

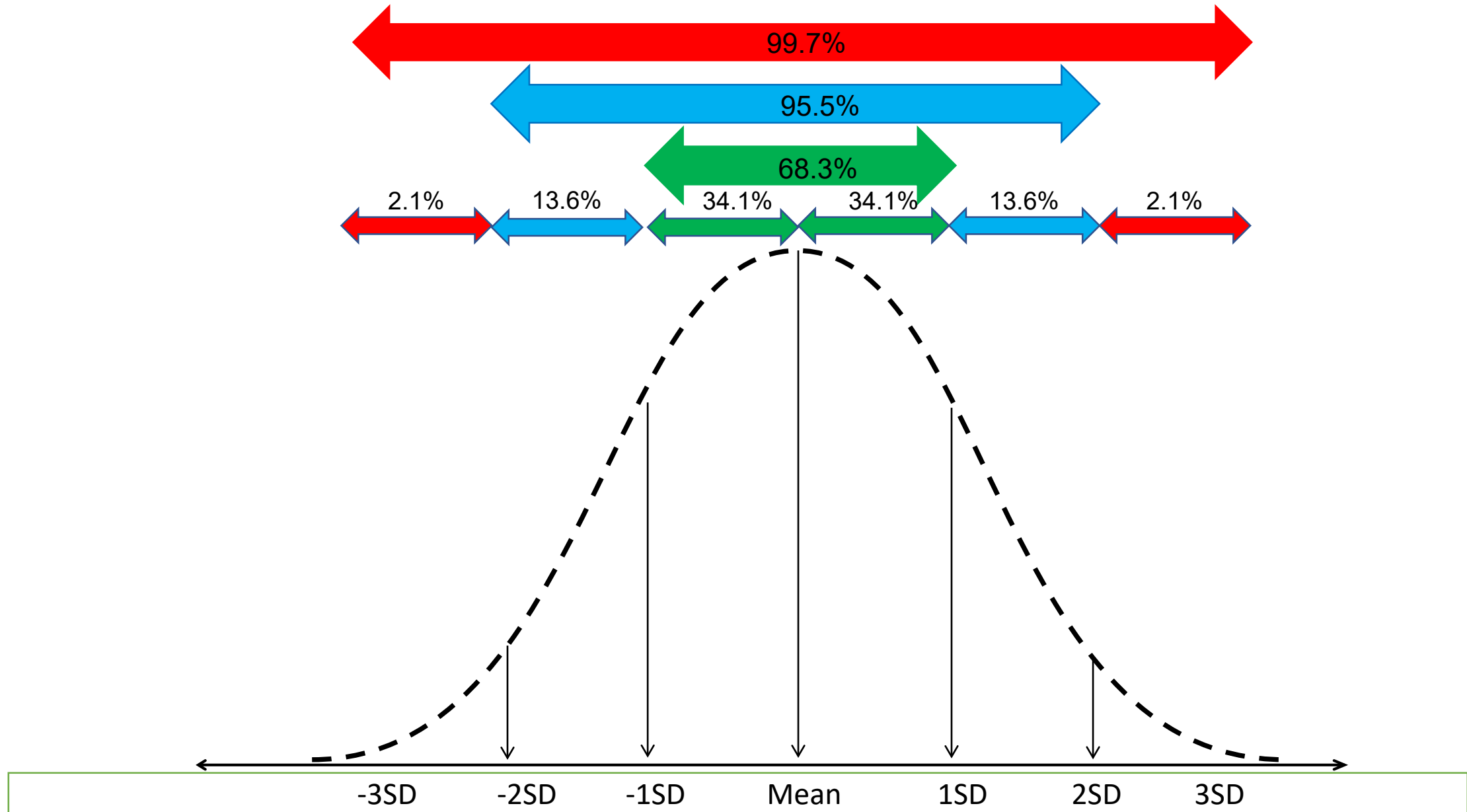


On-site Training at  
Takeo Provincial Hospital  
Laboratory  
November 12-15, 2018

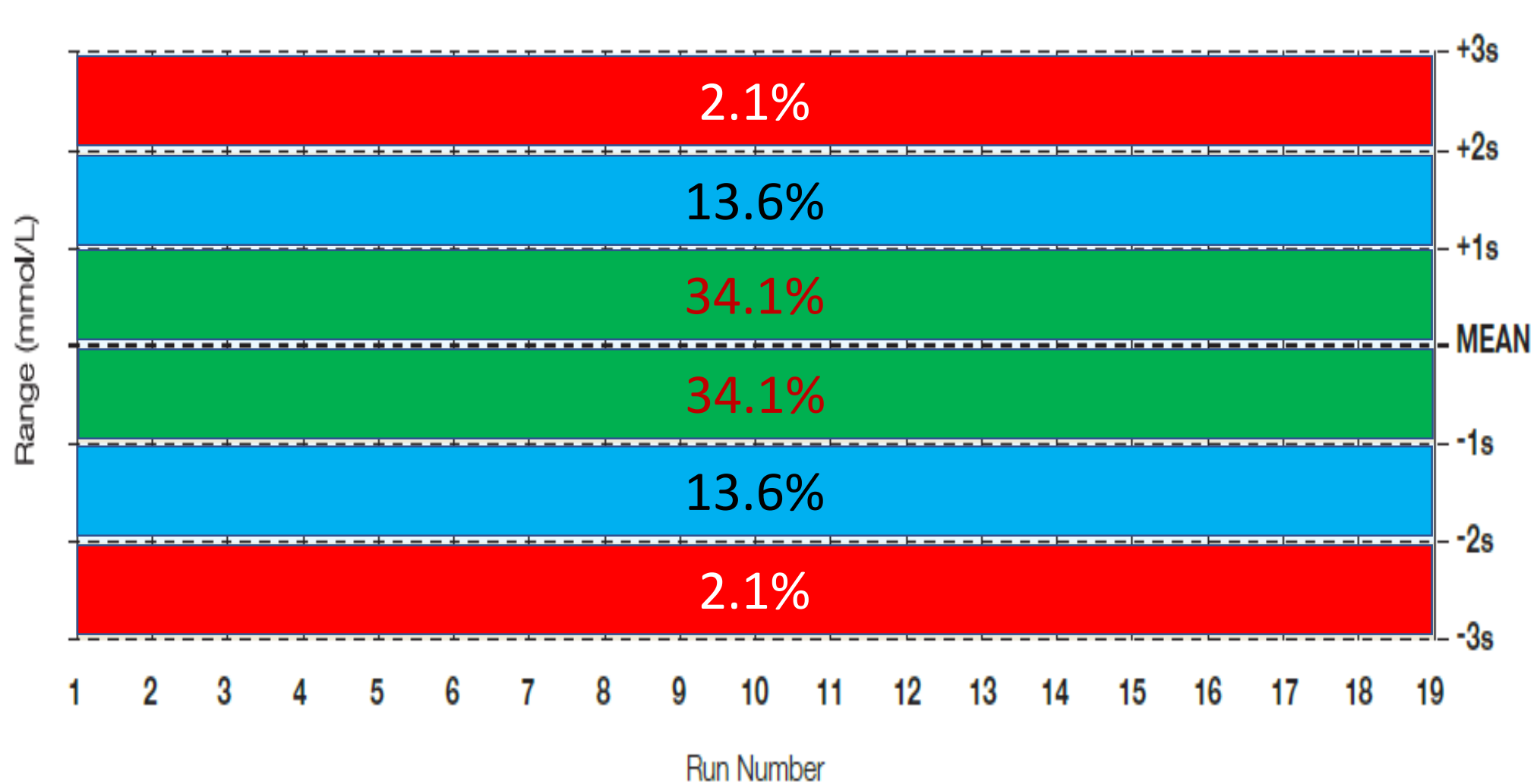
# Westgard Rules and Troubleshooting

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Senior QI Mentor, I-TECH Cambodia

# Gaussian Normal Distribution



# Gaussian Normal Distribution (Levey Jenning chart)

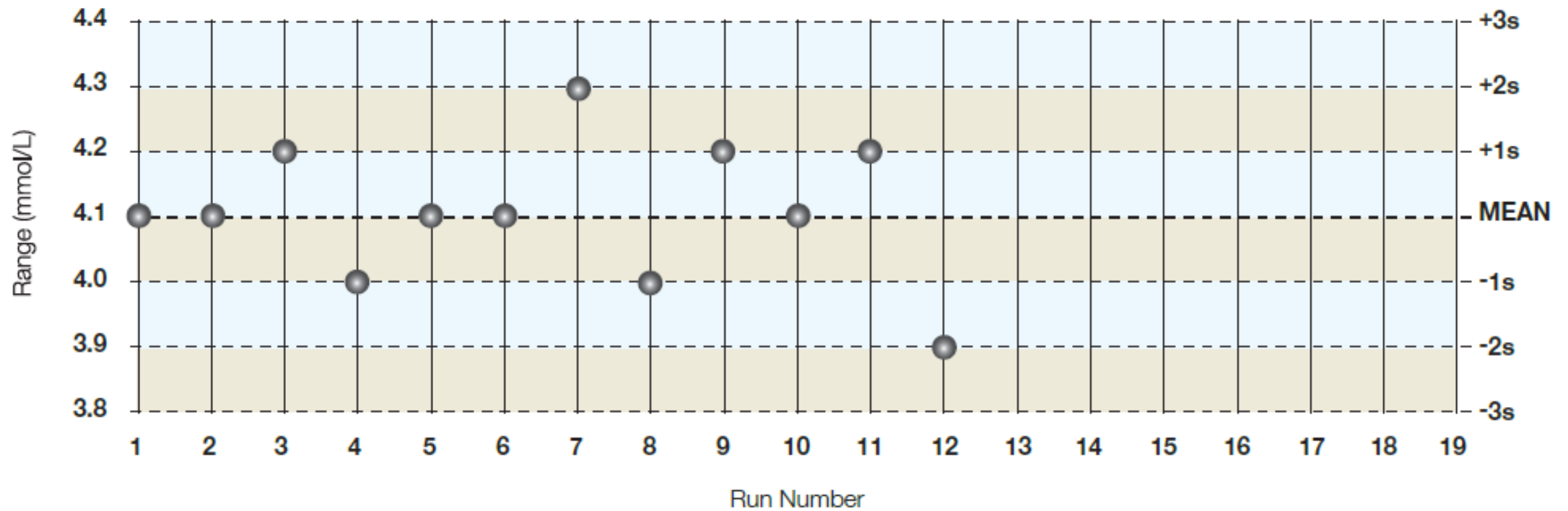


# Levey-Jennings Chart

Unassayed Chemistry Control, Lot No. 12345

Level 1 (Normal Control)

Test: Potassium



# Violation Rules (multi rules)

- $1_{2s}$

- $1_{3s}$

- $2_{2s}$

- $R_{4s}$

- $3_{1s}$

- $4_{1s}$

- $6_x$

- $7_x$

- $8_x$

- $9_x$

- $10_x$

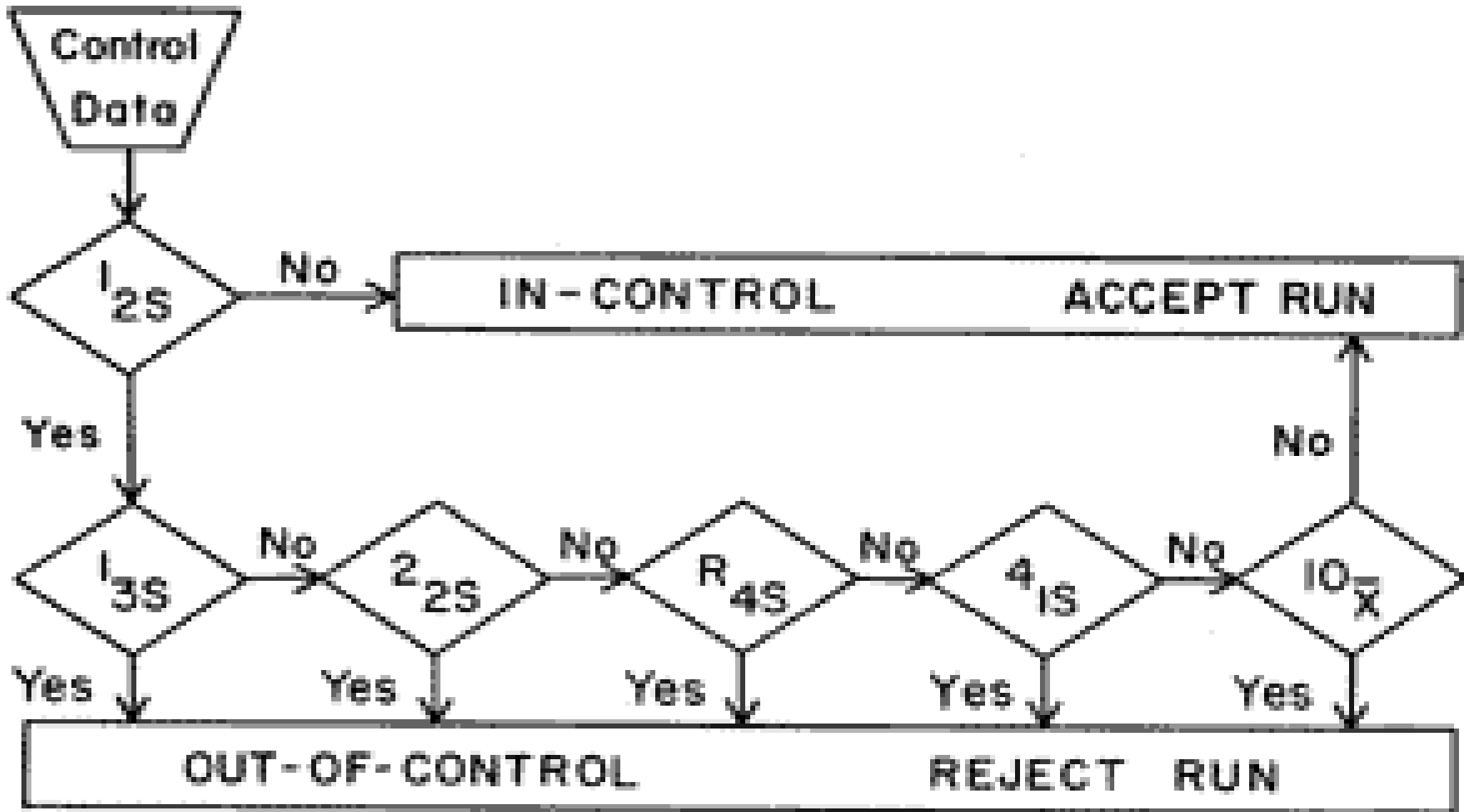
- $12_x$

- $2\text{of}3_{2s}$

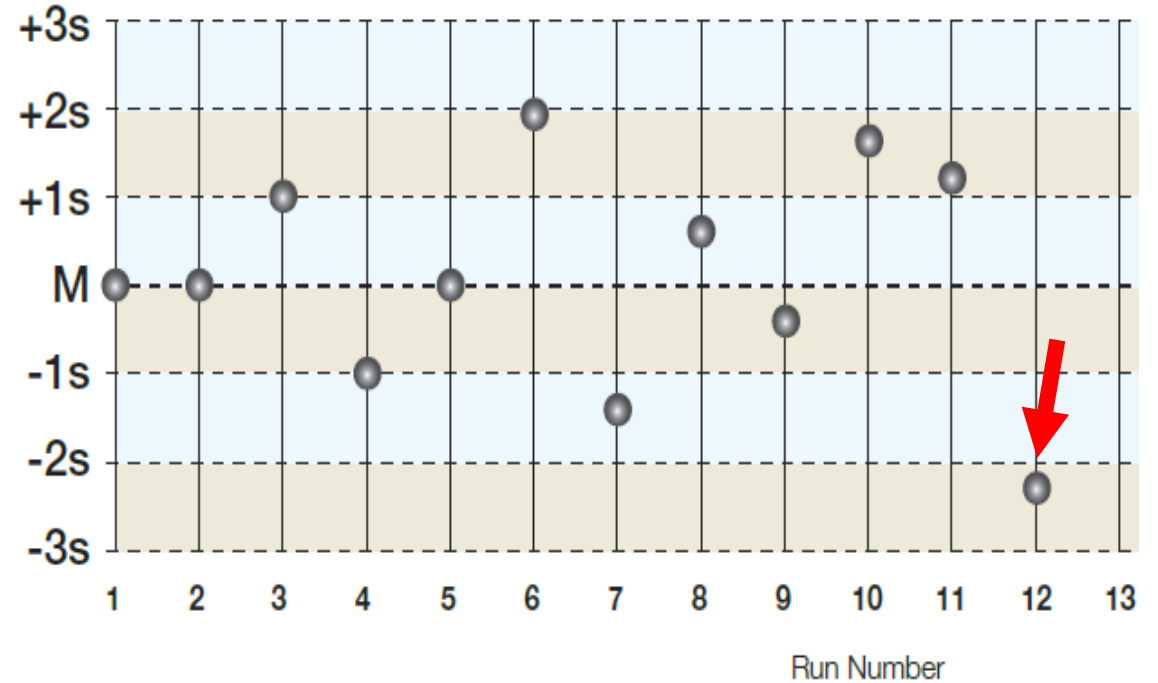
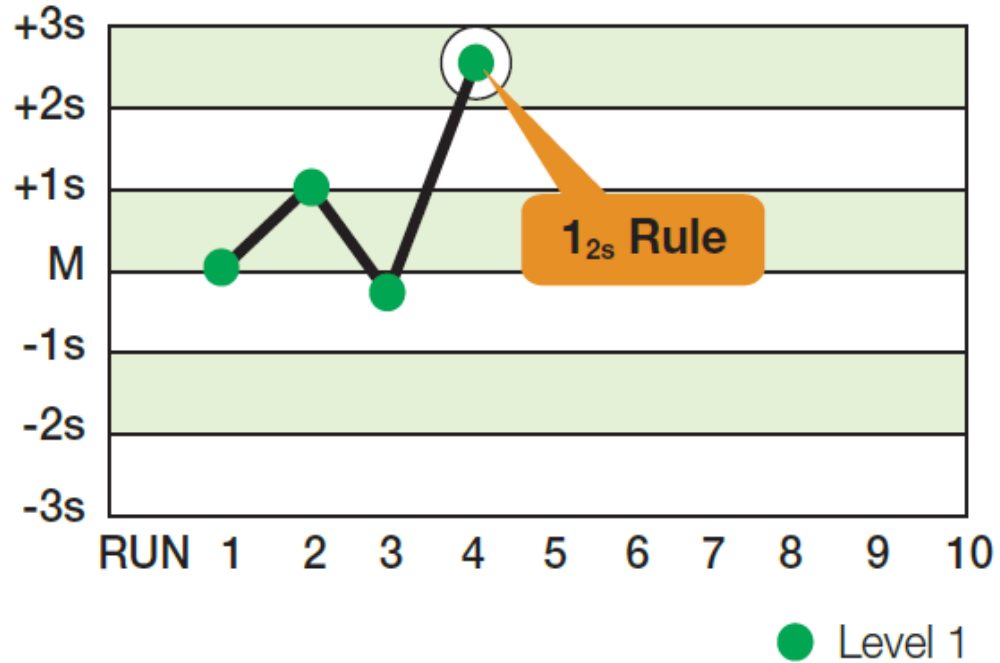
- $7_T$

- ...

# Traditional Westgard Rules



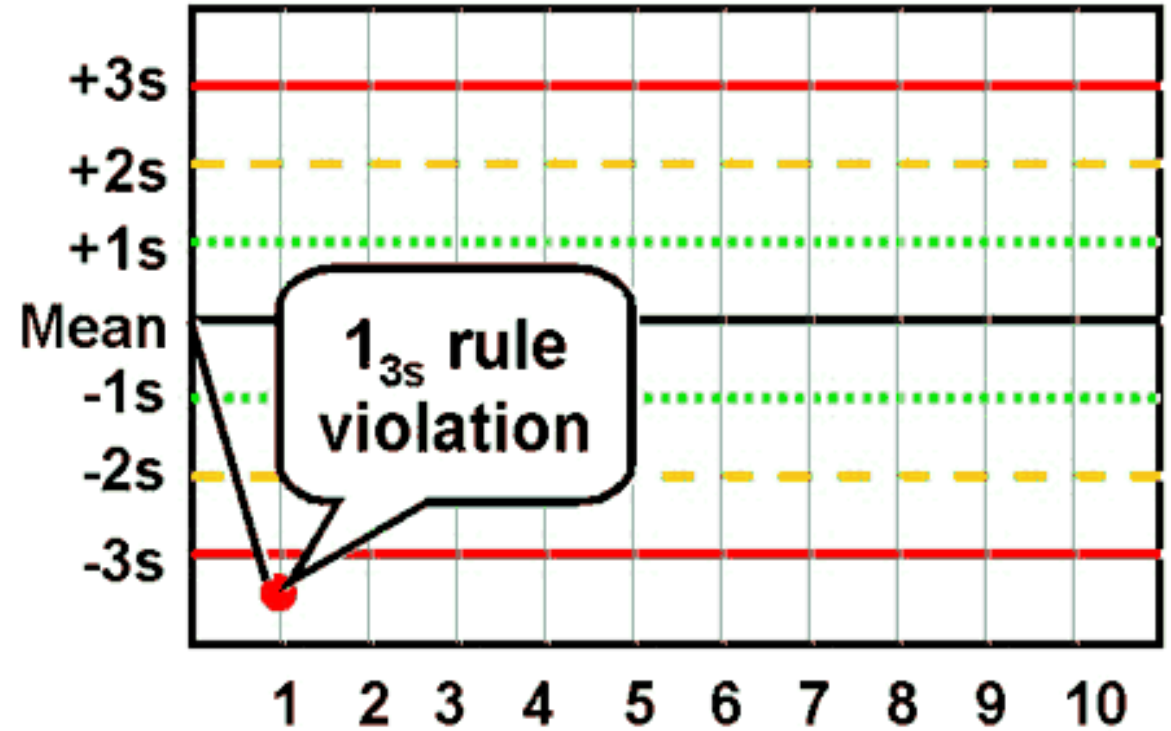
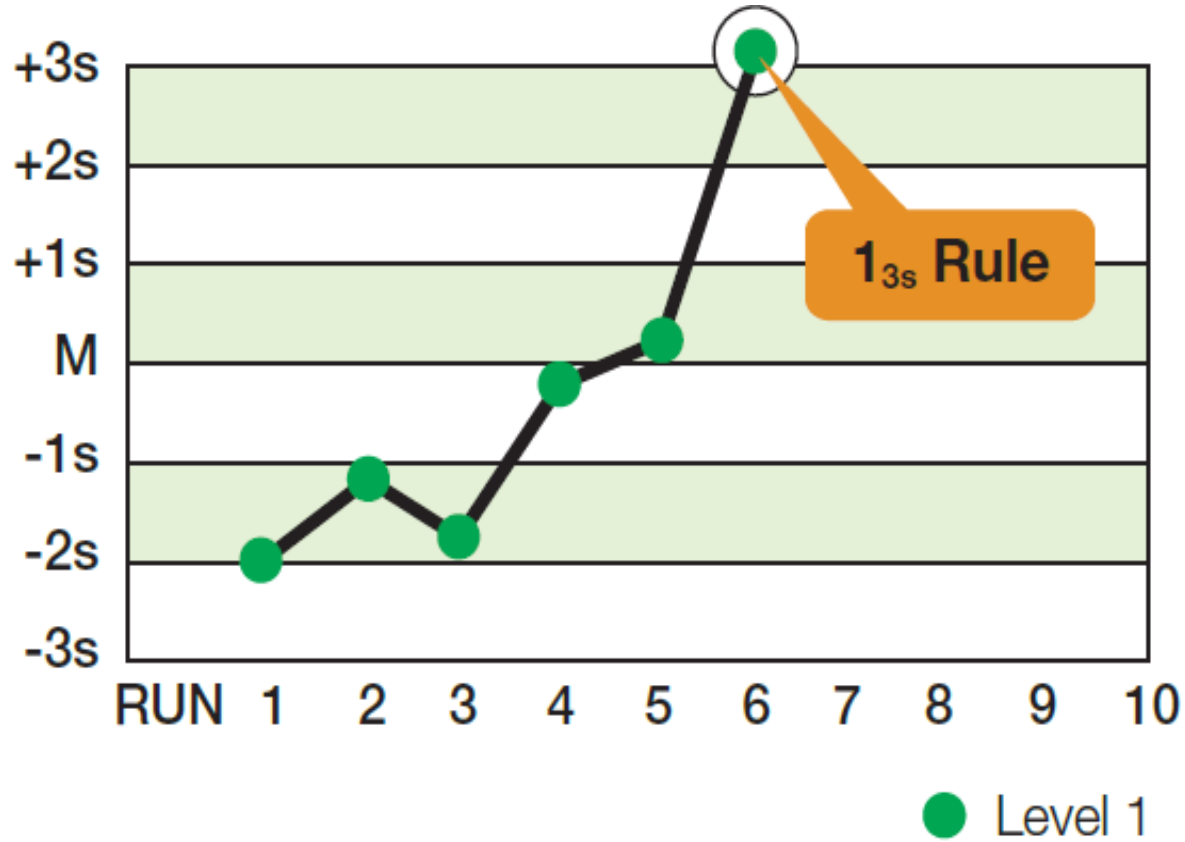
# QC Rule: $1_{2s}$



មានមួយចំណុចស្ថិតនៅក្រៅដែនកំណត់  $\pm 2s$  (តែនៅក្នុង  $\pm 3s$ ) ។

refers to any QC result outside  $\pm 2s$  limits.

# QC Rule: $1_{3s}$

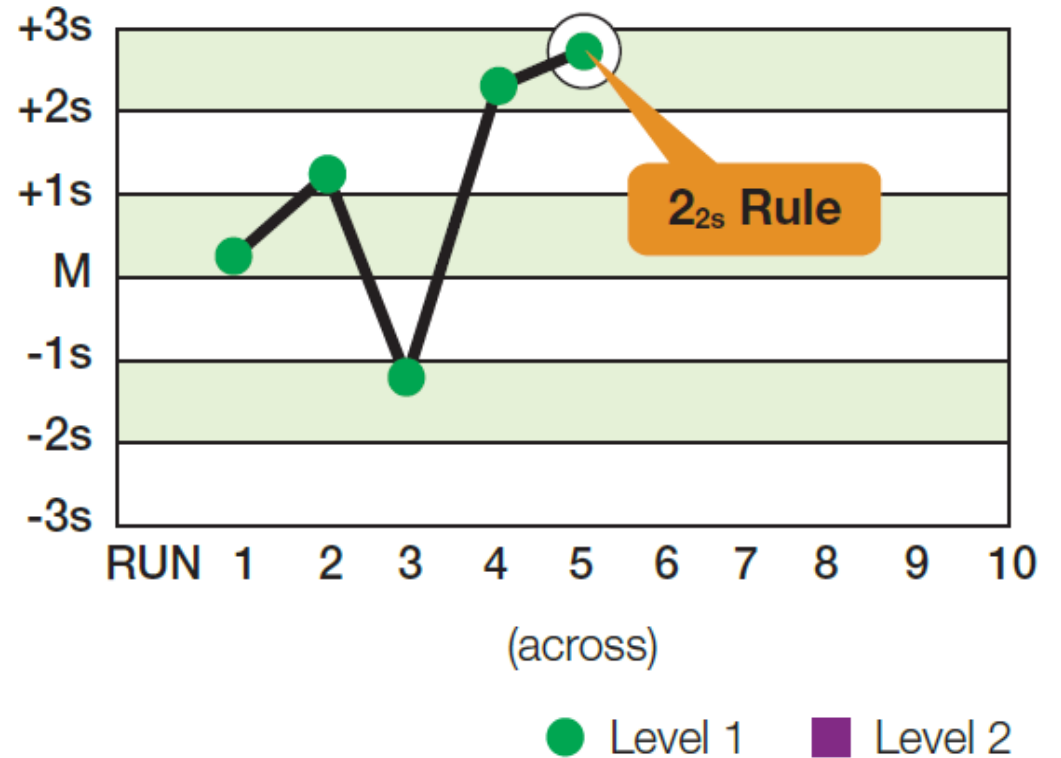
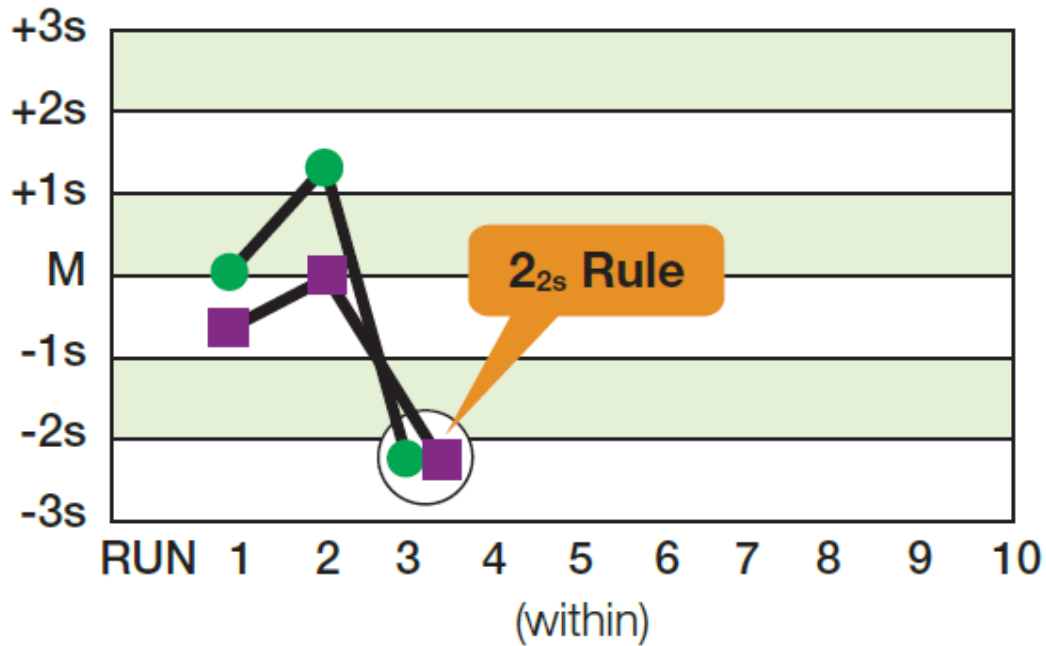


មានមួយចំណុចស្ថិតនៅក្រៅដែនកំណត់  $\pm 3s$  ។

refers to any QC result outside  $\pm 3s$  limits.



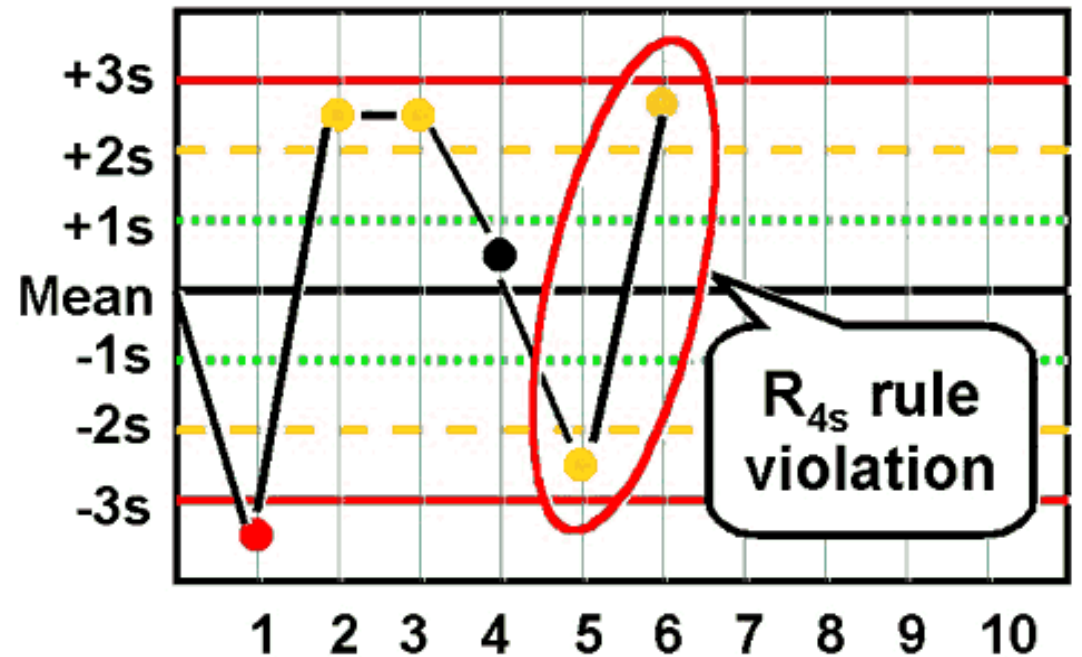
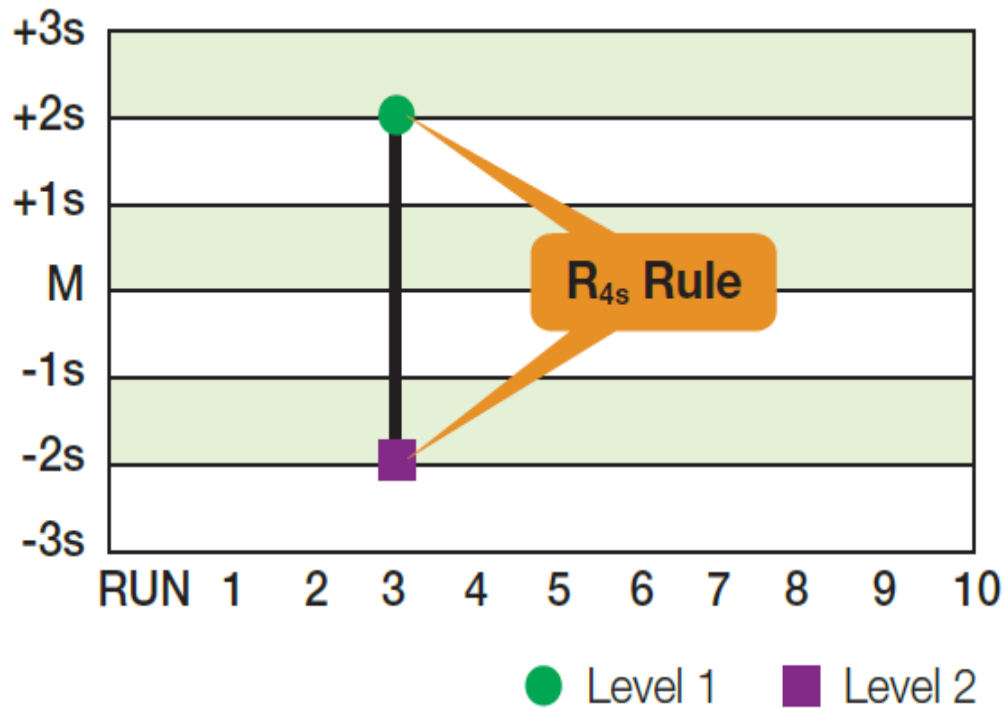
# QC Rule: $2_{2s}$



មានពីរចំណុចជាប់គ្នាស្ថិតនៅក្រៅដែនកំណត់  $\pm 2s$  តែម្ខាងនៃ Mean។

refers to two consecutive QC results outside  $\pm 2s$  limits on the same side of the mean.

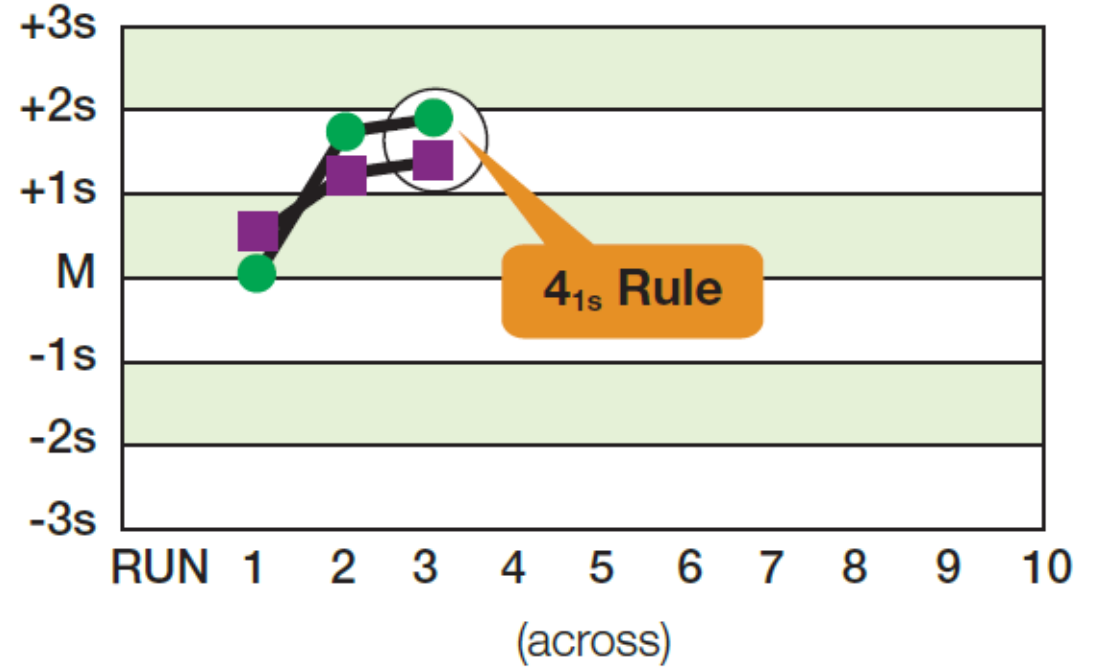
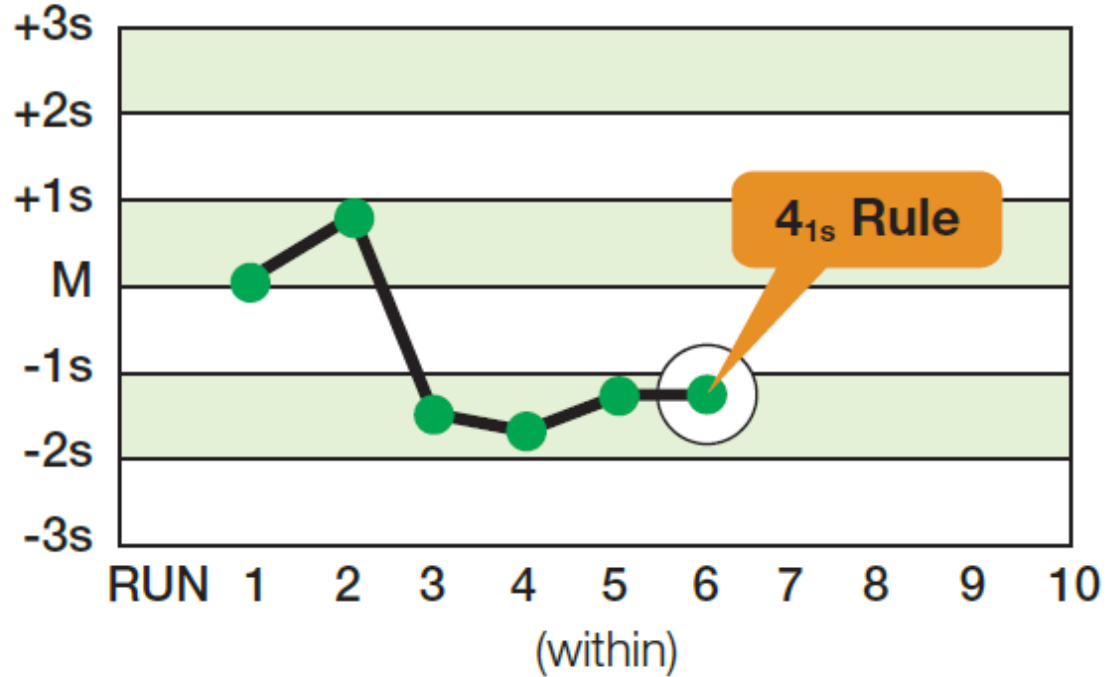
# QC Rule: $R_{4s}$



មានមួយចំណុចនៅក្រៅ  $+2s$  និងមួយចំណុចទៀតនៅក្រៅ  $-2s$ ។

refers to one QC results exceeds  $+2s$  and another exceeds  $-2s$ .

# QC Rule: $4_{1s}$

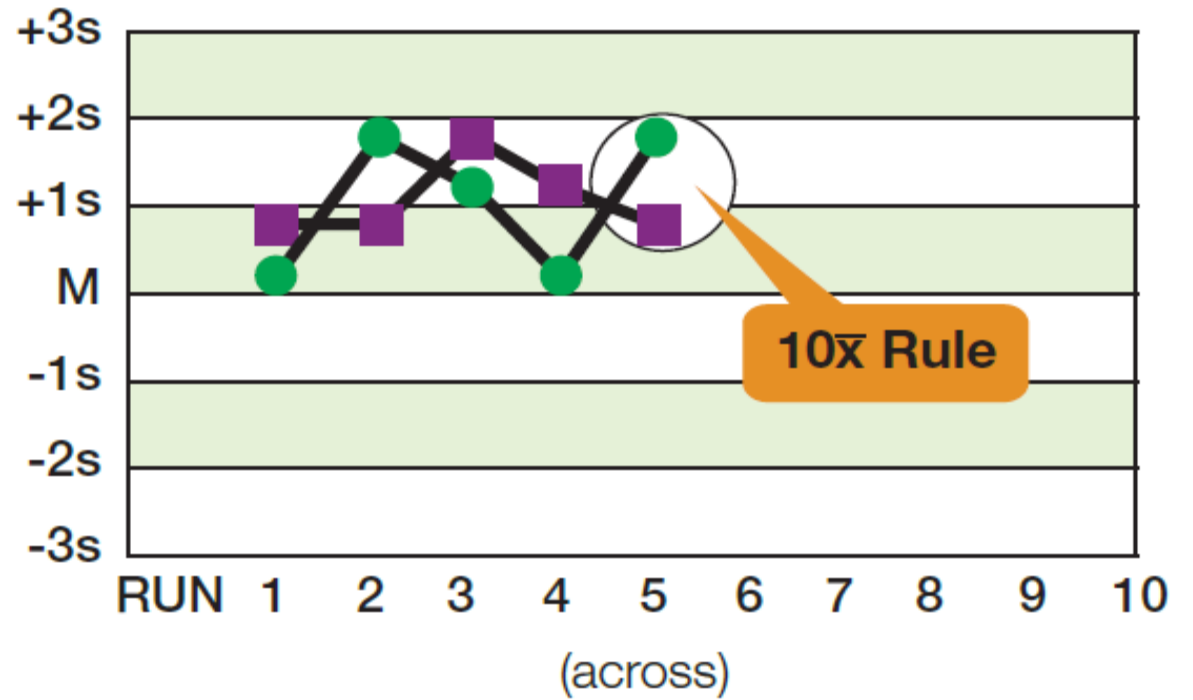
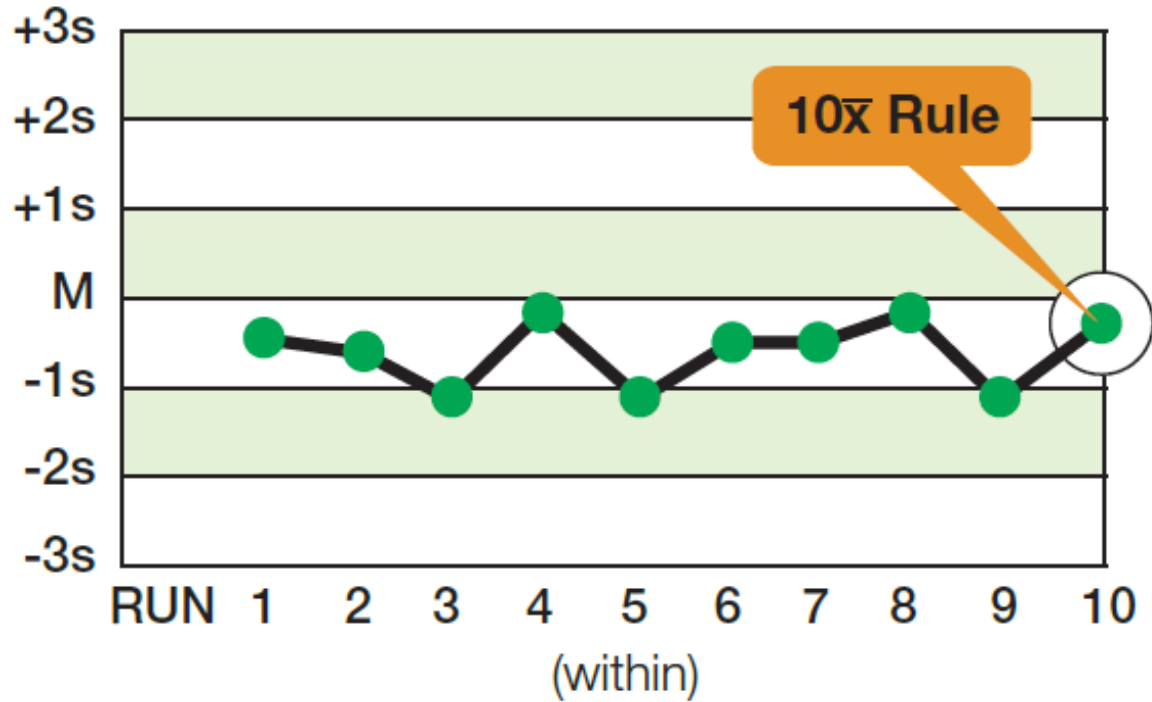


● Level 1    ■ Level 2

មានបួនចំណុចជាប់គ្នាស្ថិតនៅក្រៅដែនកំណត់  $\pm 1s$  តែម្ខាងនៃ Mean។

refers to four consecutive QC results outside  $\pm 1s$  on the same side of the mean.

# QC Rule: 10x



● Level 1    ■ Level 2

មានដប់ចំណុចជាប់គ្នាស្ថិតនៅតែម្ខាងនៃ **Mean**។

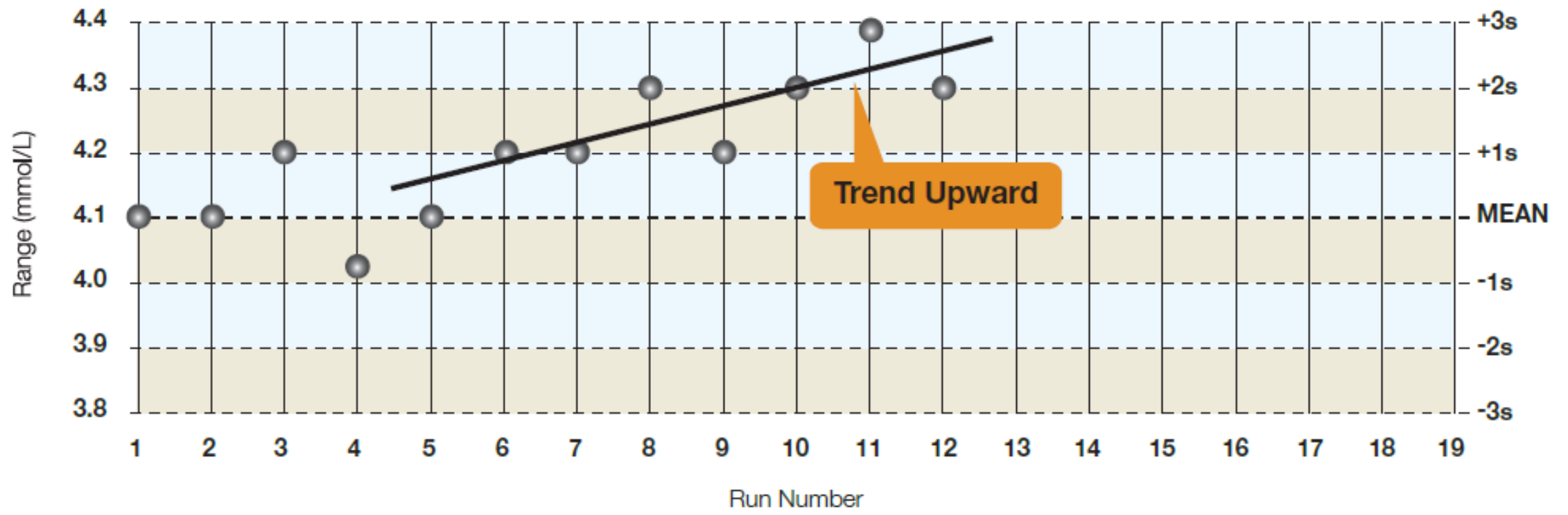
refers to ten consecutive QC results on only one side of the mean.

សូមមេត្តាយកចិត្តទុកដាក់ត្រង់ចំណុចនេះបន្តិចផងបាទ!!!

# Trend and Shift

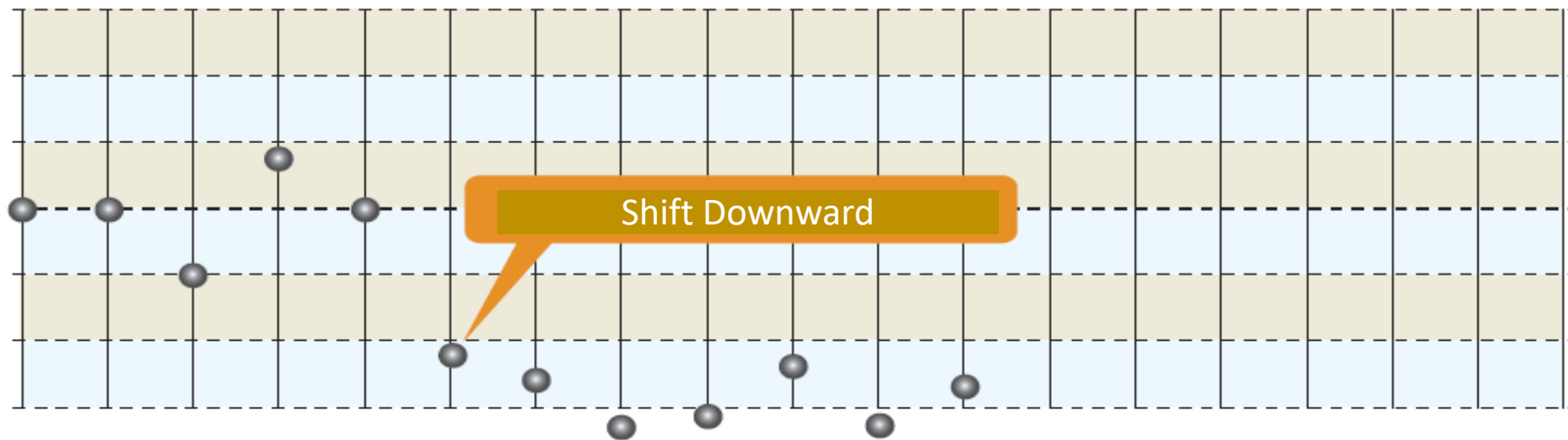
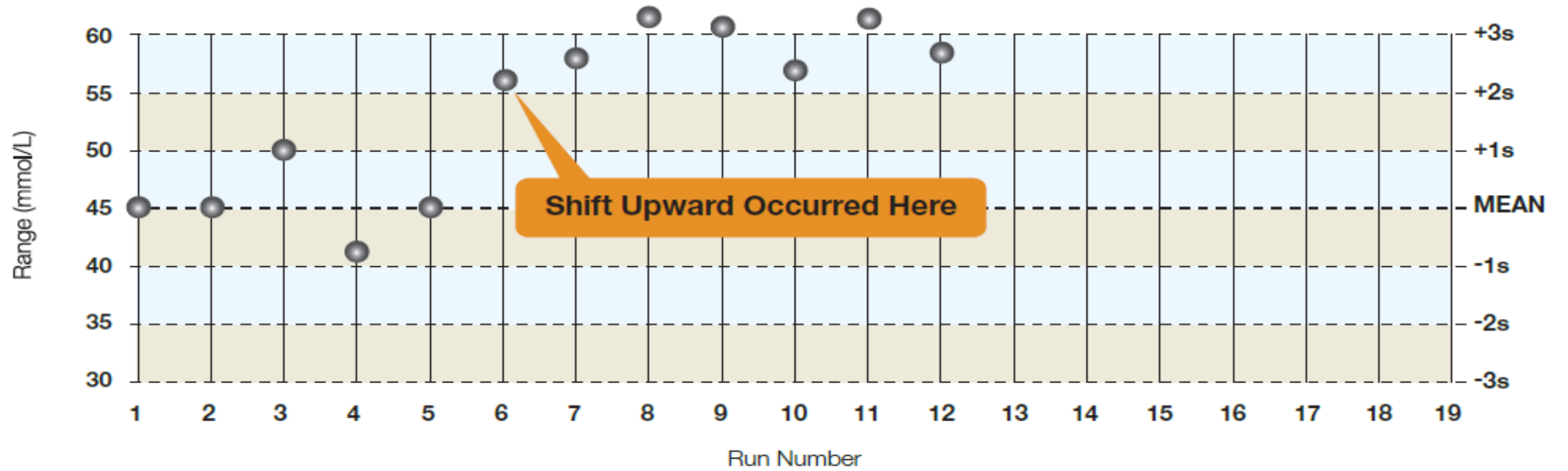
ប្រសិនបើលោកអ្នកឃើញ **Levey Jenning Chart** របស់មន្ទីរពិសោធន៍លោកអ្នកដូចខាងក្រោមនេះ

បង្ហាញថាមានអ្វីមួយខុសប្រក្រតីហើយ!! លោកអ្នកក៏ត្រូវរកមូលហេតុនិងដោះស្រាយវាផងដែរ!!!



# Systematic errors\_Causes of Trending

- Deterioration of the instrument light source
- Gradual accumulation of debris in sample/reagent tubing
- Gradual accumulation of debris on electrode surfaces
- 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





# Systematic errors\_Causes of Shifts

- Sudden failure or change in the light source
- Change in reagent formulation
- Change of 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

# Types of Errors

<b>Rule Violation</b>	<b>Systematic Error</b>	<b>Random Error</b>
1:2s	X	X
1:3s	X	X
2:2s	X	
R:4s		X
4:1s	X	
10x	X	

# Random errors (RE) caused by

- Incomplete mixing (ល្បាយមិនសព្វល្អ)
- Bubbles or particles in the reagents (មានពពុះឬបំណែកតូចៗក្នុងប្រតិករ)
- Probe and syringe variations (ទុរយោបាយមូលដ្ឋានមានការប្រែប្រួល)
- Optical problems (បញ្ហាអុបទិច)
- Sample line problems (បញ្ហាខ្សែសង្វាក់នៃសំណាក)
- Aliquoting and pipetting
- Timing variations in critical steps (បំរែបំរួលពេលវេលានៅដំណាក់កាលសំខាន់)
- Readout variation from cell to cell (បំរែបំរួលការអានពីCellមួយទៅCellមួយទៀត)
- Fluctuate electricity supplies (ចរន្តអគ្គីសនីឡើងចុះ)

# Systematic errors (SE) caused by

- Inaccurate standards/calibrators (ស្តង់ដារឬcalibrators មិនត្រឹមត្រូវ)
- Poor calibration (Calibration អន់)
- Inadequate blanks (Blank មិនគ្រប់គ្រាន់)
- Improperly prepared reagents (ប្រតិករណយមិនបានត្រឹមត្រូវ)
- Degradation of reagents (ប្រតិករចុះខ្សោយឬវិវត្តិ)
- Drift of detectors (detectors មានលំអៀង ឬងាកខុស)
- Degradation of instrument components (សមាសភាគរបស់ឧបករណ៍វិភាគវិវត្តិ)
- Improper setting of temperature baths (ការកំណត់សីតុណ្ហភាពកម្ដៅខុស)
- Pipette error (wrong volume all the time) (ប្រើពីប៉ែតដែលមានកំហុស)
- QC preparation improperly (លាយប្រតិករក្នុងត្រួលមិនត្រឹមត្រូវ)

# QC Violation Rules Troubleshooting

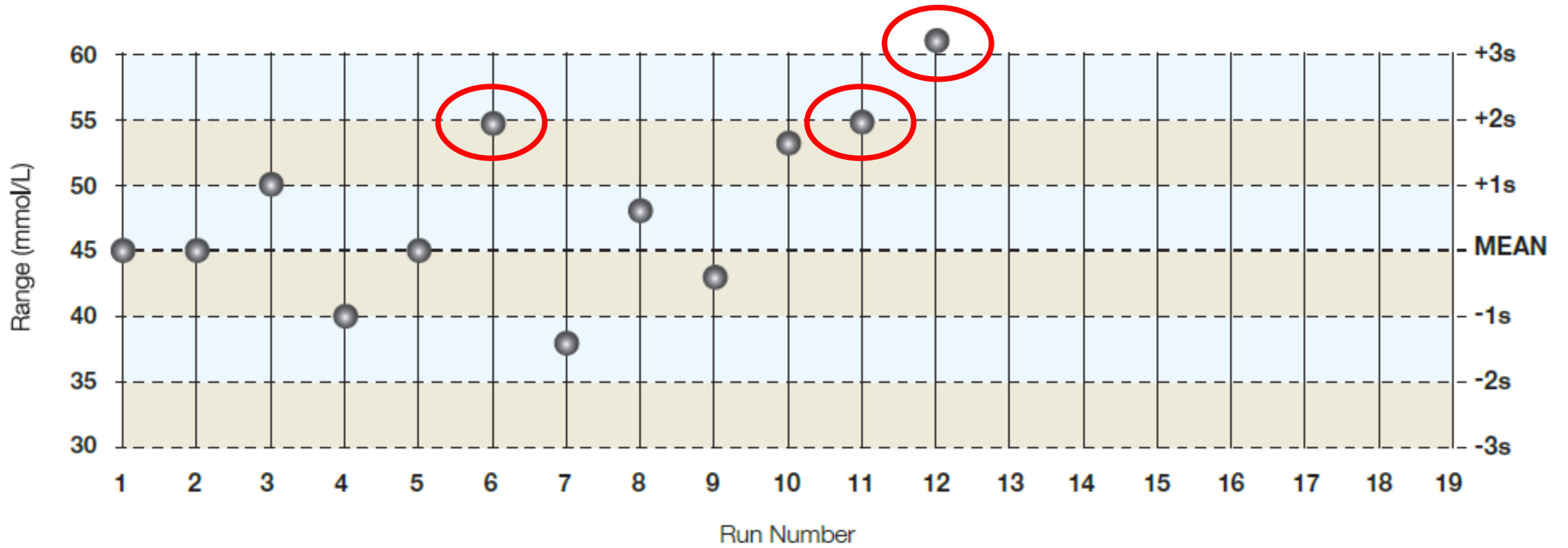
1. What Rule has been violated? (ខុស Rule មួយណា?)
2. Is it a Systematic or Random Error? (ខុសជាប្រព័ន្ធឬចៃដន្យ?)
3. What is the Potential Cause of the error? (មូលហេតុនៃកំហុស?)
4. If more than one analyte/test is out-of-control, do they have any Common Factors during testing? (ខុសតេស្តតែមួយឬច្រើនតេស្ត? បើខុសច្រើនតេស្ត តើមានកត្តាទូទៅណាមួយកើតឡើងកំឡុងពេលវិភាគ?)
5. Did we Change something recently? (ថ្មីៗនេះមានបានផ្លាស់ប្តូរអ្វីមួយឬទេ?)
6. Once we resolved the problem, did we Document the problem and its resolution? (ពេលដោះស្រាយបញ្ហារួច បានកត់ត្រាបញ្ហានិងដំណោះស្រាយទុកឬទេ?)
7. Fill out the corrective action/NC/OFI form (បានបំពេញចូលក្នុងទម្រង់កែតម្រូវឬទេ?)
8. Take preventive action with responsible person. (បានធ្វើសកម្មភាពបង្ការឬទេ?)

តោះយើងសាកល្បងរកមើល **violation rules** ខាងក្រោមទាំងអស់គ្នា!!!

Let's try the exercises below!!!

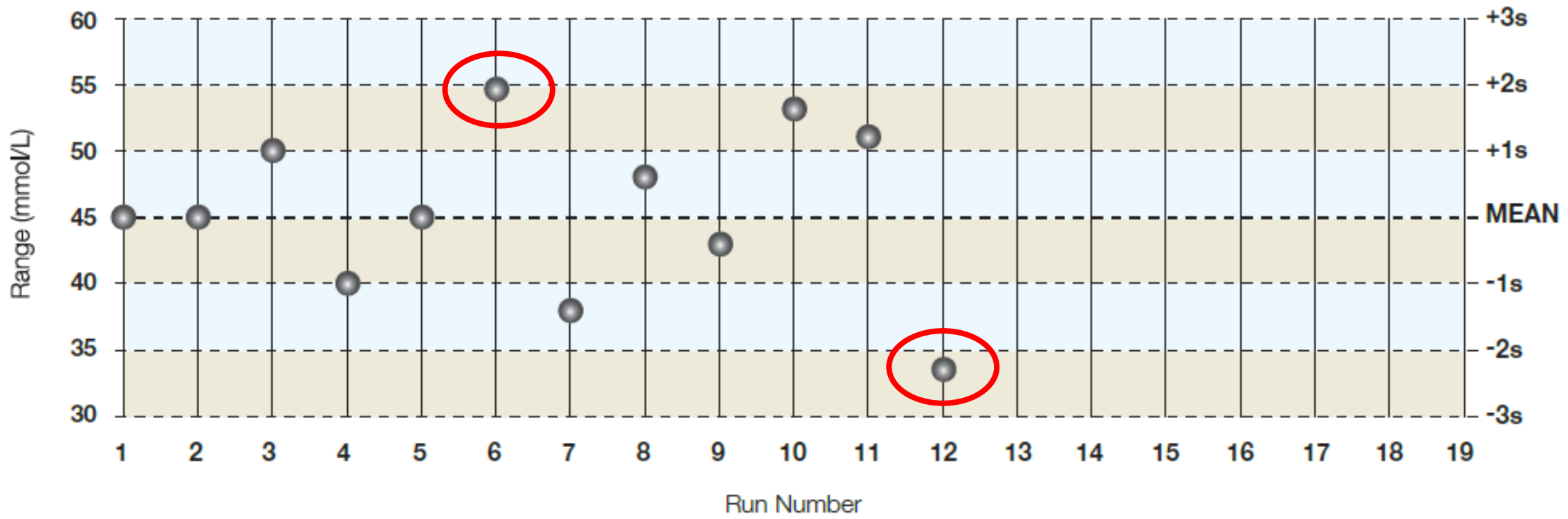
Rule Violated:

Error:



Rule Violated:

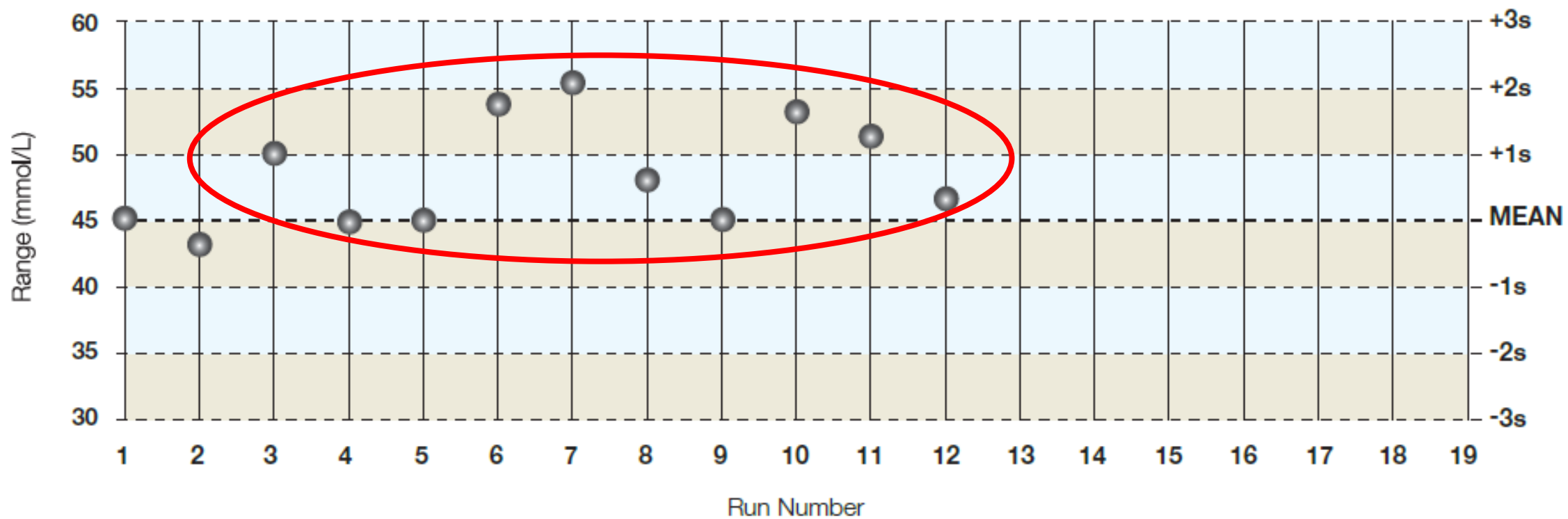
Error:





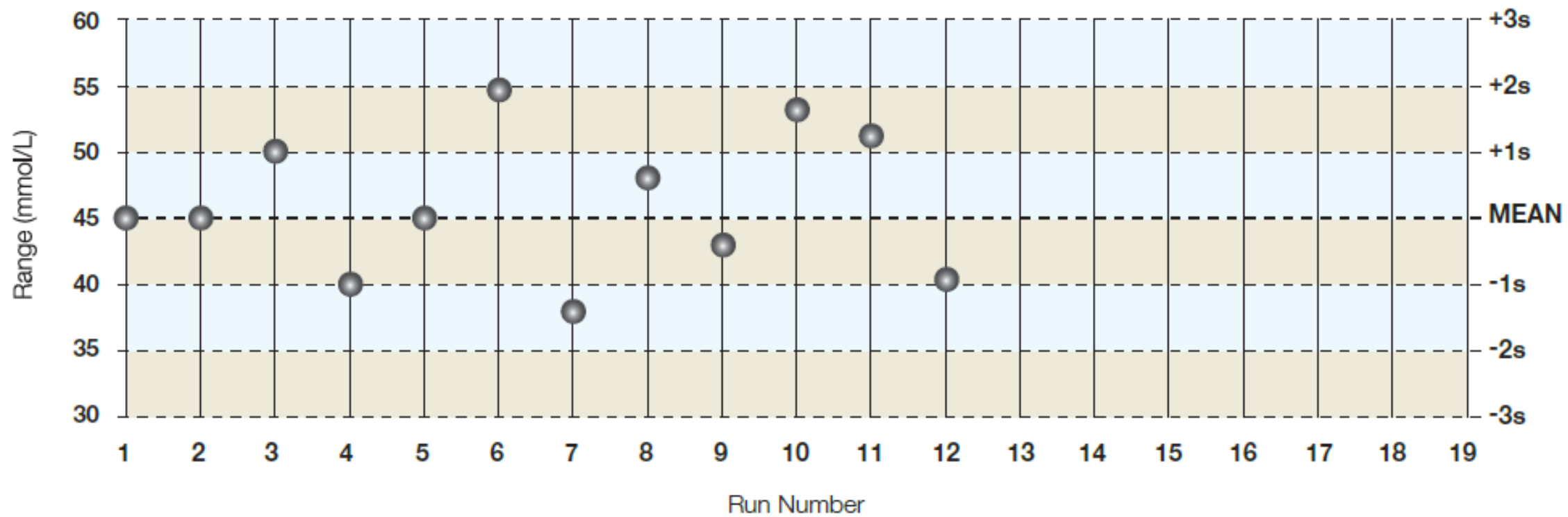
Rule Violated:

Error:



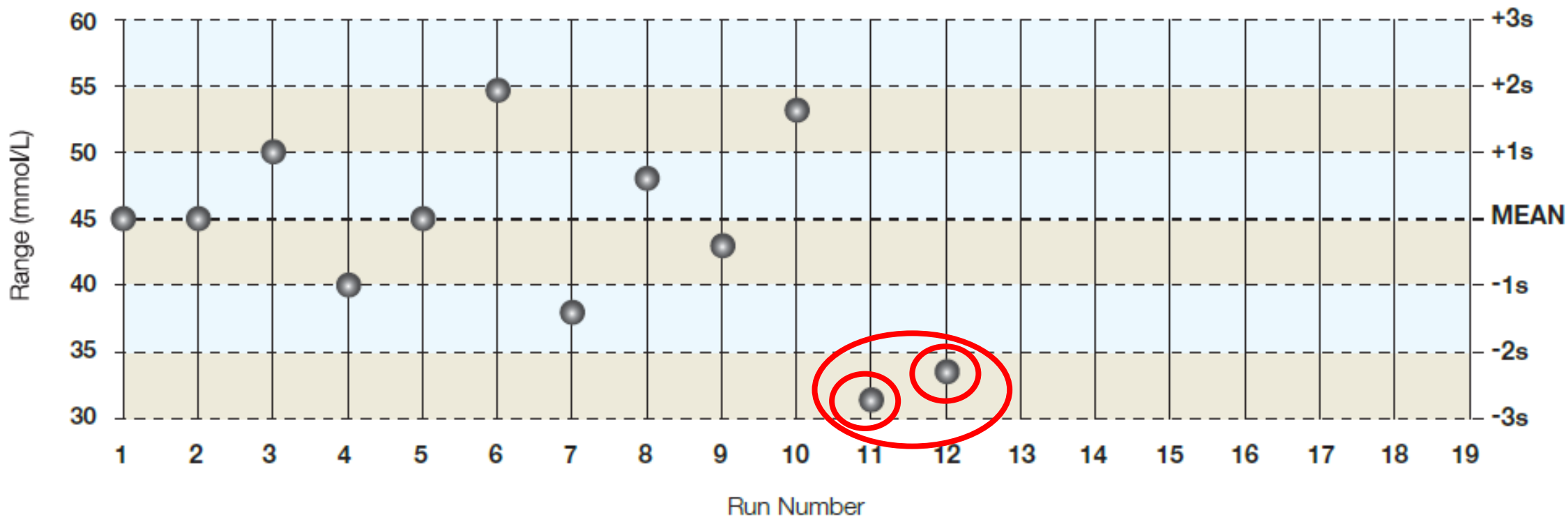
Rule Violated:

Error:



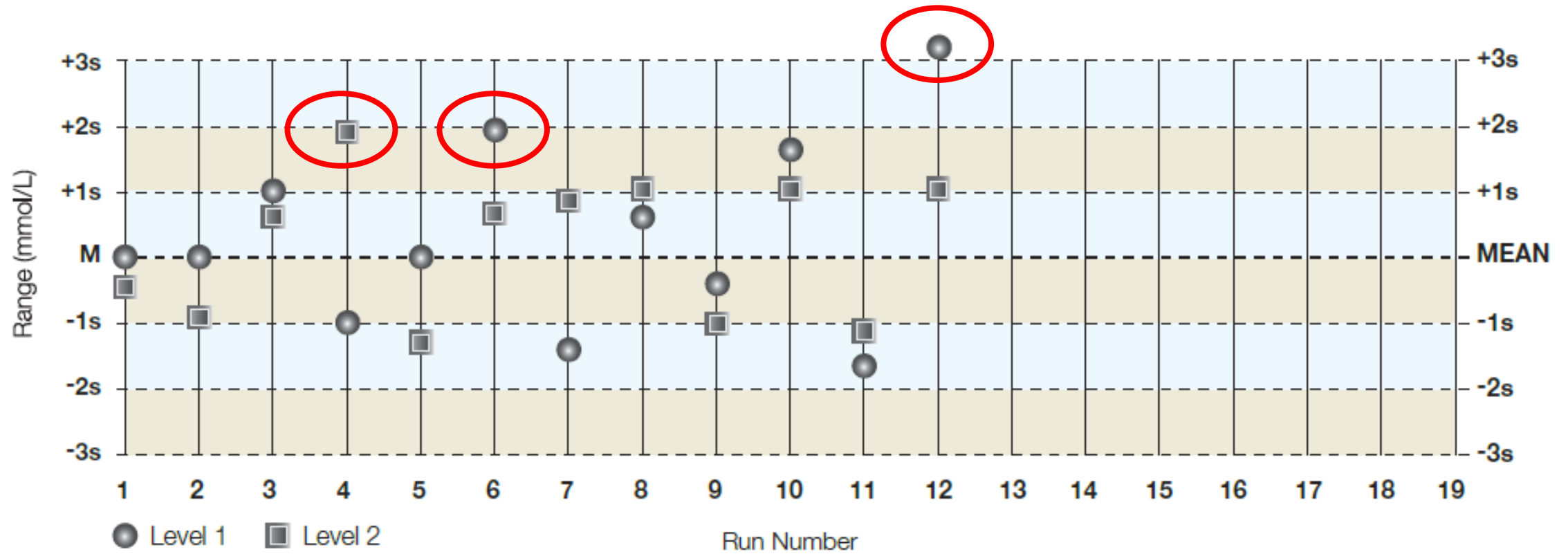
Rule Violated:

Error:



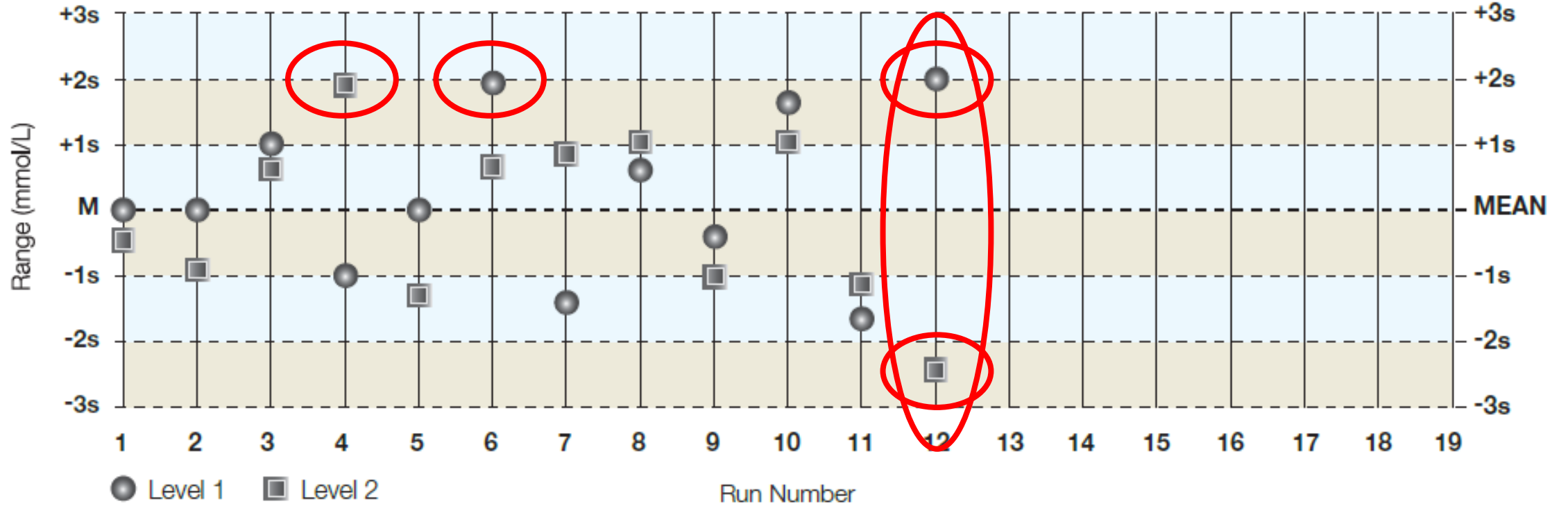
Rule Violated:

Error:



Rule Violated:

Error:



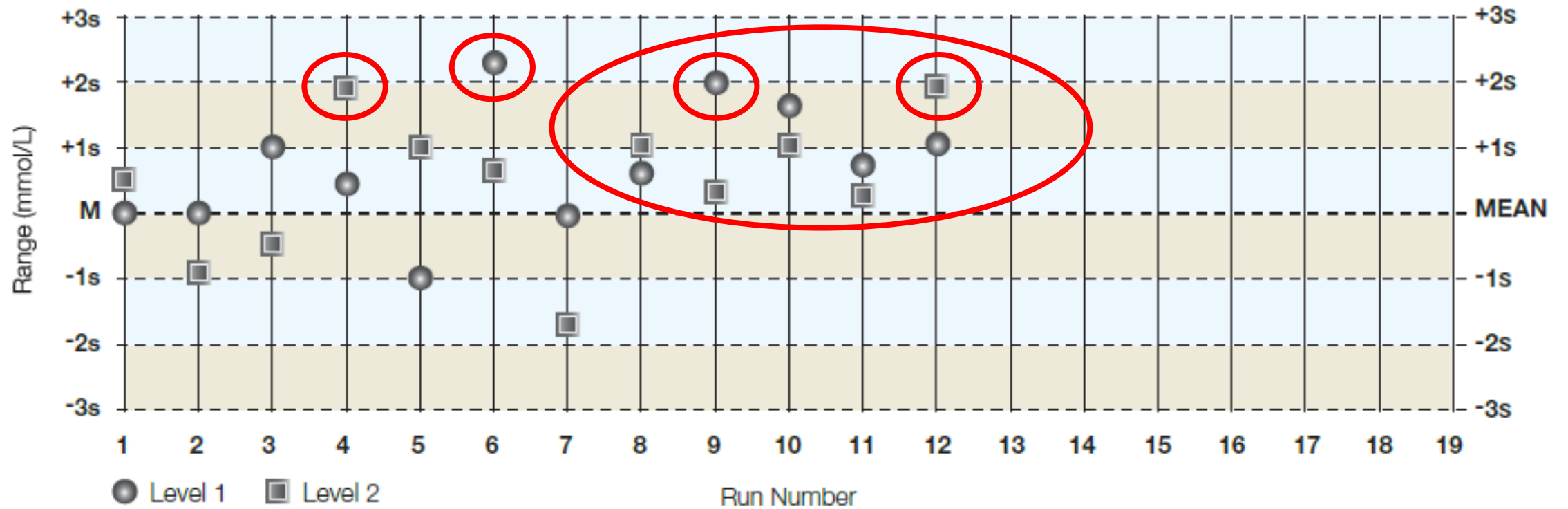
Rule Violated:

Error:



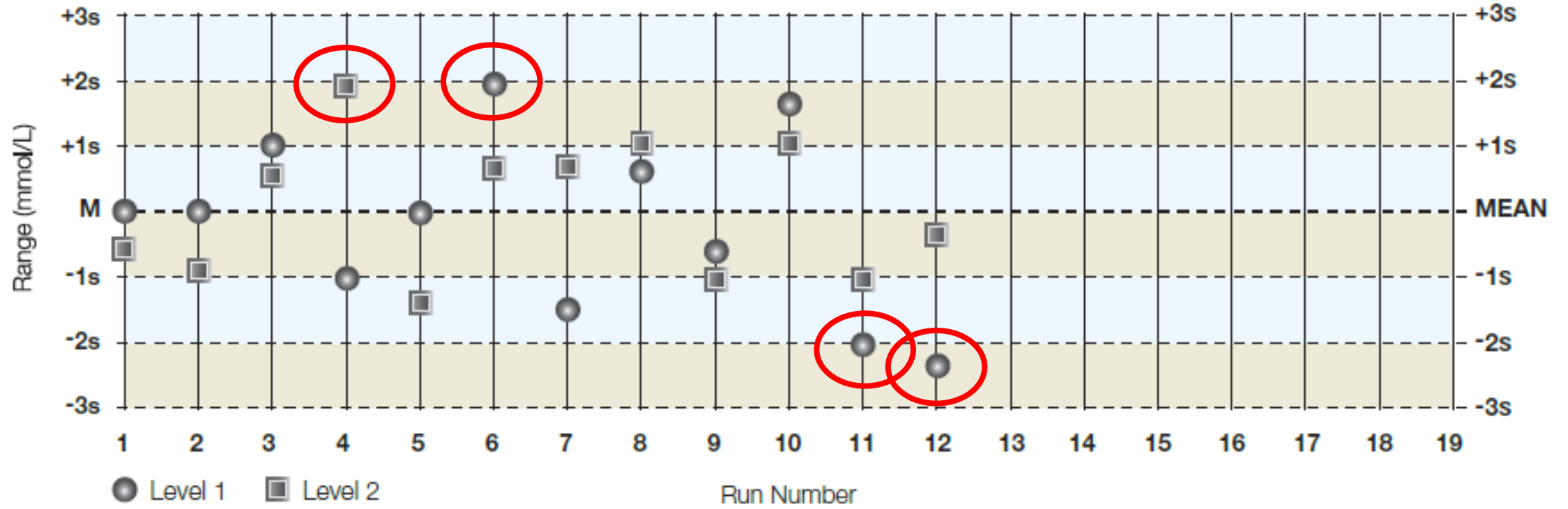
Rule Violated:

Error:



Rule Violated:

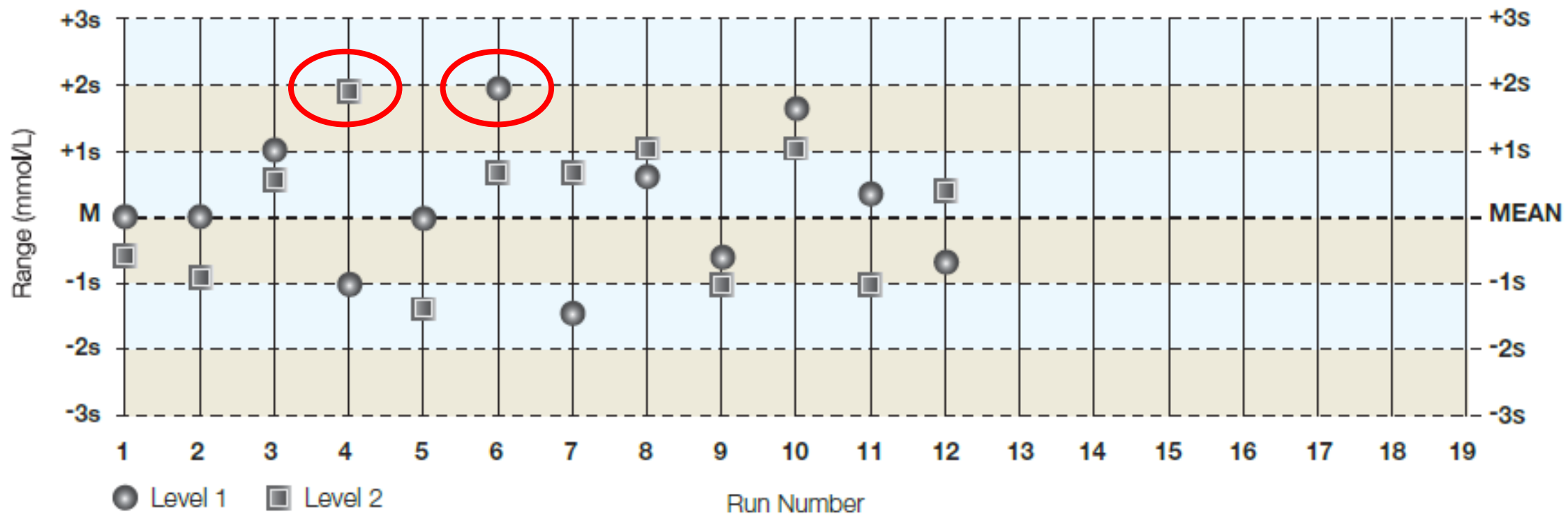
Error:





Rule Violated:

Error:



Rule Violated:

Error:

