INTERNAL QUALITY ASSURANCE IN LABORATORY

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INTRODUCTION

- A quality assurance (QA) programme is the sum of all activities and procedures undertaken by medical laboratories to improve the quality and clinical usefulness of laboratory test results.

- Quality assurance includes training of personnel, purchase and maintenance of equipment and reagents, the analytical process itself, and reporting and interpretation of results.

- The ultimate goal of any quality system is to obtain test results that are reliable, relevant and reproducible.

Quality assurance(QA) Defined by WHO

" The total process whereby the quality of laboratory reports can be guaranteed."

It has been summarized as the:

right result,
at the right time,
on the right specimen,
from the right patient,
with the result interpretation based on correct reference data,
and at the right price.

Quality control(QC)

Cover the part of QA primarily concerning with the control of errors in the performance of tests and verification of tests results.

IMPORTANCE

- Quality laboratory services lead to the:

  (a) Establishment of an accurate diagnosis in a patient;

  (b) Institution of appropriate treatment;

  (c) Assessment of prognosis;

  (d) Confirmation of successful treatment;

  (e) Detection of the source of infection (environmental analysis);

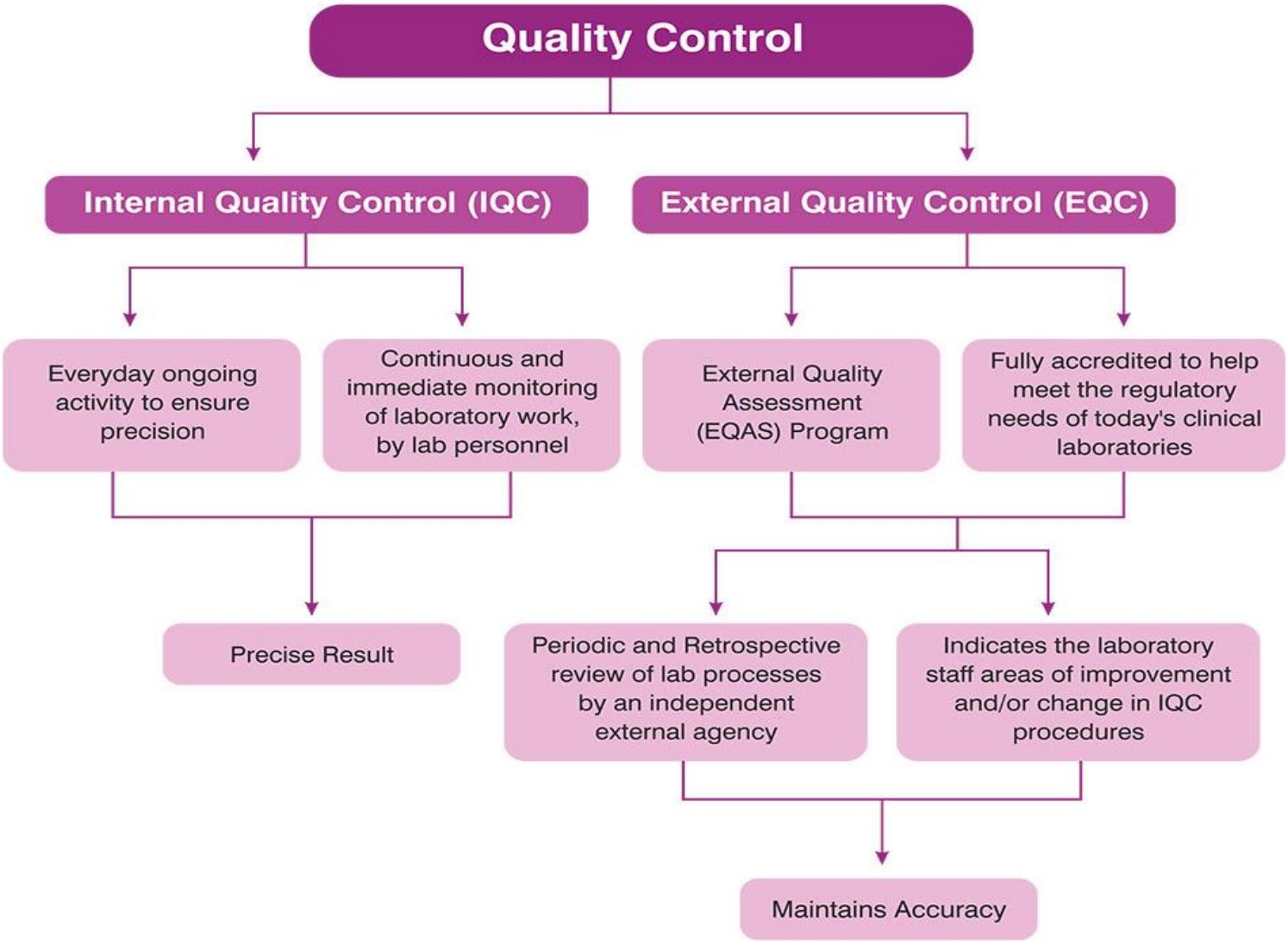
  (f) Early diagnosis of an outbreak or epidemic;

  (g) Selection of appropriate chemoprophylaxis for individual patient and community;

  (h) Tracing of the spread of infection to control it, and

  (i) Identification of the role of environmental factors

QUALITY CONTROL PROCESS



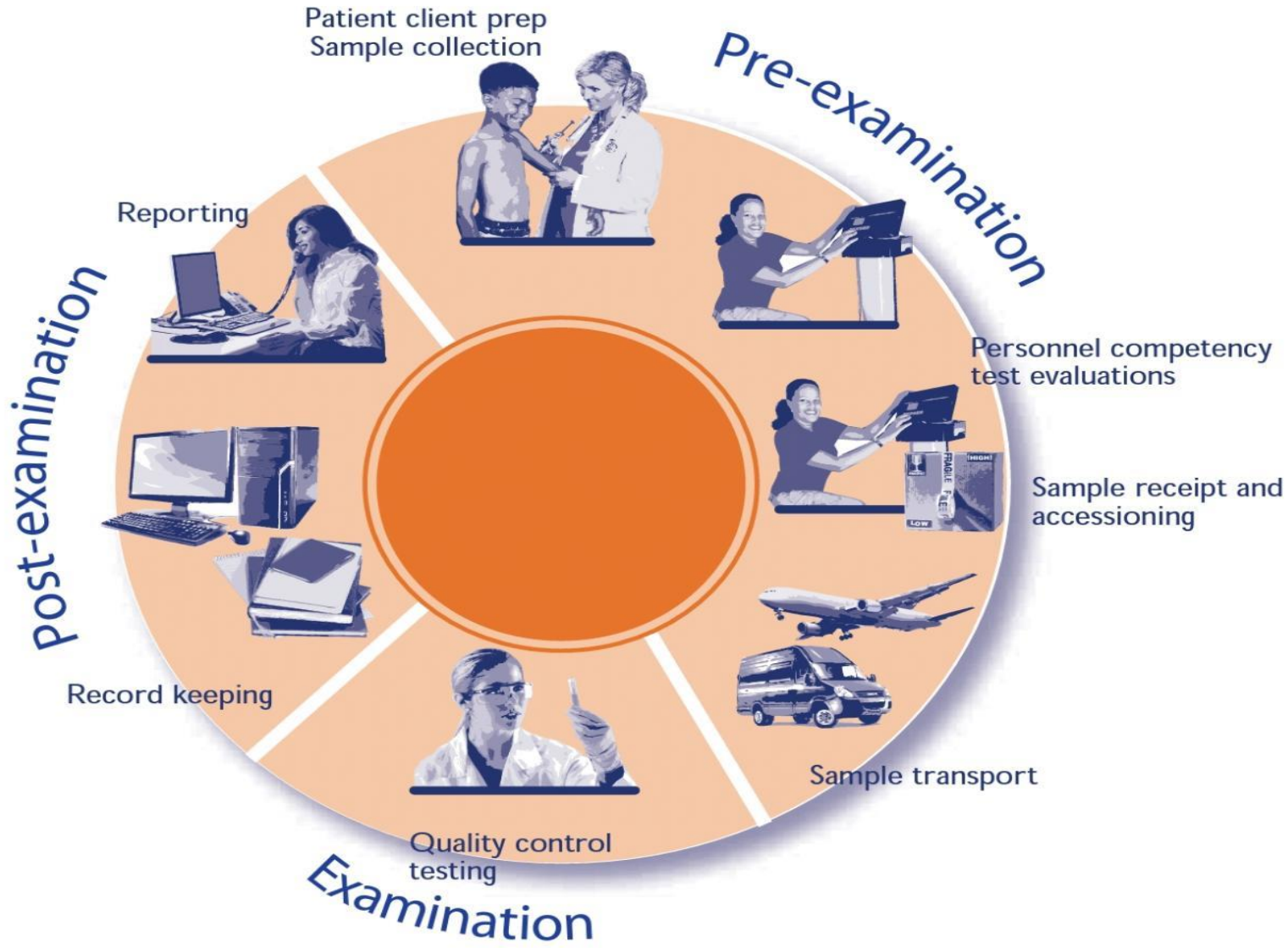
QUALITY ASSURANCE PROGRAM

- The QA program consists of the following components
  - **Internal Quality Control Or Built In controls**. Designed to verify the test system is working as expected that sufficient system specimen was added, & for utilized test devices, whether is migrated through test strip properly.
  - **External Quality Control Assessment scheme(EQAS).** Aims to analyse the accuracy of the entire testing process from receipt of sample and testing of sample to reporting of results *(also known as proficiency testing)*.

External Quality Control Assessment scheme(EQAS).

- EQAS is a check on the performance of laboratories. This mechanism involves a periodic and retrospective evaluation of the performance of a laboratory, which is undertaken by an independent and external laboratory by incorporating proficiency panels as the means of evaluation.
- Objective :to establish inter laboratory comparison, make participating laboratories conscious of their shortcomings, and suggest measures for improvement so as to ensure reliability of future testing.
- A good EQA is a tool for assessing the IQC, but is never a substitute for IQC

IQA STEPS


Patient client prep
Sample collection
Pre-examination
Personnel competency test evaluations
Sample receipt and accessioning
Sample transport
Quality control testing
Examination
Record keeping
post-examination
Reporting

IQA PROCEDURES

- A stable control material which mimics patient's sample is analyzed (day to day)
- Individual measurements are plotted on a control chart (Levey Jennings charts)
- Evaluation whether measurement is "in control" (Westgard multi-rules)

CONTROL MATERIALS

- **Controls are substances** that contains an **established amount** of the substance being **tested**.
- Controls are tested at the **same time** and in the **same way** as patient samples.
- The purpose of the control is to **validate the reliability** of the system and evaluate **operator's performance** (Machine) & environmental conditions that might impact results.
- Control materials may be **purchased, obtained** from a central or reference lab.
- QC materials are **serum based** so standard precautions should be followed when handling.
- When preparing and storing QC, always adhere **manufacturer's instructions** for reconstitution & storage.

ESTABLISHING VALUE RANGE FOR CONTROL

- Once appropriate control materials are purchased or prepared, next step is **determine the range & acceptable values.**
- This will help the lab to determine if the test run is "**In Control" or "Out of control".**
- Once data collected, the lab have to calculate the **mean & SD of results.**
- **MEAN** – Arithmetic average of results.
- **SD** – Measurement of variation in a set of results.

GRAPHICAL REPRESENTATION OF CONTROL RANGES

- The distance from the mean is measured in standard deviations. It is named after S. **Levey** and E. R. **Jennings** who in 1950 suggested the use of Shewhart's individuals control **chart** in the clinical laboratory. On the x-axis the date and time, or more usually the number of the control run, are plotted.

- Levey – Jenning Chart can be drawn showing mean value as well as + or – 1, 2, 3 SD.

In General

- If the value is within + or – 2 SD, the run can be accepted as "**IN CONTROL**".

- Errors that occurs may be either **Random** or **Systemic**.

- **Accuracy:**
- A test method is said to be accurate when it measures what it is supposed to measure. This means it is able to measure the true amount or concentration of a substance in a sample.
- Picture a bull's-eye target with a dart correctly hitting the centre ring and you see what an accurate test produces: the method is capable of hitting the intended target.
- **Precision**
- A test method is said to be precise when repeated determinations (analyses) on the same sample give similar results. When a test method is precise, the amount of random variation is small. The test method can be trusted because results are reliably reproduced time after time.

- **Root Cause Analysis**

• To determine: – What happened – Why it happened – What to do to prevent it from happening again

• Must be impartial, methodical, information driven

• Include all personnel involved in the error for the analysis rather than speculate

• Clearly state the purpose is not to assign blame

RANDOM & SYSTEMIC ERRORS

RANDOM

- Variations in QC results that has no pattern.
- Reflects failure in some part of testing system.
- Not likely to reoccur.

SYSTEMIC

- Not acceptable
- Indicates failure in system.
- Should be corrected.
- Shifts & Trend.

SHIFTS & TRENDS

SHIFTS

- When the control is on the same side of the mean for five consecutive runs.

SYSTEMIC

- When the control is moving in one direction and appears to be heading towards out of control value.

WESTGUARD RULES

Figure 6: 1_{2s} Rule

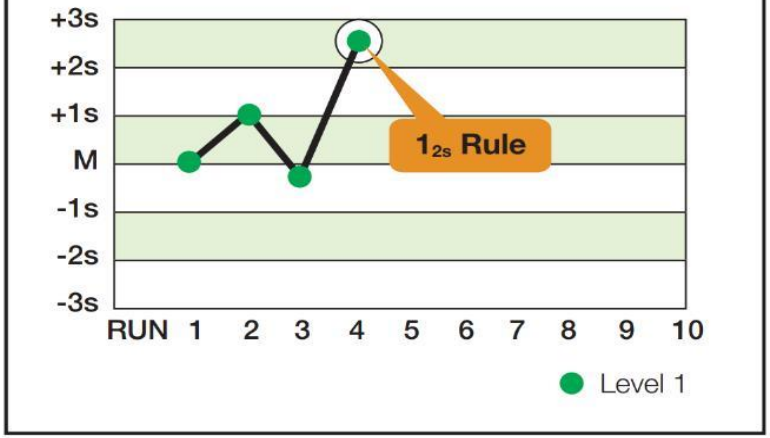
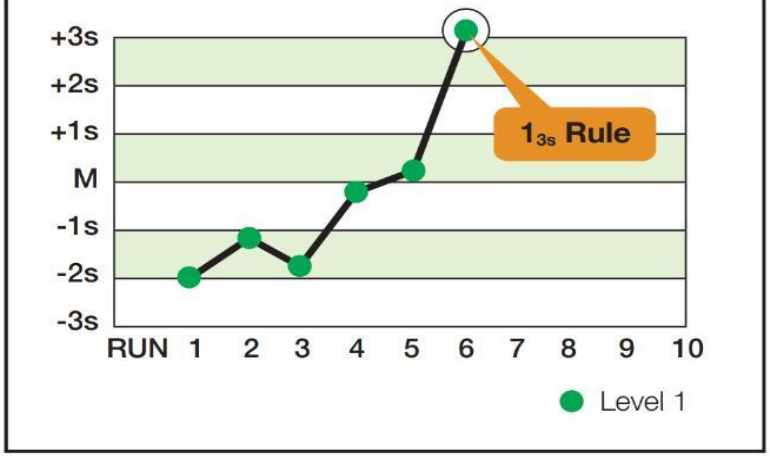
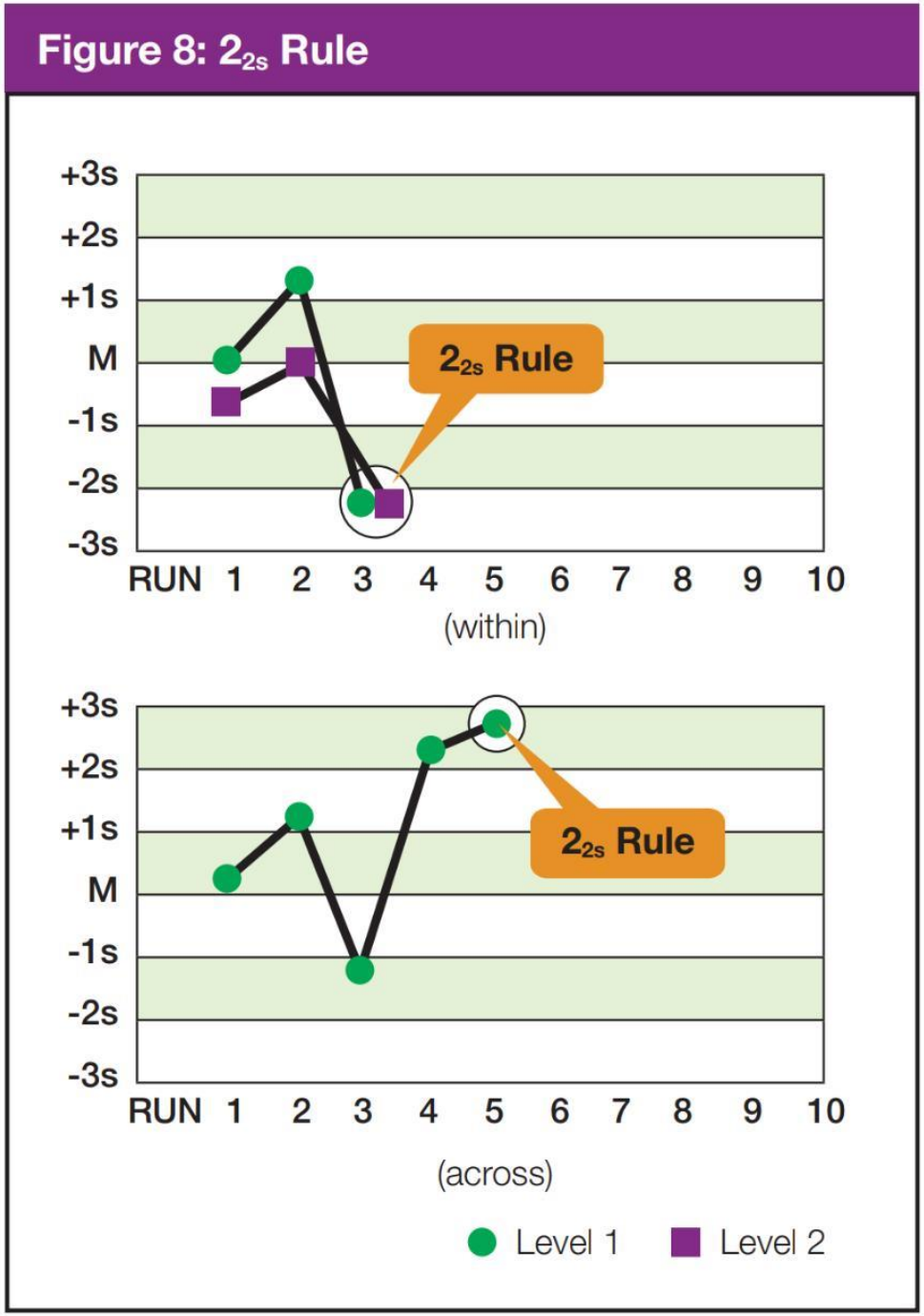


Figure 7: 1_{3s} Rule

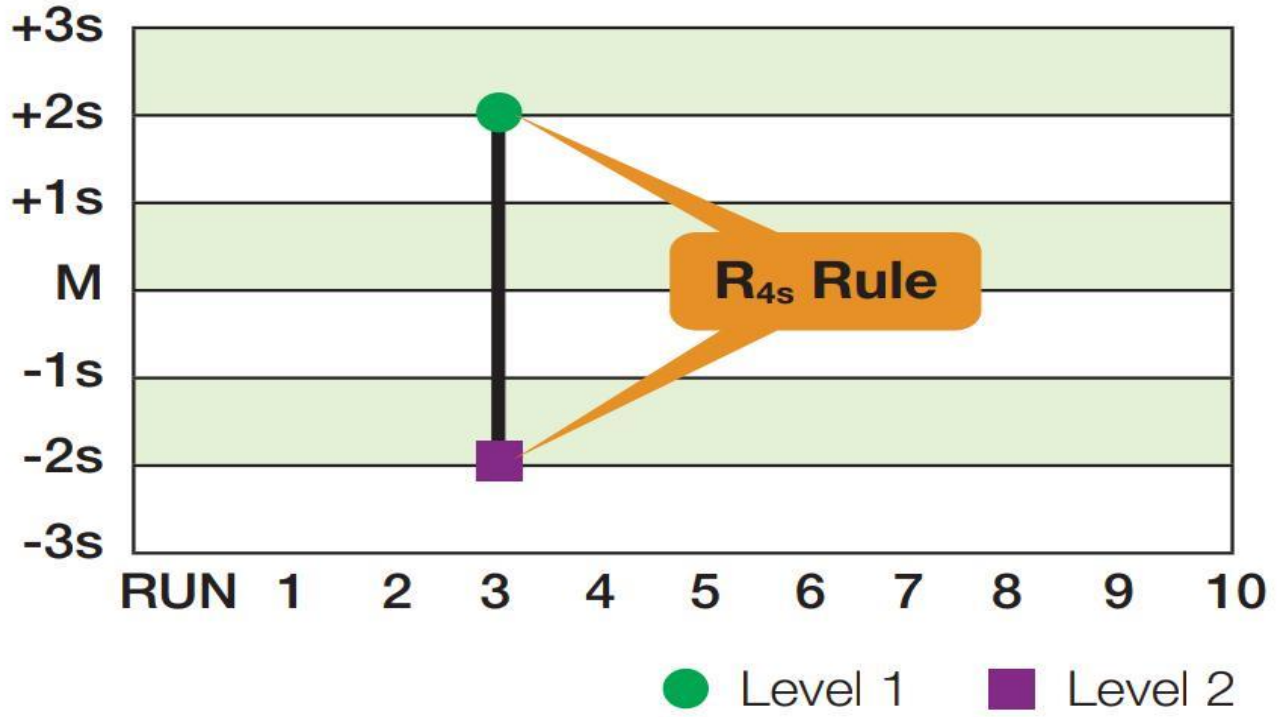


WESTGUARD RULE



WESTGUARD RULES

Figure 9: R_{4s} Rule



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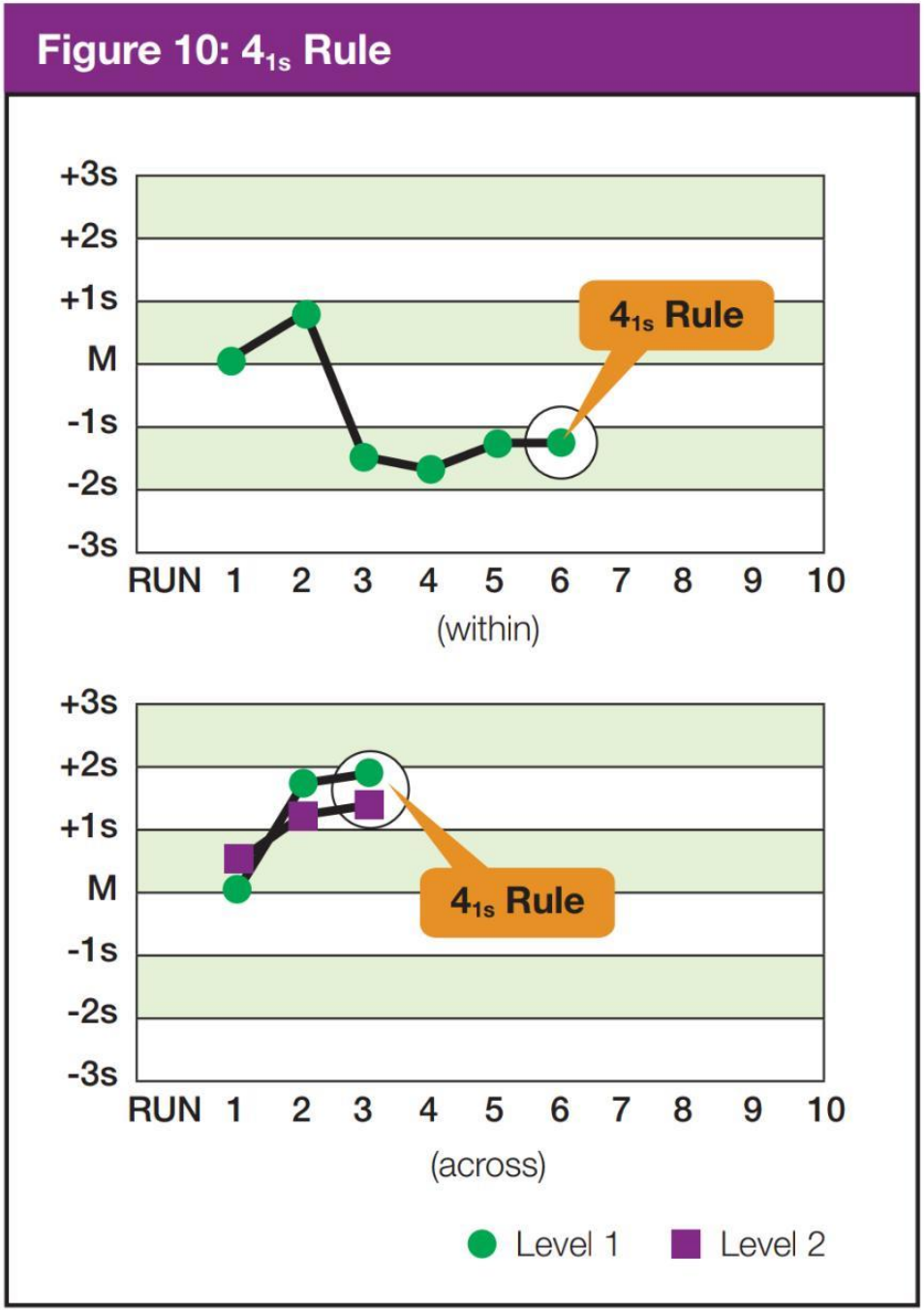

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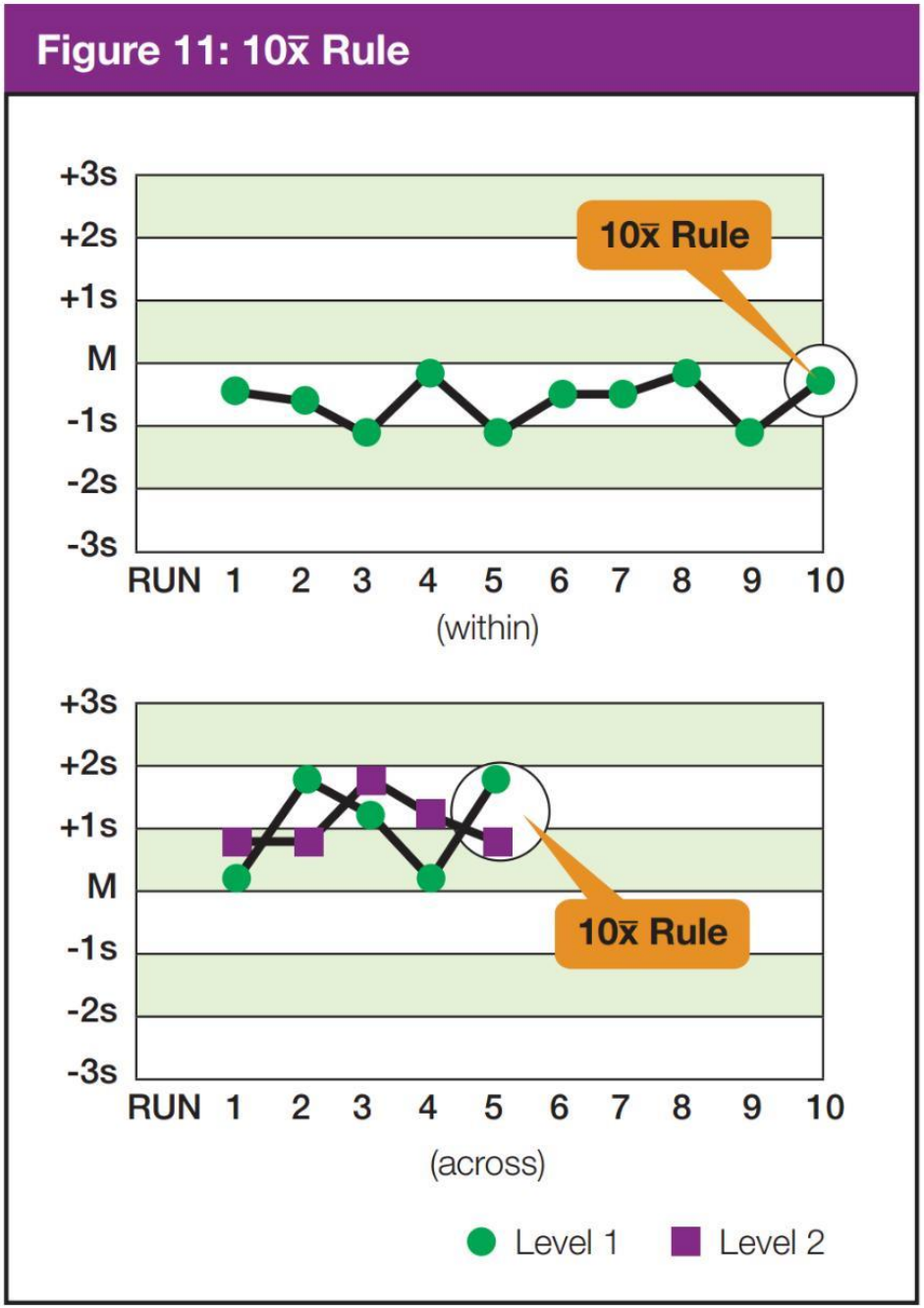

THANK YOU