CONTROL DE CALIDAD

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EDUCACIÓN CONTINUA -CTMPR

OBJETIVOS

- Definir y aplicar los elementos básicos de un programa de control de calidad en el Laboratorio.
- Definir, calculary y aplicar los siguientes parámetros estadísticos: media, SD, CV, CV ratio y SDI.
- Describir, escoger y aplicar cada una de las reglas de Westgard.
- Identificar cuál regla de Westgard identifica error sistemático y error al azar.
- Identificar y diferenciar “trend” y “shift”.
- Construir gráfica de Levey Jennings y evaluar datos para identificar eventos fuera de control.
- Investigar y corregir problemas cuando existen ciertos patrones
- Descubrir puntos a considerar al adquirir productos para control de calidad.

QUALITY ASSURANCE (QA)

- QA refers to planned and systematic processes that provide confidence of a product's or service's effectiveness. – Wikipedia
- It makes ‘quality’ a main goal of a production.
- **Lab QA:** all of the procedures, actions, paperwork that take place to be sure the results given to the physician are accurate.
  - From pt. ID, to specimen selection, to organization of lab, to clear result report forms.

CONTROL DE CALIDAD

- Proceso estadístico utilizado para vigilar y evaluar el proceso analítico que produce resultados de pacientes.
- QC se utiliza para validar que el instrumento o método está operando dentro de especificaciones pre-definidas.
- La confiabilidad de los resultados descansa en el uso regular de material de control de calidad y un control estadístico del proceso.
- **Lab QC** = Running controls and statistically analyzing the data before releasing patient results

QUALITY ASSURANCE & QUALITY CONTROL

- Quality Assessment and Quality Control measures must include a means to identify, classify, and limit error.

STANDARDS

- Highly purified substance, whose exact composition is known.
- Non- biological in nature
- Uses
  - **Run with pt. sample to validate the run**
    - Ex. With each run of a Urine Osmolality a Std. is often run to determine the accuracy and precision of the run
  - **Generate Calibration Curve**
    - Different concentrations of the Std. are used to plot a graphic curve
    - Patient samples are compared to the calibration curve and the concentration of the analyte is quantified.

REFERENCE SOLUTIONS

- Biological in nature
- Have an ‘assigned’ value
- Used exactly like a standard

CONTROLS

- Resemble the patient sample
- Have same characteristics as patient sample, color viscosity etc.
- Can be purchased as
  - ‘assayed’ – come with range of established values
  - ‘un-assayed’ - your lab must use statistical measures to establish their range of values.
- The results of any run / analysis must be compared to the ‘range of expected’ results to determine acceptability of the analysis.

CONTROLS, CONT'D.

- Depending on the test 1 or more levels of control will be required.
- Control **within** expected range = IN CONTROL= accept the QC and report patient results
- Control outside of expected range= OUT of CONTROL=address

QUÉ ES UN CONTROL

- Material parecido a muestra de paciente hecho de suero humano, orina o CSF. Puede ser líquido o liofilizado y está compuesto de uno o más constituyentes de concentración conocida.
- *Controles deben ser analizados en las mismas condiciones que las muestras de los pacientes.*

CORRIDA ANALÍTICA

- Las buenas practices requieren procesar controles diariamente (24 hrs).
- Si la prueba es estable por menos de 24 horas o ha ocurrido algún cambio que puede afectar la estabilidad de la prueba los controles se deben procesar con mayor frecuencia.
  - Blood gases
  - Coagulación

COMPARING RESULTS TO THE APPROPRIATE RANGE

- **Control results** - compared to their own range of expected results determined by the control manufacturer or individual laboratory
- **Patient values** – compared to published reference values or patient population reference ranges established within the laboratory.

QC LOG

Table 1: Example of a QC Log with Patient Results

Test: Potassium	**Instrument:** Instrument No. 1		**Unit of Measure:** mmol/L
Range ▸	Level I Normal Control 3.7 – 4.3 mmol/L	Level II Abnormal Control 6.7 – 7.3 mmol/L	Patient Results
1 November	4.0	7.0	4.2, 4.0, 3.8, 5.0, 5.8, 4.2
2 November	4.1	7.0	3.8, 4.4, 4.6, 3.9, 4.8, 4.4, 3.9
3 November	4.0	6.9	4.4, 3.9, 3.7, 4.7
4 November	4.2	7.1	4.7, 5.6, 4.2, 3.7, 4.3
5 November	4.1	7.0	4.2, 4.3, 4.1, 4.3
6 November	4.1	7.0	4.6, 4.4, 5.5, 3.8, 3.2
7 November	4.2	8.0	2.8, 4.6, 4.2, 3.2, 3.9, 4.1, 6.0, 4.3

PREGUNTAS

- Qué es qc
- Dos componentes de QC en el Laboratorio
- Frecuencia con que se procesan controles

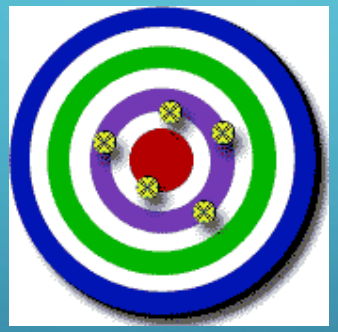
TRUE VALUE, PRECISION AND ACCURACY

- **True value** – an ideal concept, which cannot be achieved
- **Accepted True value** – The value approximating the 'True Value'; the difference between the two values is negligible.
- **Precision:** Reproducibility
- **Accuracy:** Proximity to Accepted True Value

PRECISION AND ACCURACY

Low Accuracy,
High Precision

High Accuracy,
Low Precision



High Accuracy,
High Precision

ERROR

- Error is the discrepancy between the result obtained in the testing process and its ‘True Value’ / ‘Accepted True Value’

- Pre-Analytical Errors=40%
- Analytical Errors=20%
- Post-Analytical Errors=20%

PRE-ANALYTICAL ERRORS

- Before the specimen is run
- Examples: Clerical, patient ID, specimen selection and contamination, improper storage of reagents and specimen, improper transport, etc.
- Through Quality Assurance measures, the laboratory tries to maintain control over these factors
  - Well trained phlebotomy staff, nurses, and physicians
  - Use of easy patient & specimen identification methods, such as bar code identification.

ANALYTICAL ERROR

- **Testing errors**
- **Random or indeterminate**
  - Hard or impossible to trace
  - Examples: Electricity surge, One-time events, etc
- **Systematic or determinant**
  - Identifiable cause
  - Examples: Specimen carryover, contaminated reagents, instrument component malfunction, dirty electrodes, etc.
  - Through Quality Control measures, such as always running controls, the laboratory limits these errors.

POST-ANALYTICAL ERRORS

- After testing
- Examples: Clerical, result reported on wrong patient, instrument to host computer errors, etc.

- Quality Assurance measures such as comprehensive and easily read Report sheets for manual tests must be implemented when problems are identified.

QUALITATIVE QC VS. QUANTITATIVE QC

- Quantitative tests
  - Measured quantity/concentration of analyte in the control
  - **Data must be graphed and evaluated by numerical statistics**
    - Examples: WBC count, Glucose, quantitative HCG
- Qualitative tests and Semi-Quantitative
  - Qualitative=Pos/Neg or Present/Absent
  - Semi-Quantitative=Small, Medium, Large
  - Generally not statistically analyzed
    - Examples: Clinitest, Acetest, qualitative HCG

QC DATA ANALYSIS: MEASURES OF CENTRAL TENDENCY

- **Measures of Central tendency**

  (how numerical values can be expressed as a central value)

  - *Mean* - Average value
  - *Median* - Middle observation
  - *Mode* - Most frequent observation

QC DATA ANALYSIS: VARIANCE AND STANDARD DEVIATION

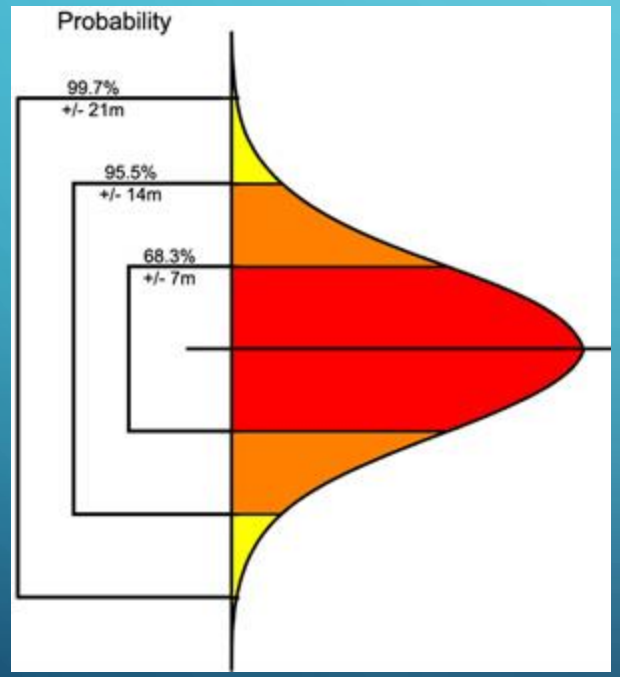
- An important tool in the statistical analysis is determining:
  - **Variance** = $\sigma^2 = \frac{\sum (X - \mu)^2}{N}$
  - **Standard Deviation (SD)** - a measure of the scatter around the arithmetic average (mean) in a Gaussian distribution.
    - SD= $\sigma = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \bar{x})^2}$ or **Square Root of variance**

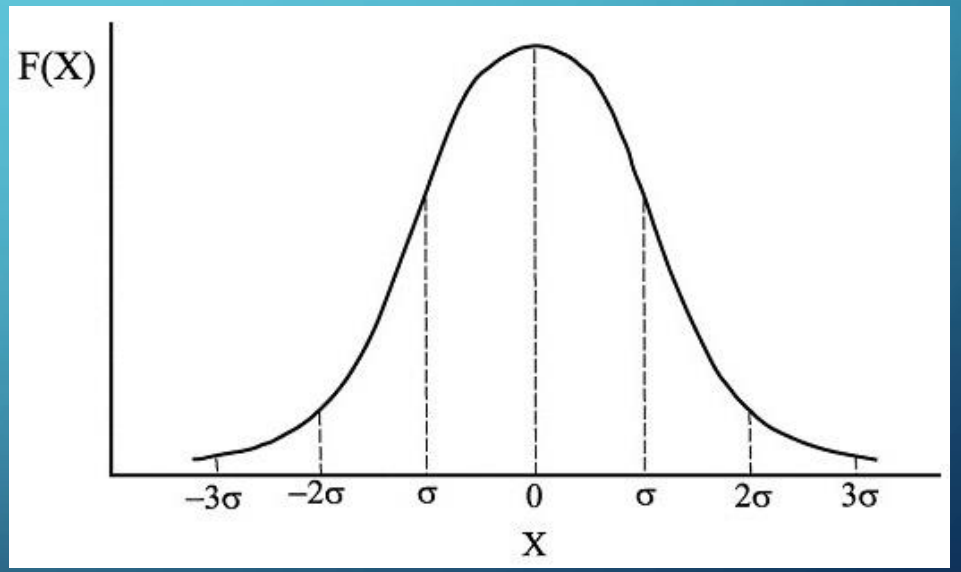
HOW TO MANUALLY CALCULATE VARIANCE AND STANDARD DEVIATION:

1. Subtract the mean from each score.
2. Square each Result
3. Sum all of the squares
4. Divide the sum of the squares by the number of data points (N)
5. The result is the VARIANCE
6. Take the square root of the variance.
7. The result is the SD.

QUALITY CONTROL

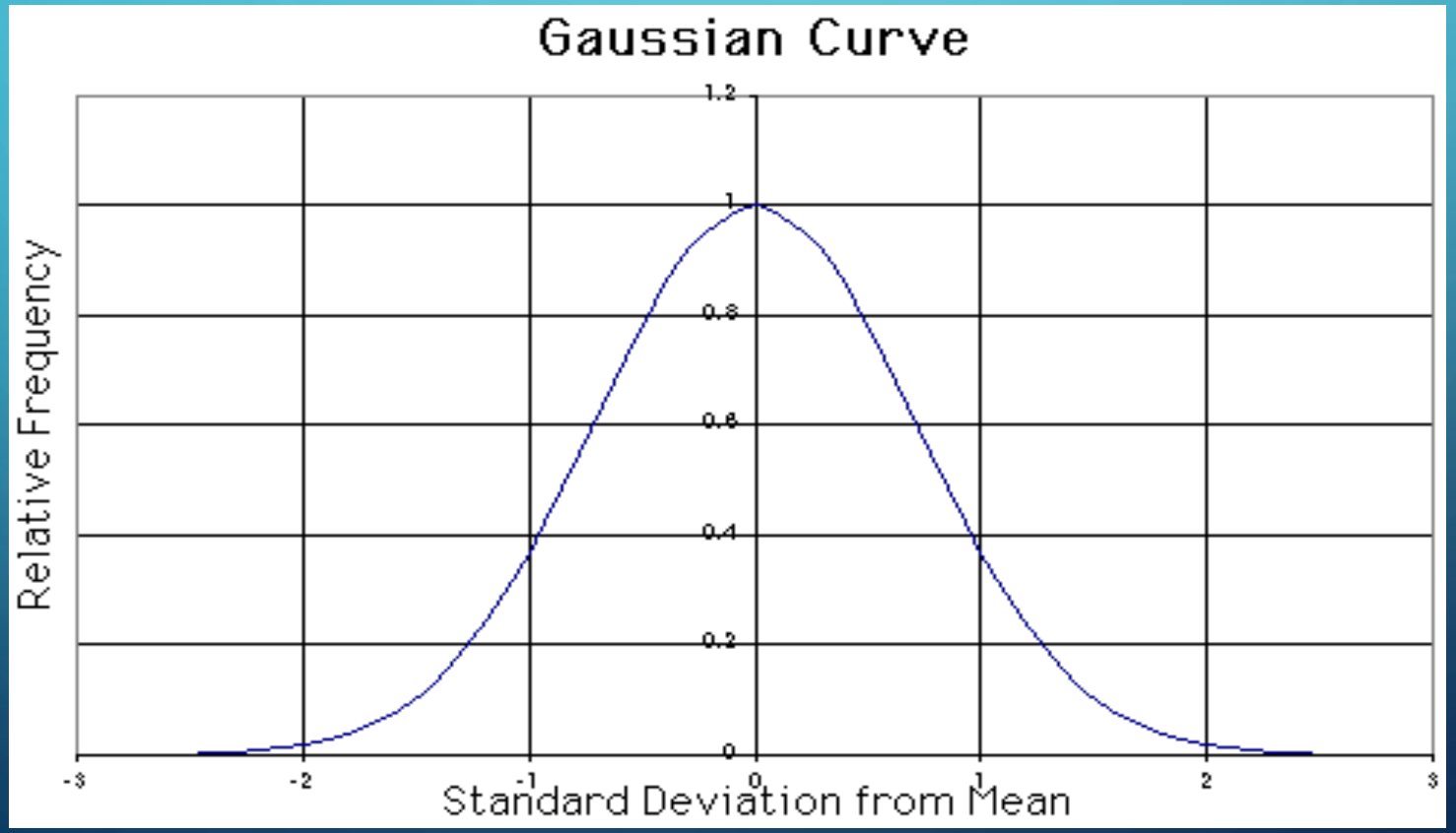
- **95% confidence limit (± 2 SD)** - 95% of all the results in a Gaussian distribution



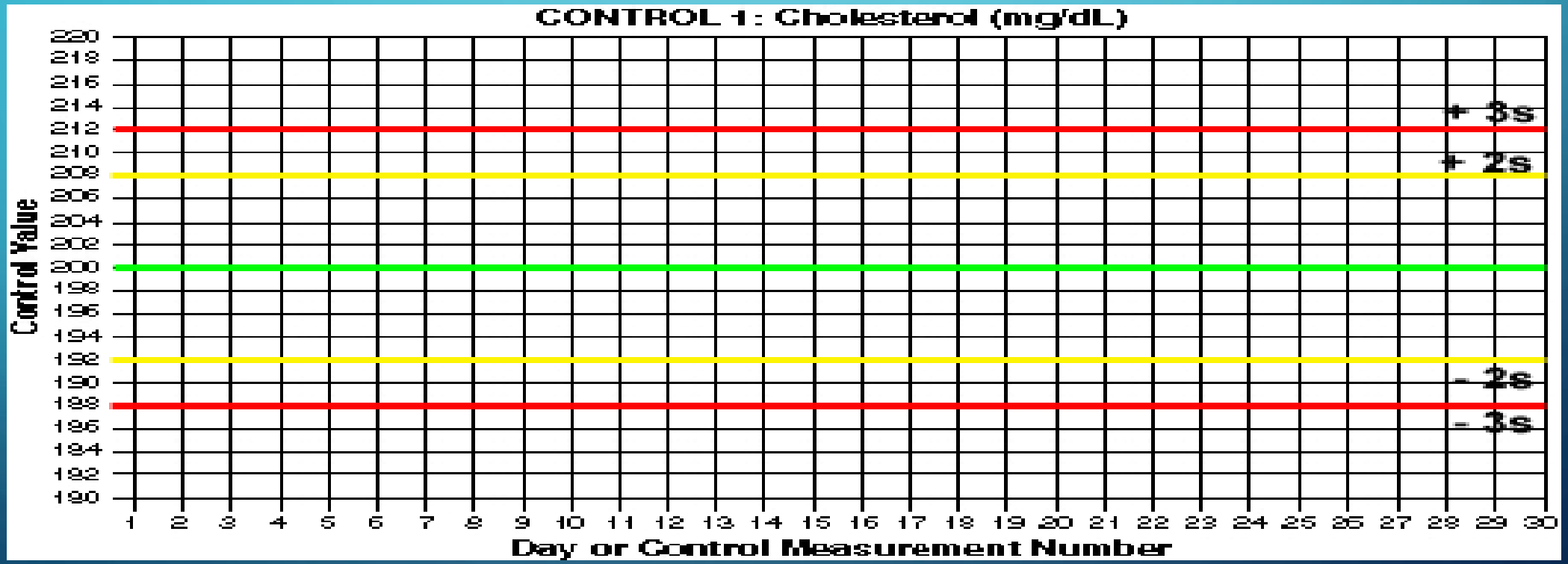


HOW MANY POINTS FALL WITHIN EACH SD LIMIT?

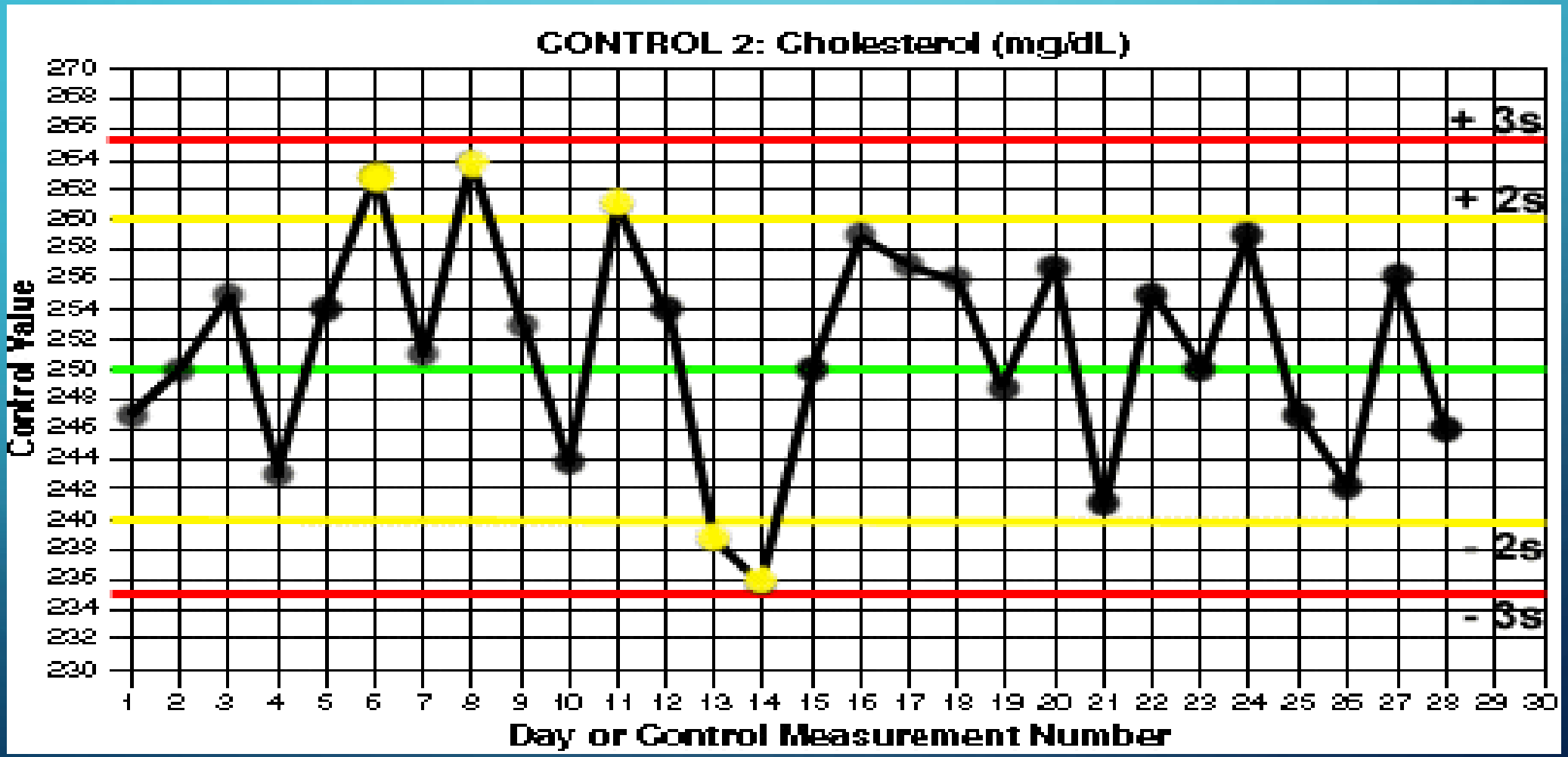
- **Dispersal** / or how the individual data points are distributed about the central value



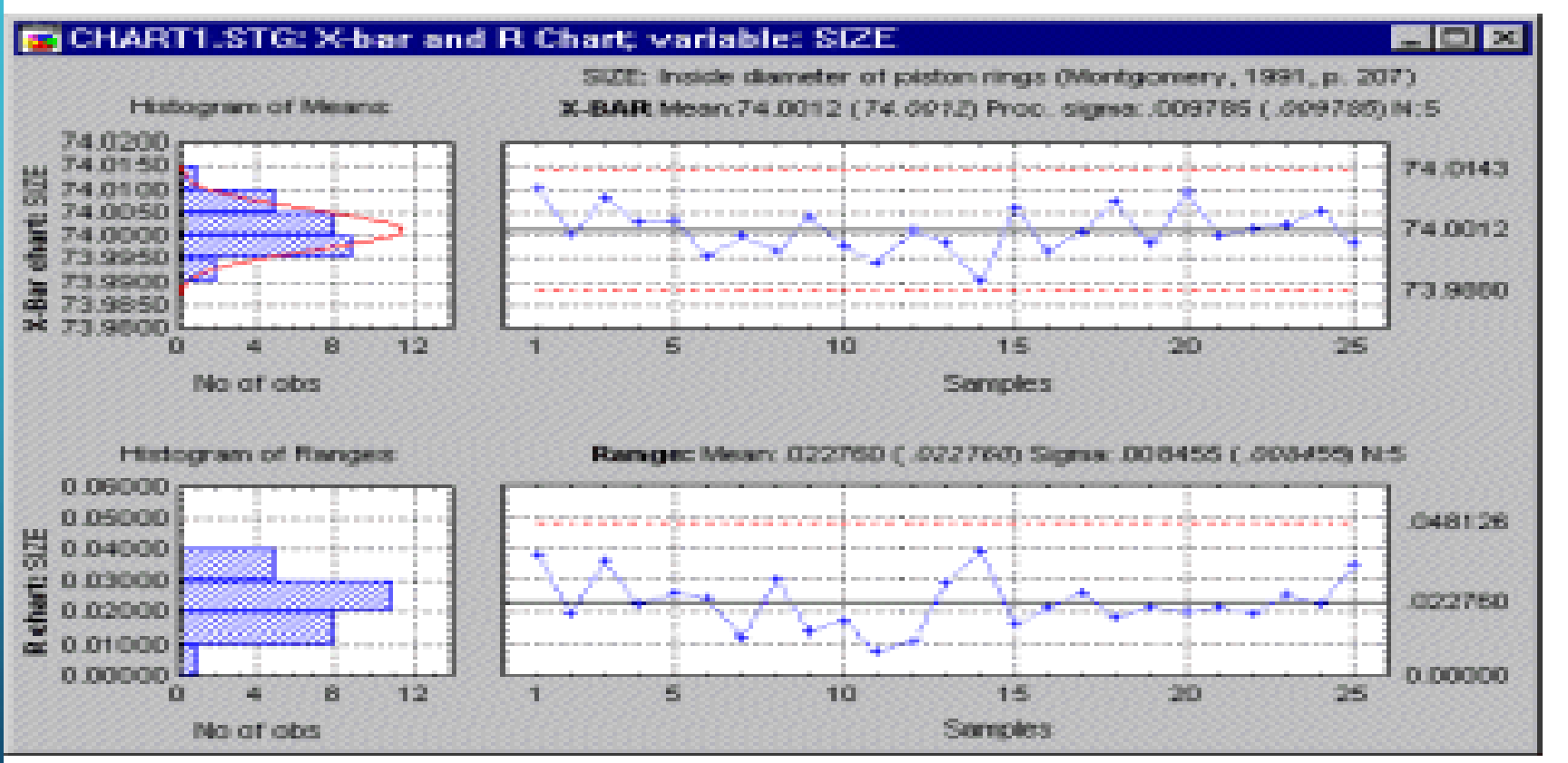
LEVEY-JENNINGS QC GRAPH (NO POINTS)



LEVEY-JENNINGS QC CHART FOR 1 MONTH



CLINICAL CHEMISTRY QUALITY CONTROL

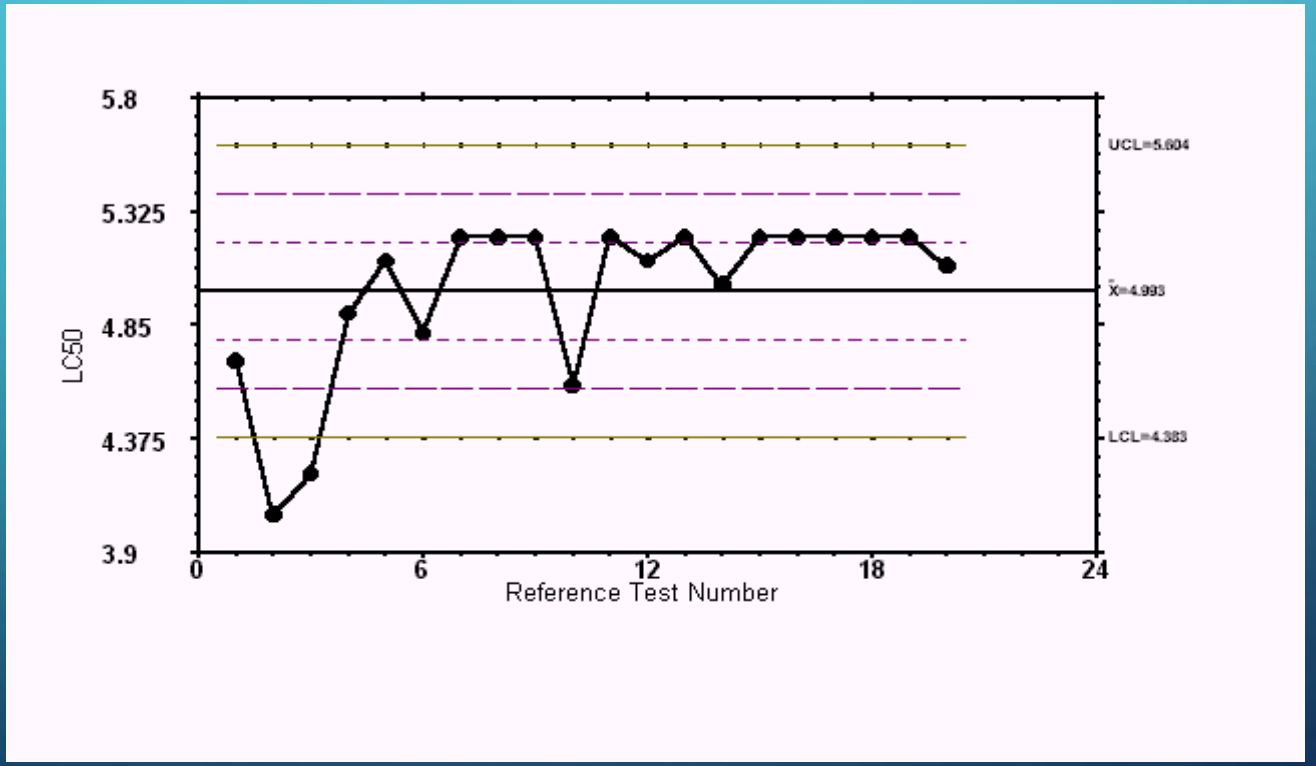


ERRORS

- Sistematic – change in the mean of the control values.
  - Gradual – trend
  - Abrupt - shift
- Random – Deviation away from an expected result

STATISTICAL CONCEPTS

- Shift – when there are 6 consecutive data results on the same side of the mean, abrupt change in the control mean. Dramatic positive or negative change in test system performance.

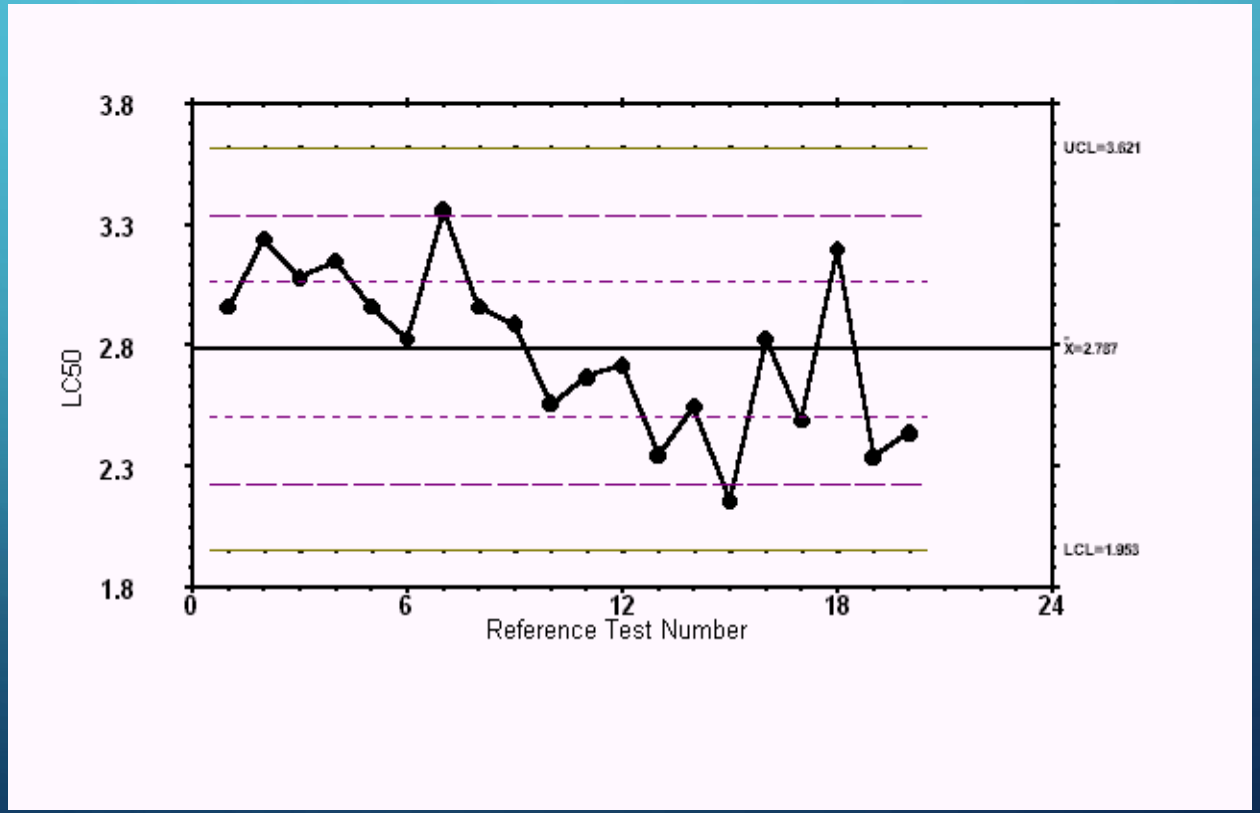


POSSIBLE CAUSES FOR A SHIFT

- Sudden failure or change in light source
- Change in reagent formulation
- Change in reagent lot
- Major instrument maintenance
- Sudden change in incubation temperature (enzymes only)
- Change in room temperature or humidity
- Failure in the sampling system
- Failure in reagent dispense system
- Inaccurate calibration/recalibration

STATISTICAL CONCEPTS

- Trend – when there is a consistent increase OR decrease in the data points over a period of 6 days. (A line connecting the dots will cross the mean). A trend indicates a gradual loss of reliability in the test system. Trends are usually subtle.



POSSIBLE CAUSES FOR A TREND

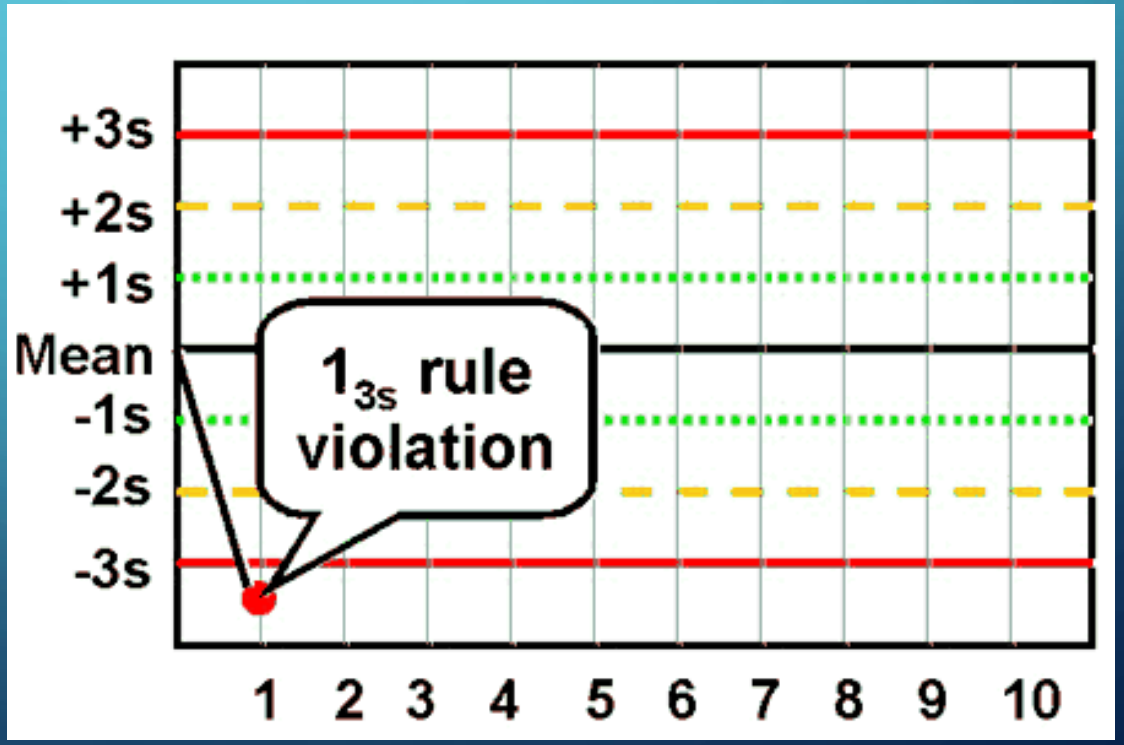
- Deterioration of the instrument light source
- Gradual accumulation of debris in sample/regent tubing
- Gradual accumulation of debris on electrode surafeces
- Aging of reagents
- Gradual deterioration of control materials
- Gradual deterioration of incubation chamber temperature (enzymes only)
- Gradual deterioration of light filter integrity
- Gradual deterioration of calibration

QUALITY OF CONTROL REFERENCE (GURU)

- James O. Westgard, PhD
  - University of Wisconsin
  - Teaches in CLS program
  - Director of Quality Management Services at the U of W Hospital
  - Westgard rules
  - http://www.westgard.com/mltirule.htm

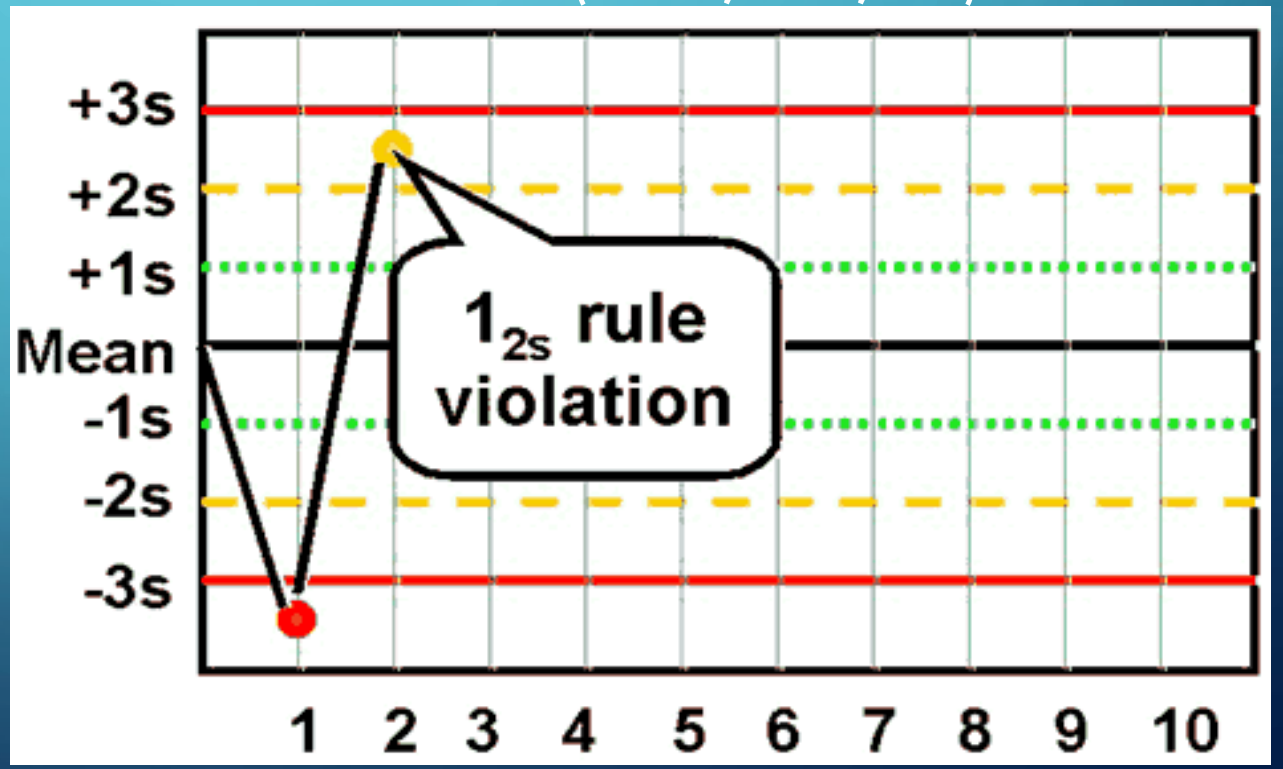
1_{3S} WESTGARD RULE

- 1_{3s}
  - A single control measurement exceeds three standard deviations from the target mean
- Action - Reject



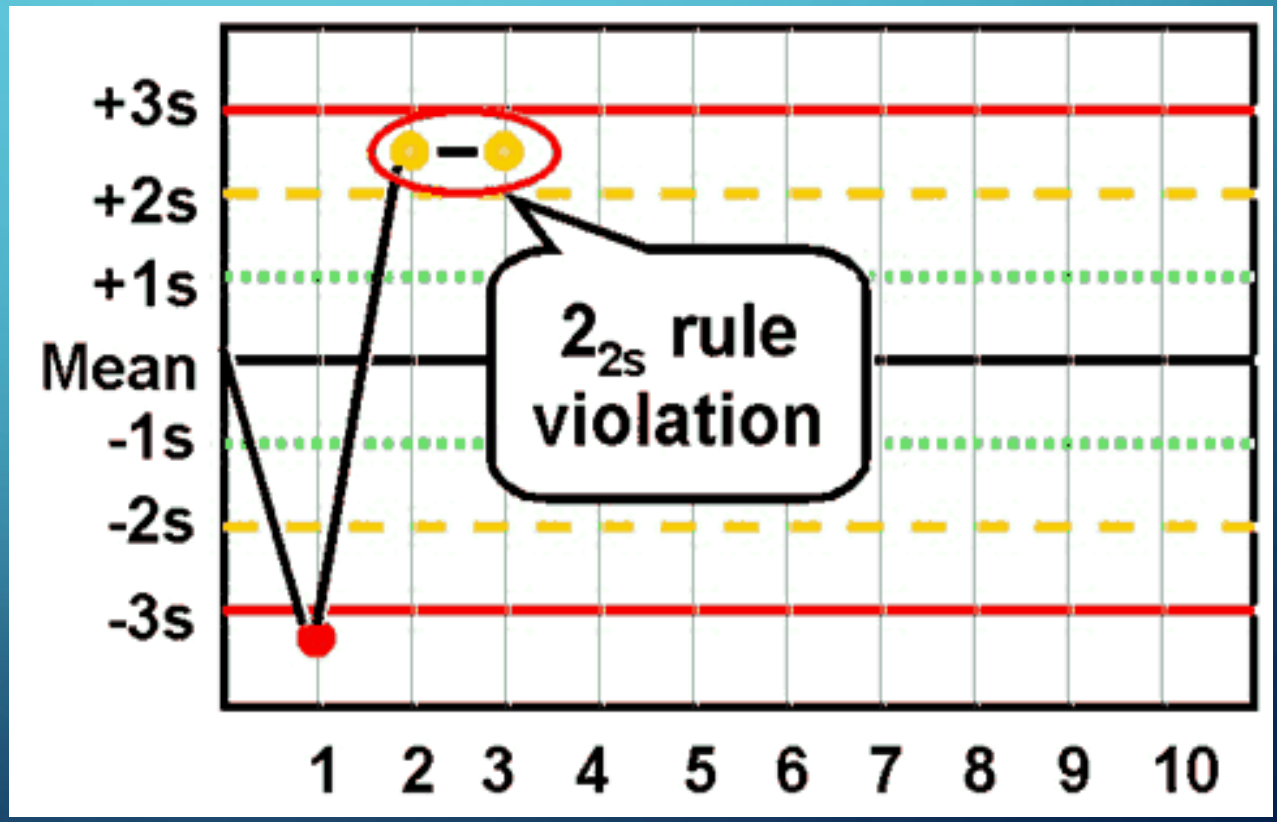
1_{2S} WESTGARD RULE

- 1_{2s}
  - A single control measurement exceeds two standard deviations from the target mean
- Action – must consider other rule violations (trend, shift, etc)
  - This is a warning



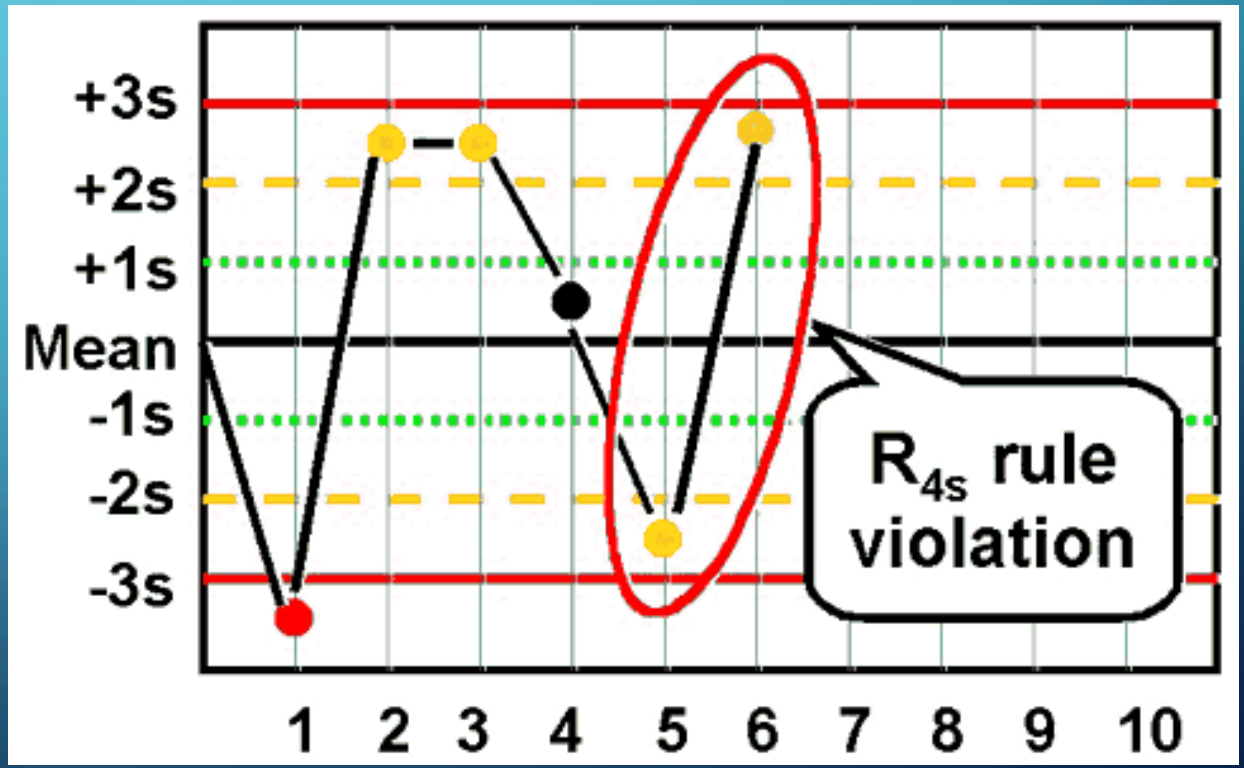
2_{2S} WESTGARD RULE

- 2_{2s}
  - Two consecutive control measurements exceed the same mean plus 2S or the same mean minus 2S control limit.
- Action – Reject



R_{4S} WESTGARD RULE

- R_{4s}
  - One control measurement in a group exceeds the mean plus 2S and another exceeds the mean minus 2S.
- Action – Reject



4_{1S} WESTGARD RULE

- 4_{1s}
  - Four consecutive control measurements exceed the same mean plus 1S or the same mean minus 1S control limit.
- Action – Reject

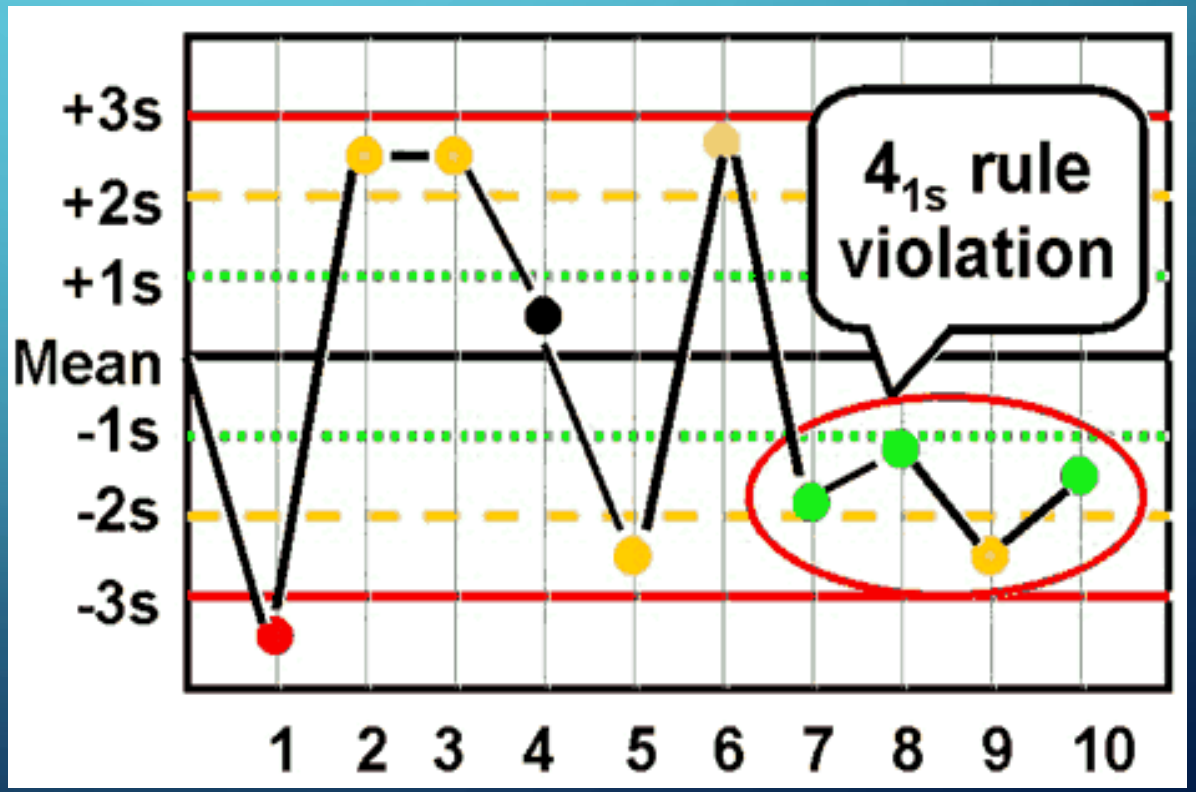


Chart 1

Rule Violated:	Error:

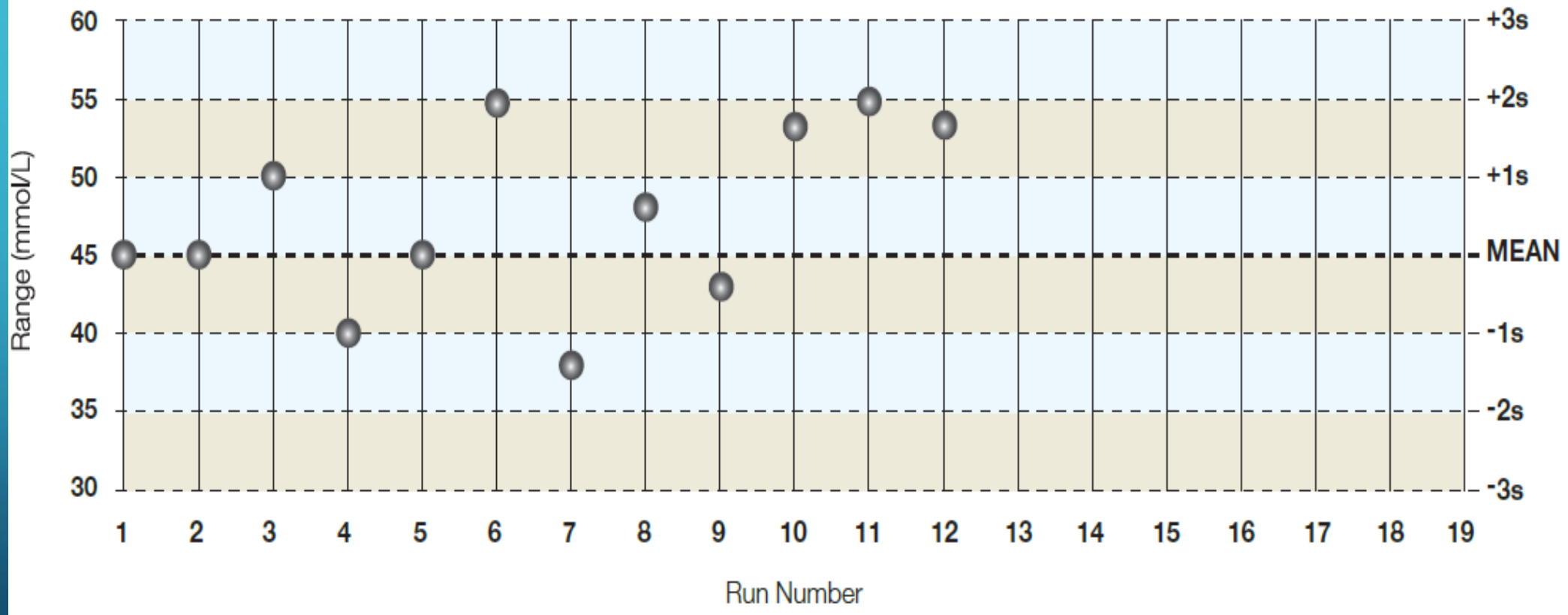


Chart 2

Rule Violated:	Error:

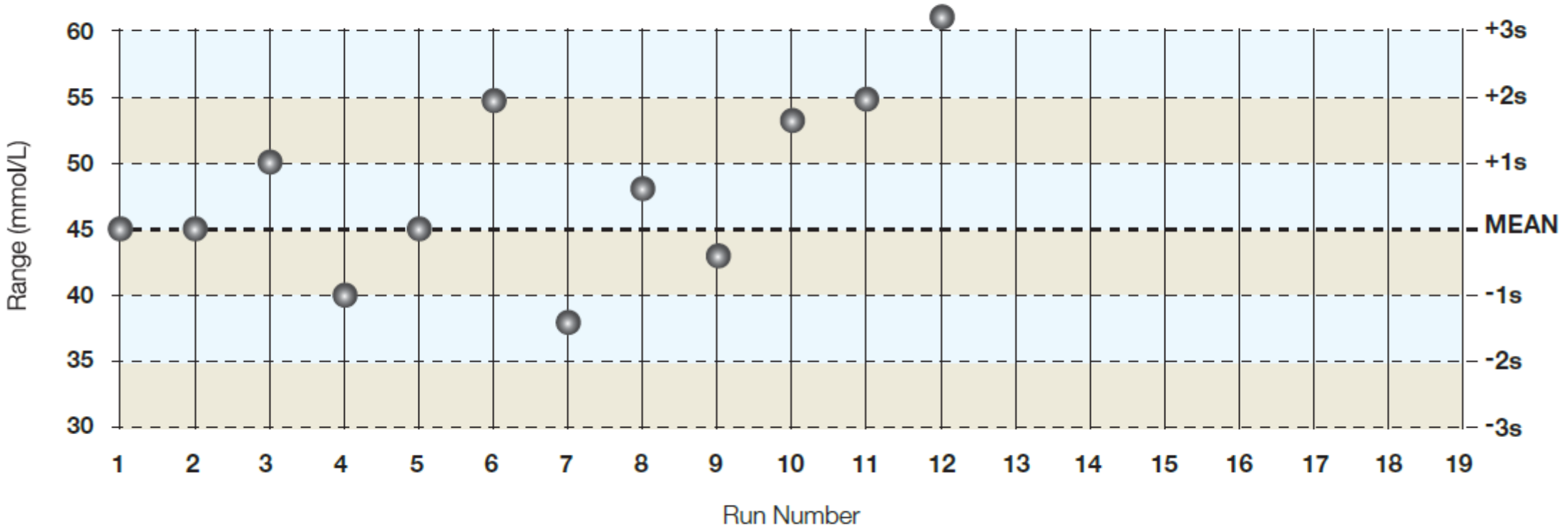


Chart 3

Rule Violated:	Error:

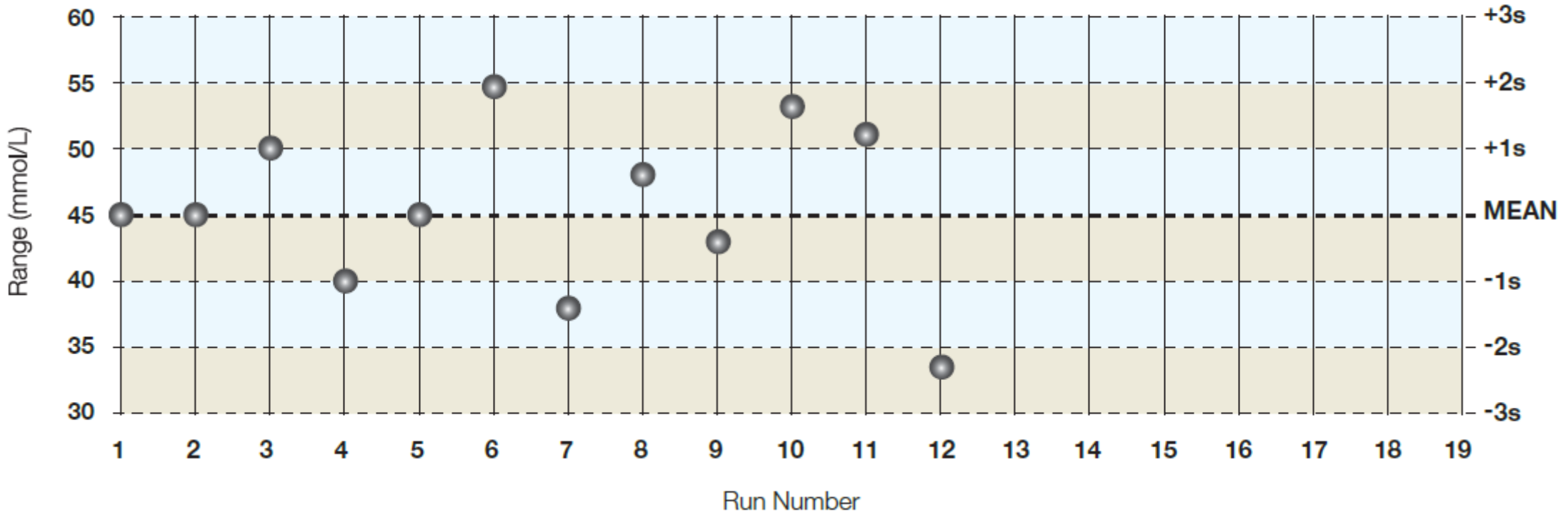


Chart 4

Rule Violated:	Error:

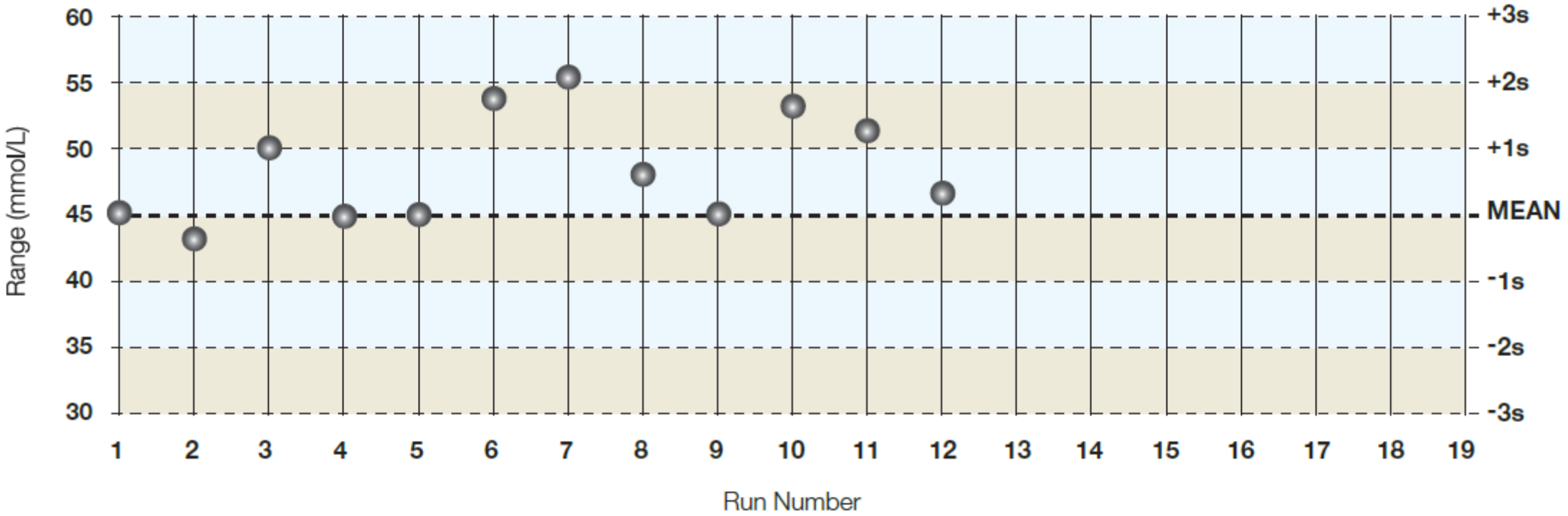


Chart 5

Rule Violated:	Error:

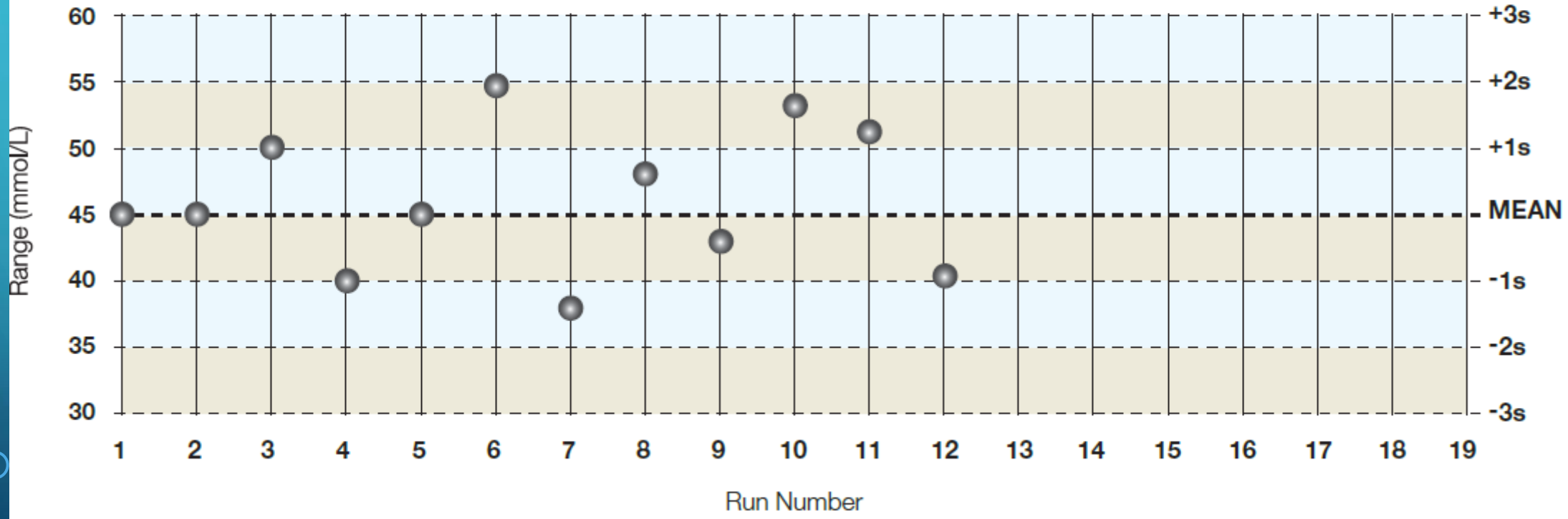


Chart 6

Rule Violated:	Error:

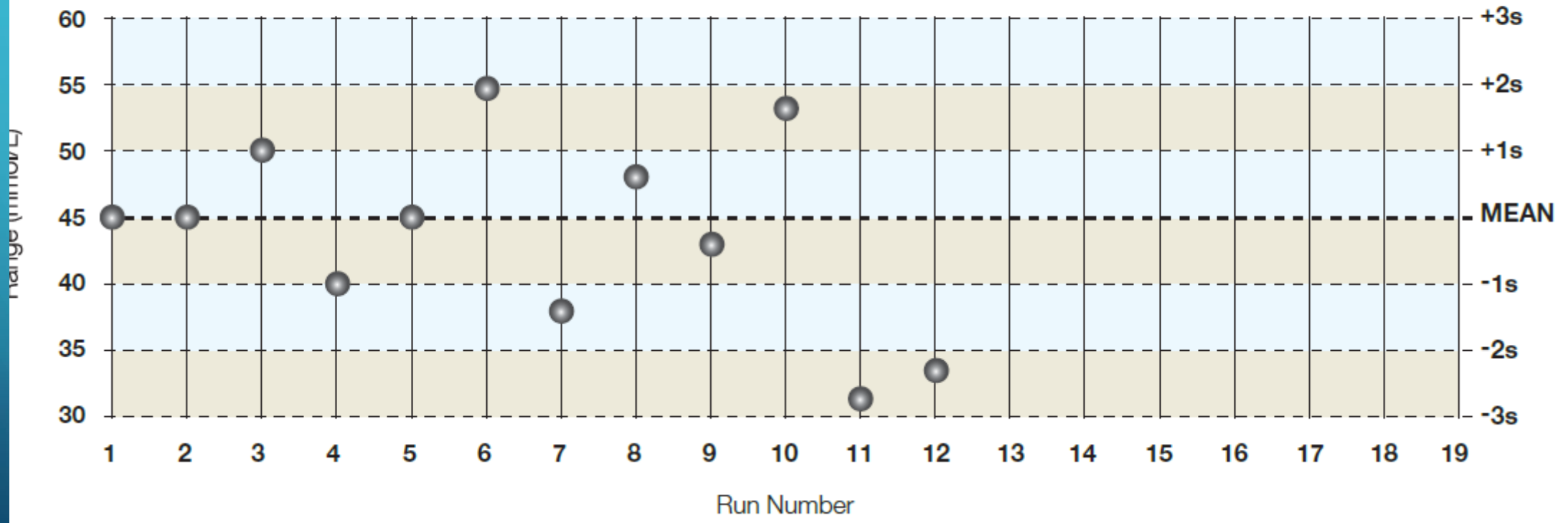


Chart 7

Rule Violated:	Error:

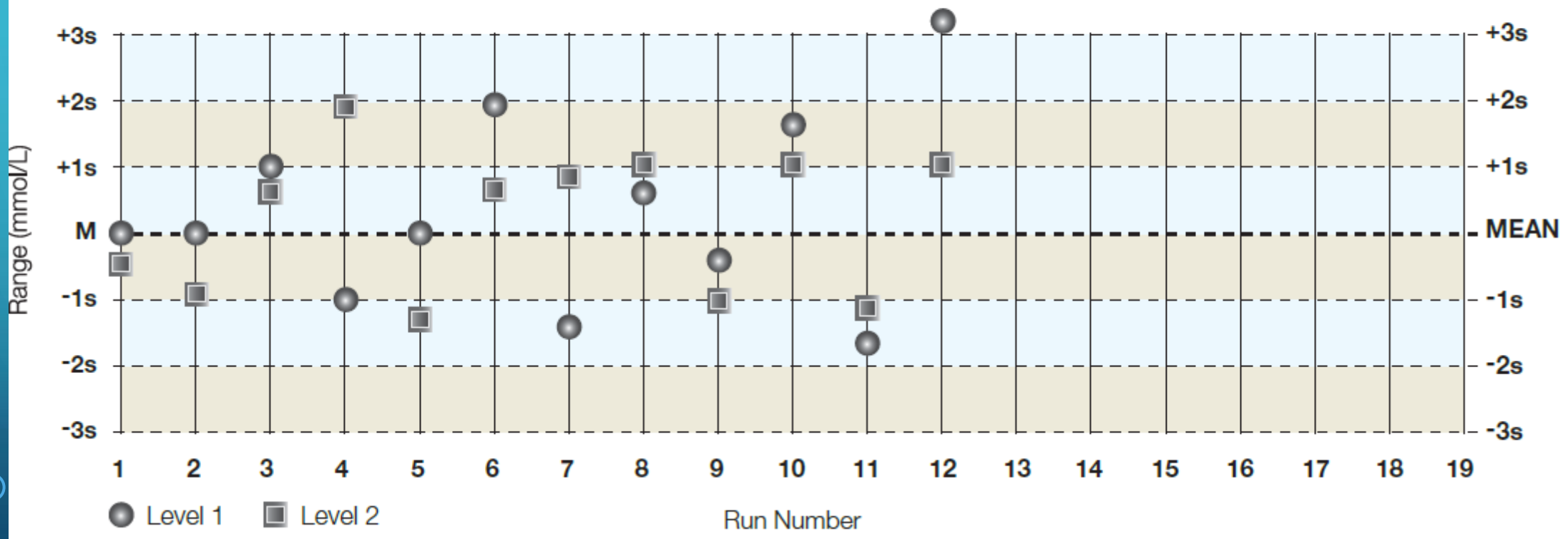


Chart 8

Rule Violated:	Error:

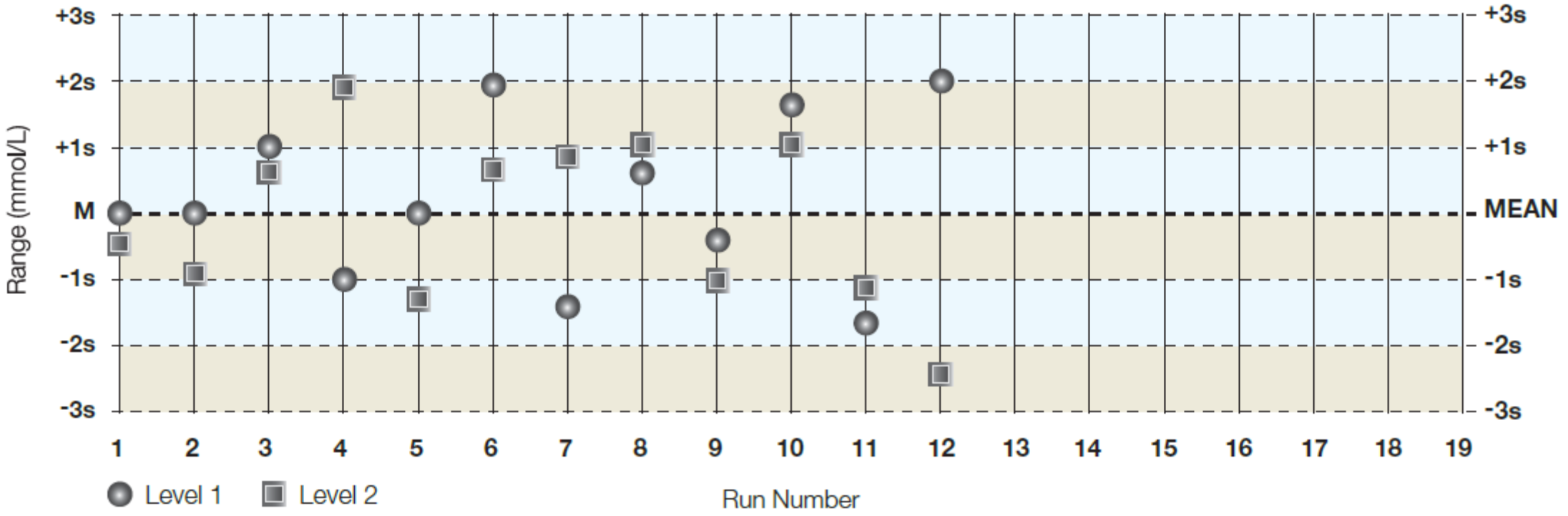
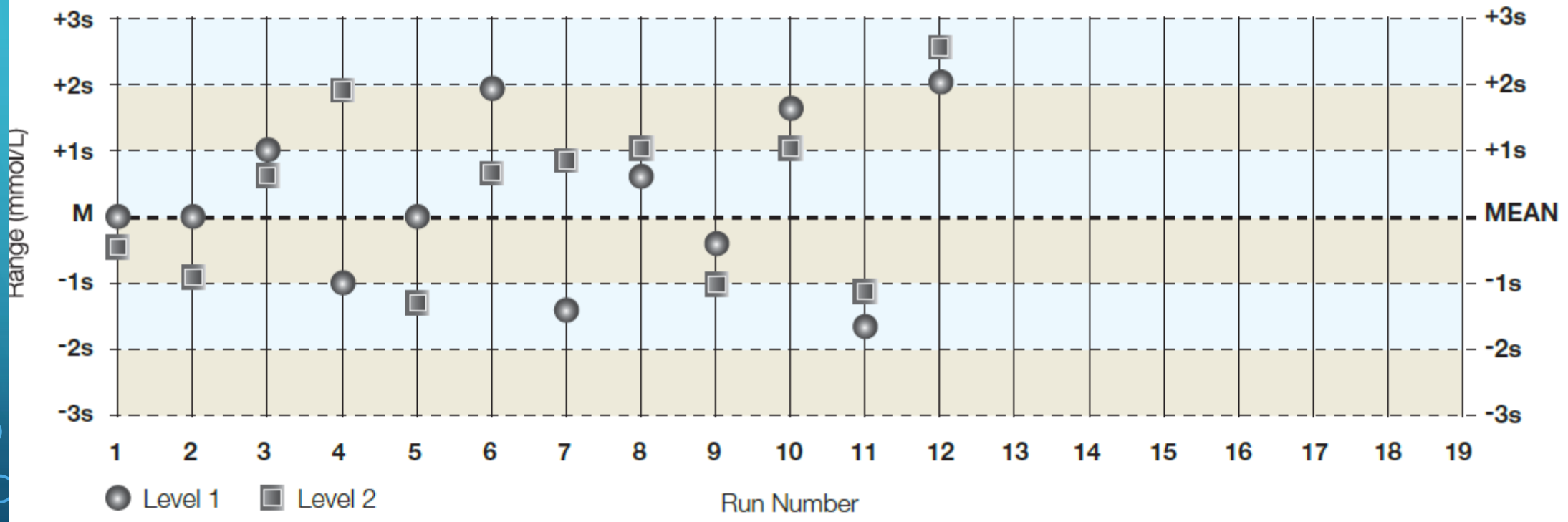


Chart 9

Rule Violated:	Error:



IF QC FAILS?

One Possible Plan of Action: (your lab may advise another)

1. Assay the same qc aliquot.
2. Assay a new qc aliquot from the same vial.
    1. Look at vial of control. If using the last drops—reconstitute or open new vial.
    2. If plenty of QC left in vial, mix well, repour, rerun. Most issues resolve by now. However…
3. If the QC fails again, check the volumes and expiration dates of the reagents. Change out if necessary.
4. Calibrate the instrument, run cleaning sequence, or perform maintenance as needed.
5. Rerun control.
6. If controls fail repeatedly after multiple efforts, SCREAM; then call technical support.

Use discretion keeping in mind that controls, calibrators, and reagents are expensive.

EXAMPLE OF WHAT NOT TO DO:

When QC failed, the MT reran the controls around 15 times without checking reagent status, recalibrating, performing maintenance, or calling technical support.

Lesson: Attempt to fix the problem before rerunning controls.

OTHER QC CHECKS

- **Delta checks**
  - Compares a current test result on a patient to last run patient test, flagging results outside expected physiological variation.
  - Many False positives, but DO NOT ignore-- investigate
- **MCHC=Hgb / Hct * 100 (expect 32-36)**
- **Rule of 3=Hemoglobin x3 = hematocrit**
- **Compare patient BUN / creatinine (10/1 – 20/1)**

SELECTING A CONTROL PRODUCT