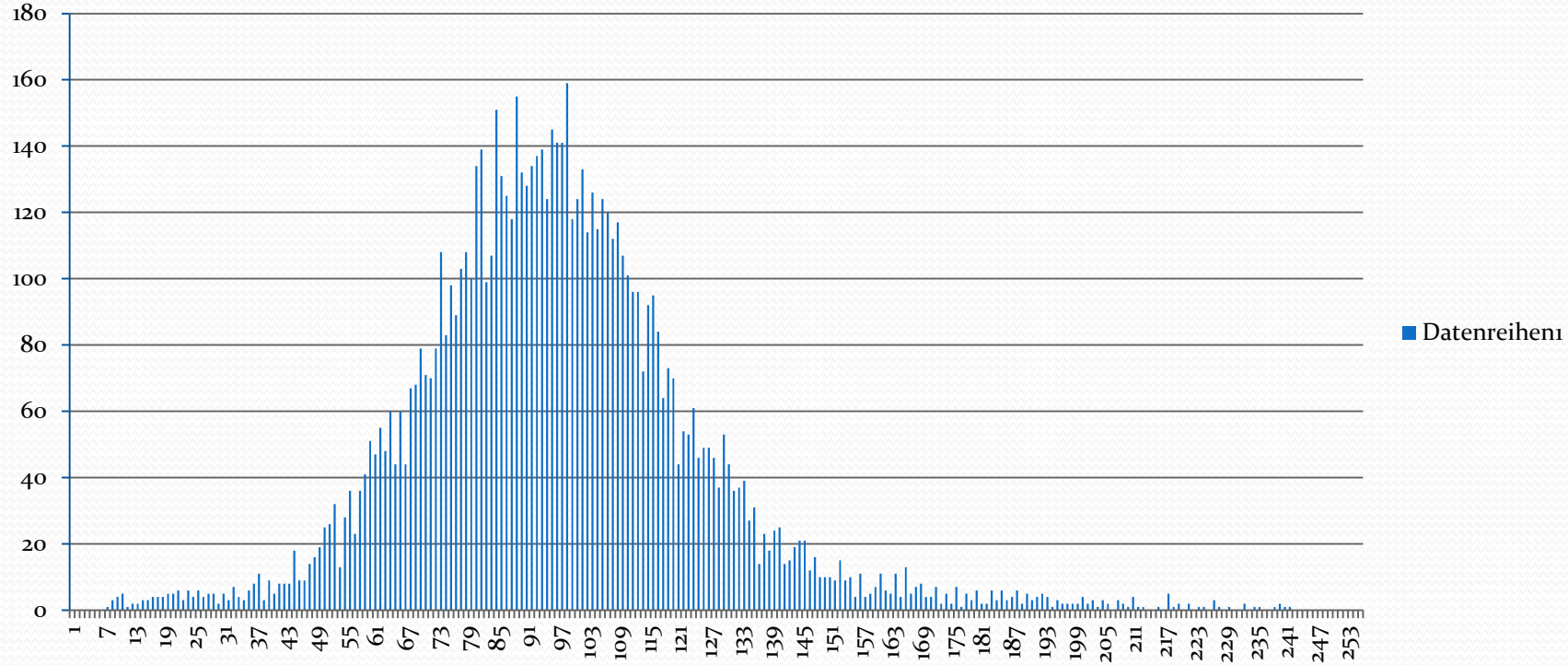
- **Pre examination** (Preventive aspect)
  - Operator training/ competency
  - Standardization of collection procedure
  - Specimen collection
  - Specimen mixing
  - Sample integrity & Analyte stability
- **Examination**
  - Calibrations / Controls (Assessment aspect)
  - Acceptable performance, Test Limitations
- **Post examination**
  - Delta checks
  - Moving averages
  - EQA
  - Proficiency testing

**Corrective Actions are also a part of QA.**

# Laboratory Quality control

Procedure designed to detect, reduce and correct deficiencies in the laboratories internal analytical process prior to the release of patient results and to improve the quality of the results reported by the laboratory.

# NORMAL / GAUSSIAN DISTRIBUTION




**Law of Probability**

**Mean** – Average (Central Tendency)

**Standard Deviation** – SD – Unit for Spread of Values – **Analytical variation (CV)**

# Statistical Methods for Assessment

- Levy Jennings chart
- Mean – Target Value
- Standard deviation (SD)
- Coefficient of Variation (CV)
- Control limits
- Westgard rules
- S.D.I.
- % Deviations
- Sigma Metric / Score

# QUALITY CONTROL PLANNING IN LAB

- **Define** – Quality Goals / Performance Standards
- **Measure** – Current Performance
- **Analyze**
- **Implement Improvements**
- **Control** the Performance

# QUALITY GOALS – Performance Standards

- Defining **required quality of analyte.**

**(Total Allowable Error)**

- Used in two ways:

- To **define allowable Systematic error** (i.e. Bias)
- To **define allowable Random error** (target SD/CV for QC).

- **In reference** with the **Medical Decision level** conc. of analyte

S = serum; U = urine; P = plasma; B = blood

$CV_w$ = within-subject biological variation; $CV_b$ = between-subject biological variation; Imp = imprecision; $TE_a$ = total allowable error

| | | BIOLOGICAL VARIATION | | DESIRABLE SPECIFICATIONS | | | |
|---|---|---|---|---|---|---|---|
| | ANALYTE | CV w | $CV_b$ | Imp (%) | Bias (%) | TE a (%) p<0.05 | TE a (%) p<0.01 |
| B | Hemoglobin | 2.8 | 6.6 | 1.4 | 1.8 | 4.1 | 5.1 |
| B | Hematocrit | 2.8 | 6.4 | 1.4 | 1.7 | 4.1 | 5.0 |
| B | Erythrocytes, count | 3.2 | 6.1 | 1.6 | 1.7 | 4.4 | 5.5 |
| B | Mean corpuscular hemoglobin (MCH) | 1.6 | 5.2 | 0.8 | 1.4 | 2.7 | 3.2 |
| B | Mean corpuscular hemoglobin conc. (MCHC) | 1.7 | 2.8 | 0.9 | 0.8 | 2.2 | 2.8 |
| B | Mean corpuscular volume (MCV) | 1.3 | 4.8 | 0.7 | 1.2 | 2.3 | 2.8 |
| B | Red cell distribution wide (RDW) | 3.5 | 5.7 | 1.8 | 1.7 | 4.6 | 5.7 |
| B | Leukocytes, count | 10.9 | 19.6 | 5.5 | 5.6 | 14.6 | 18.3 |
| B | Neutrophils, count | 16.1 | 32.8 | 8.1 | 9.1 | 22.4 | 27.9 |
| B | Lymphocytes, count | 10.4 | 27.8 | 5.2 | 7.4 | 16.0 | 19.5 |
| B | Monocytes, count | 17.8 | 49.8 | 8.9 | 13.2 | 27.9 | 34.0 |
| B | Eosinophils, count | 21.0 | 76.4 | 10.5 | 19.8 | 37.1 | 44.3 |
| B | Basophils, count | 28.0 | 54.8 | 14.0 | 15.4 | 38.5 | 48.0 |
| B | Platelets | 9.1 | 21.9 | 4.6 | 5.9 | 13.4 | 16.5 |
| B | Mean platelet volume (MPV) | 4.3 | 8.1 | 2.2 | 2.3 | 5.8 | 7.3 |

# TOTAL ALLOWABLE ERROR

| Sort | Analyte | Fluid | Method | Limit | Source |
|---|---|---|---|---|---|
| HGB | Hemoglobin | | | +/- 7% | 1 CLIA, 2 WLSH, 3 NYS, 6 AAB |
| HGB | Hemoglobin | B- | | 4.1% | 5 BV |
| HGB | Hemoglobin concentration | | | 3 g/L, 3% | 7 RCPA |
| HCT | Hematocrit | | | +/- 6% | 1 CLIA, 2 WLSH, 3 NYS, 6 AAB |
| HCT | Hematocrit | B- | | 4.1% | 5 BV |
| WBC | Leukocyte count | | | +/- 15% | 1 CLIA |
| WBC | Leukocytes, count | P- | | 14.6% | 5 BV |
| PLT | Platelet count | | | +/- 25% | 1 CLIA, 2 WLSH, 3 NYS, 6 AAB |
| PLT | Platelet, count | B- | | 13.4% | 5 BV |
| MPV | Mean platelet volume (MPV) | (B)Plat- | | 5.8% | 5 BV |

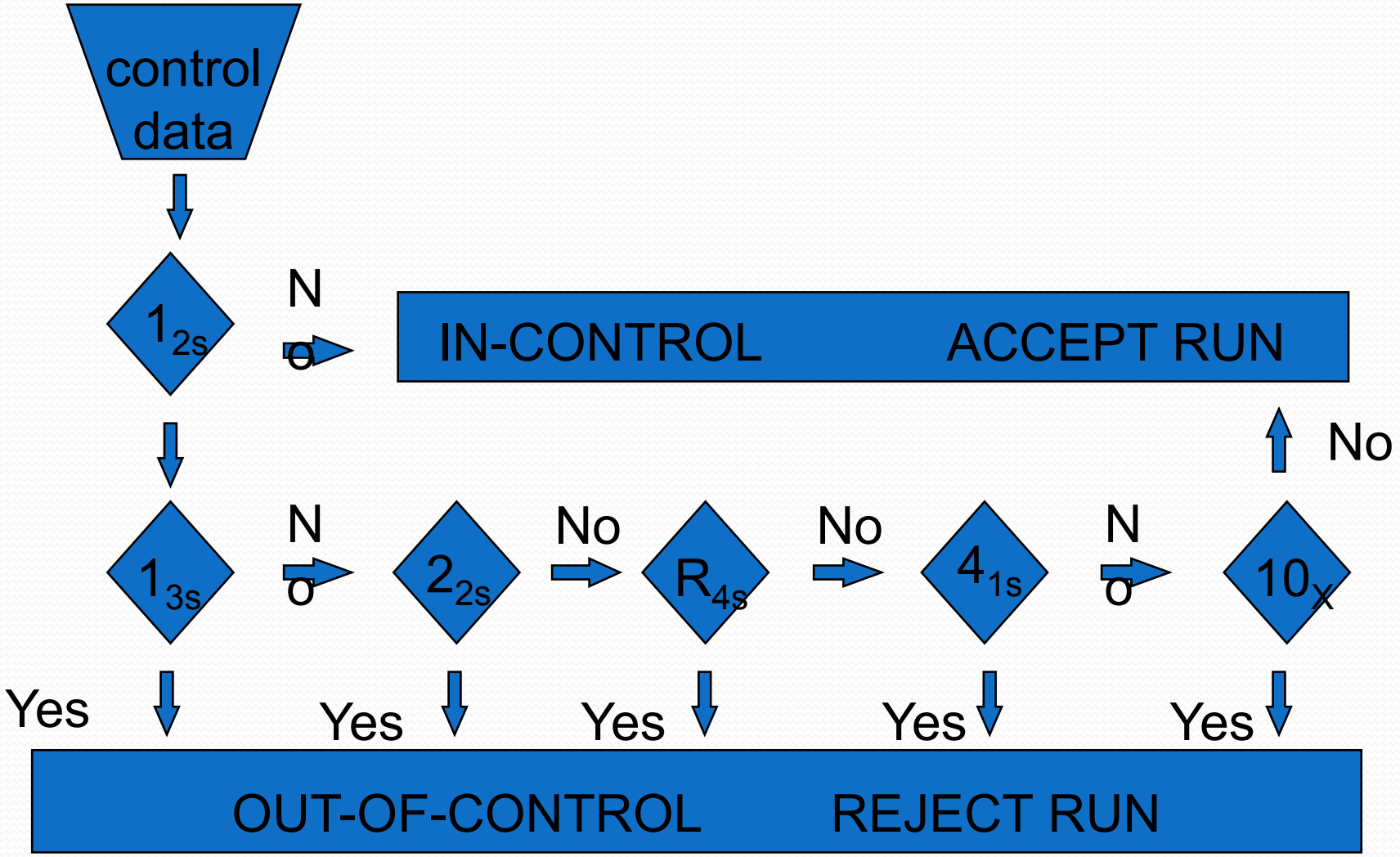
# Internal Quality Control

- Commercial Controls
- Retained Samples
- Moving Averages

# QUALITY CONTROL

- **Internal assessment of Analytical quality** by regular measurement of known/ assigned value sample
- QC material for Hematology analyser provided by Manufacturer every 30 to 90 days
- So **Lab must revalidate** or revise their acceptable limits …… As MEAN +/- multiples of SD

# Westgard Multi-Rule Quality Control Scheme



# WESTGARD RULE APPLICATION IN CELL COUNTERS

- **High BV to Analytical variation ratio - > 3.**
- **Preferred Rules - 1:3sd, 2:2sd, R-4sd across 18 – 20 parameters** (Moderate probability of False rejection)
- **1:3.5sd can only be applied for directly measured** parameters on a Highly precise analyser

# OTHER CONTROL CHECKS

- **Stored Samples** – Not preferred as Stability & conditions for preservation may not be monitored properly
- **Interparametric Checks** – "Times 3"
- **Delta Checks** – Based on **2 or 3 Process CV** limits
  - *MCV, MCHC* – Crossing Delta limits - Possible *Preanalytical* issues
  - *Hb, Hct, WBC* – Crossing indicates Possibly *clinical* issues – (physiological or Therapeutic intervention)

# DUPLICATE TESTING ON PATIENT'S SAMPLE

- **Derive SD from differences between the 10 pairs of results**
- Subsequent **duplicate** tests **should not differ from each other by more than 2 SD**
- **Detects random errors but it is not sensitive to gradual drift** nor will it detect **incorrect calibration**
- **QC imprecision also can be used (Reference Change Value)**

# AVERAGE OF NORMAL (A.O.N)

- For establishing ranges first a data 300 – 500 patients is suggested.
- Bull's approach of using X bar b
- Suggested for **Average of 20 'healthy' patient results**
- '**Truncation**' (Discarding biased results from Onco therapy wards, pediatric patients etc.) suggested for Hospital based labs
- For determining number of patient results to be considered formula suggested is $N_p > 2 \times N_c \times ( S^2_p / S^2_a )$ where $N_c$ is number of control levels
- **Usually MCV, MCH, MCHC used**
- **Persistent shifts** should be **investigated**

# Interlaboratory (Peer Group) QC Comparison

- Beneficial as **instrument specific QC sample**, same analyser groups & reagents can provide better control ranges - **Assurance of Accuracy**

- **Helps RCA** in Out-of-Control scenario

# Proficiency Testing Program (EQA)

- **Objective evaluation by an outside agency (national or regional basis)**
- **Comparative performance with other labs and with its own previous performance (using deviation index)**
- Retrospective **analysis** of performance

# TECHNICAL ANALYTICAL RESULT IS NOT A REPORT

- Clinical Background
- Instrument & Technology Knowledge
- Errors & Management
- Reasoning
- Documentation
- Feedback System

# Thank You

Questions?