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Evaluating a QC Strategy's Risk of Reporting Incorrect Patient Results

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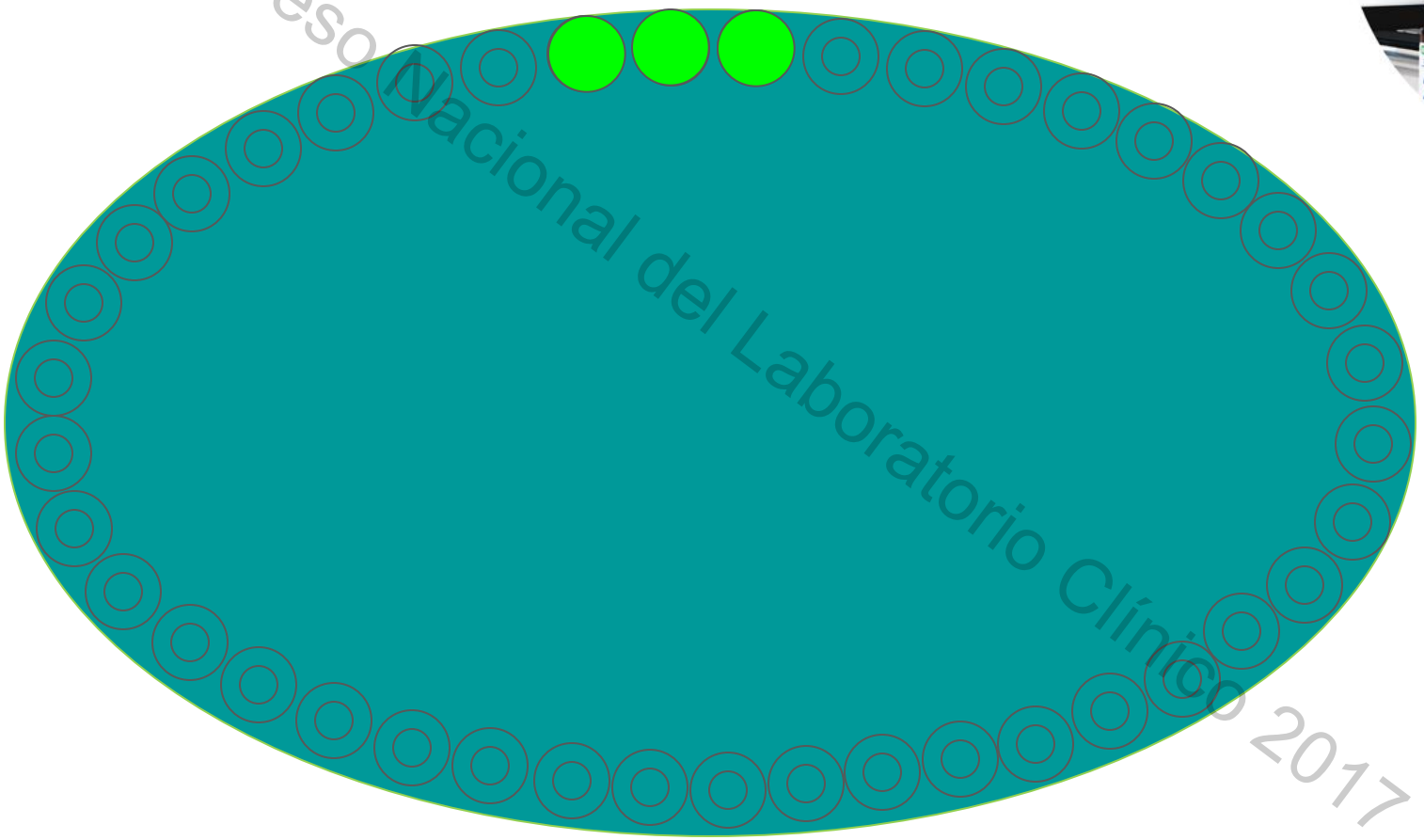
Traditional Laboratory QC

- Traditional QC strategies were designed in an era when most laboratory testing was performed in batches
- Both patient samples and QC samples were included in each batch
- The QC sample results were used to decide whether the patient sample results in the batch were acceptable
- There is a direct relationship between the quality of the QC sample and the patient sample results in batch testing.

QC procedures designed to validate a batch process…



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…or invalidate a batch process

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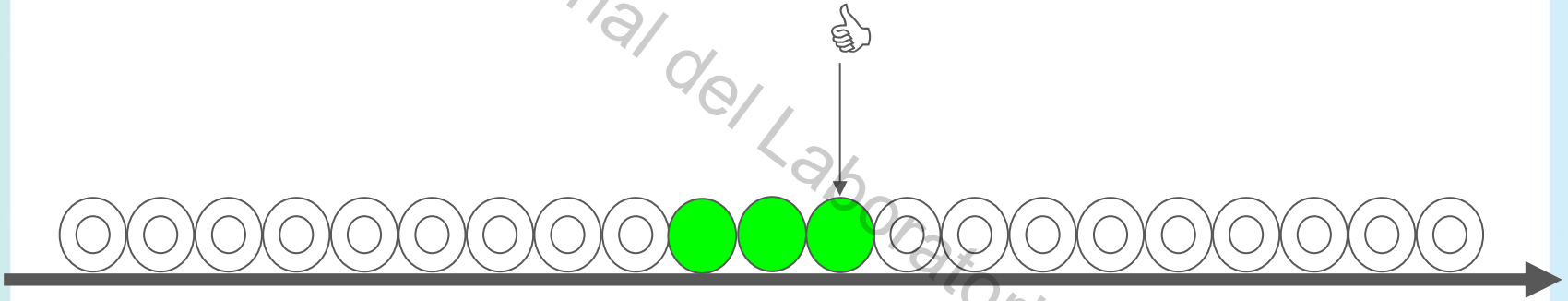
The Era of Laboratory Automation

- The majority of new laboratory instruments perform discrete testing
- With automated discrete analyzers there no longer is an association between QC results and a batch of patient samples
- QC results reflect the status of the test system at a point in time

Discrete Instrumentation



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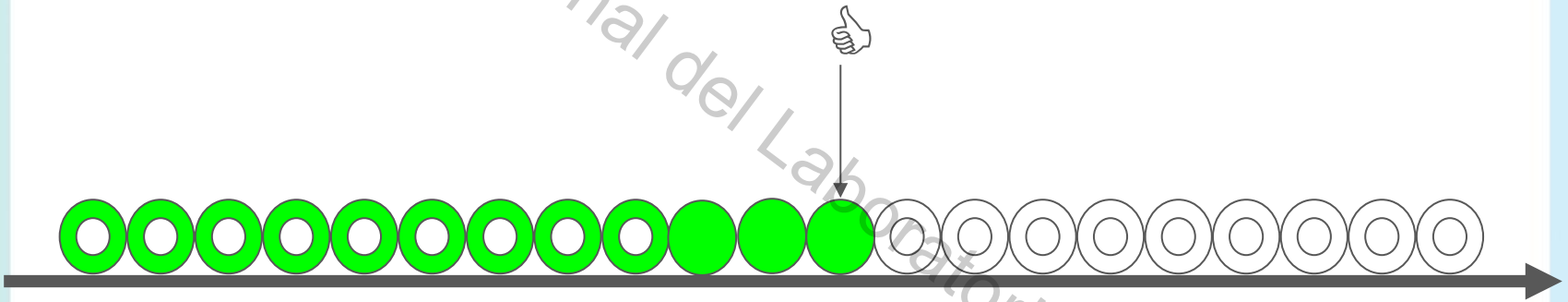
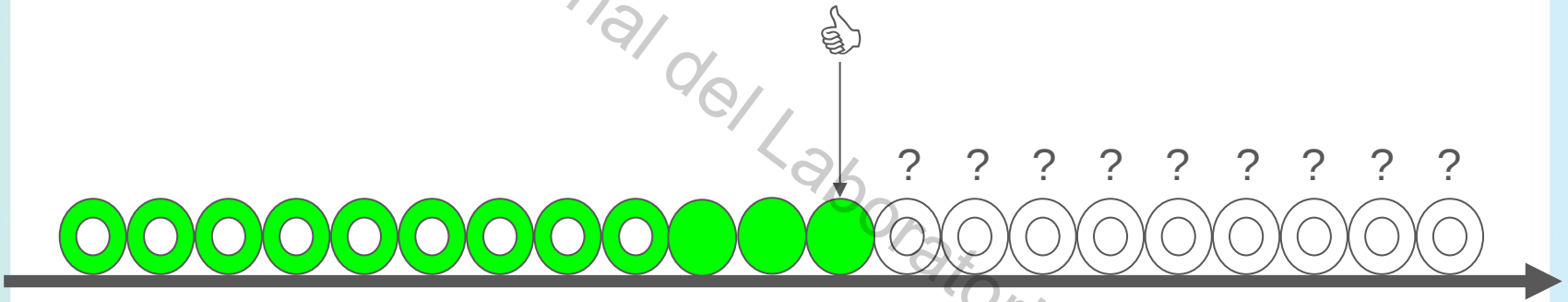
Discrete Instrumentation



A successful QC event can give us confidence that there is no persistent malfunction.

Discrete Instrumentation



A successful QC event cannot guarantee future quality.

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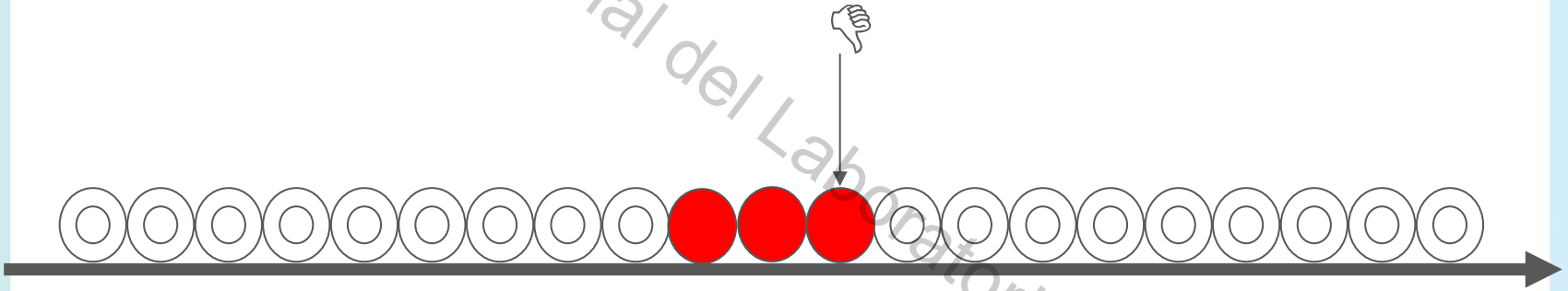
Discrete Instrumentation



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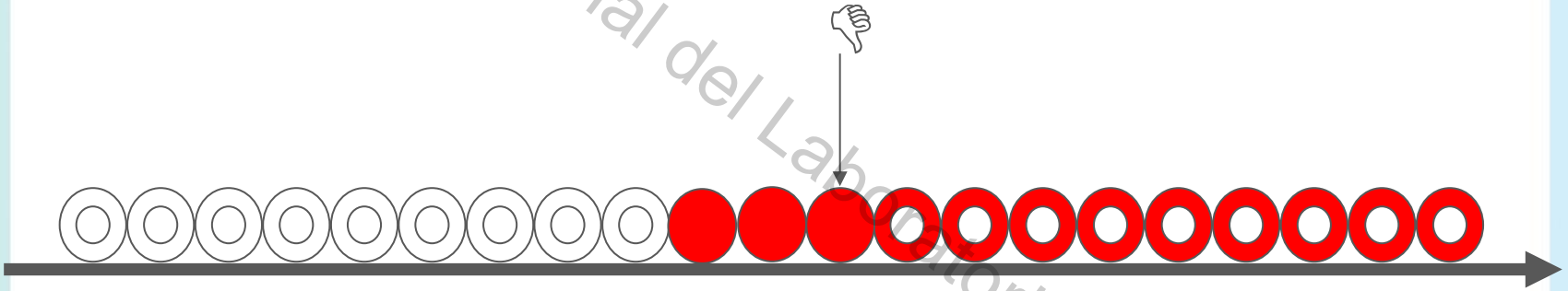
Discrete Instrumentation



If we test after a QC rejection we risk reporting incorrect patient results.

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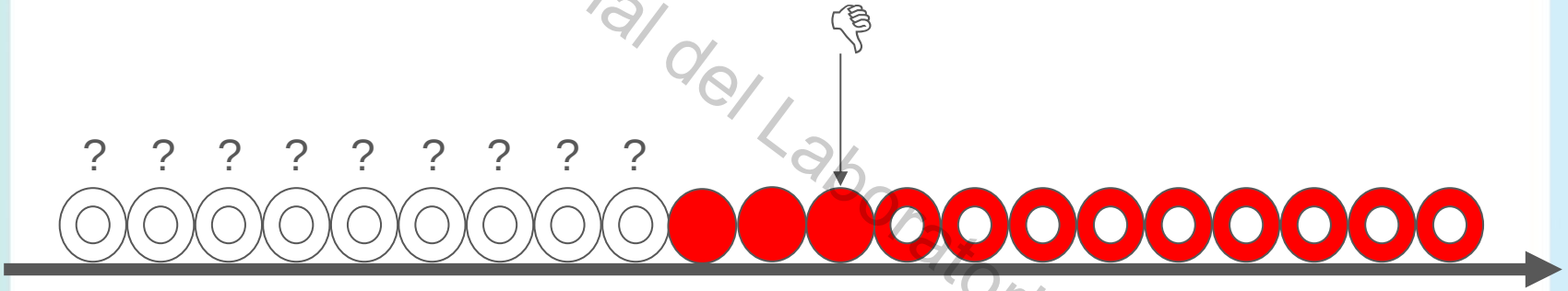
Discrete Instrumentation



A QC rejection does not tell us when the malfunction started.

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A New Approach to QC Design

- Because there is no direct relationship between the quality of the control and the quality of the patient specimen, we need a new approach to quality design.
- We can evaluate the risk of reporting incorrect results for a QC strategy by either direct computation or simulation.
- Simulation is much easier to understand.

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Components of a QC Strategy

A QC strategy consists of:

- A QC rule
- Number of QC specimens used
- Number of patient specimens between QC events

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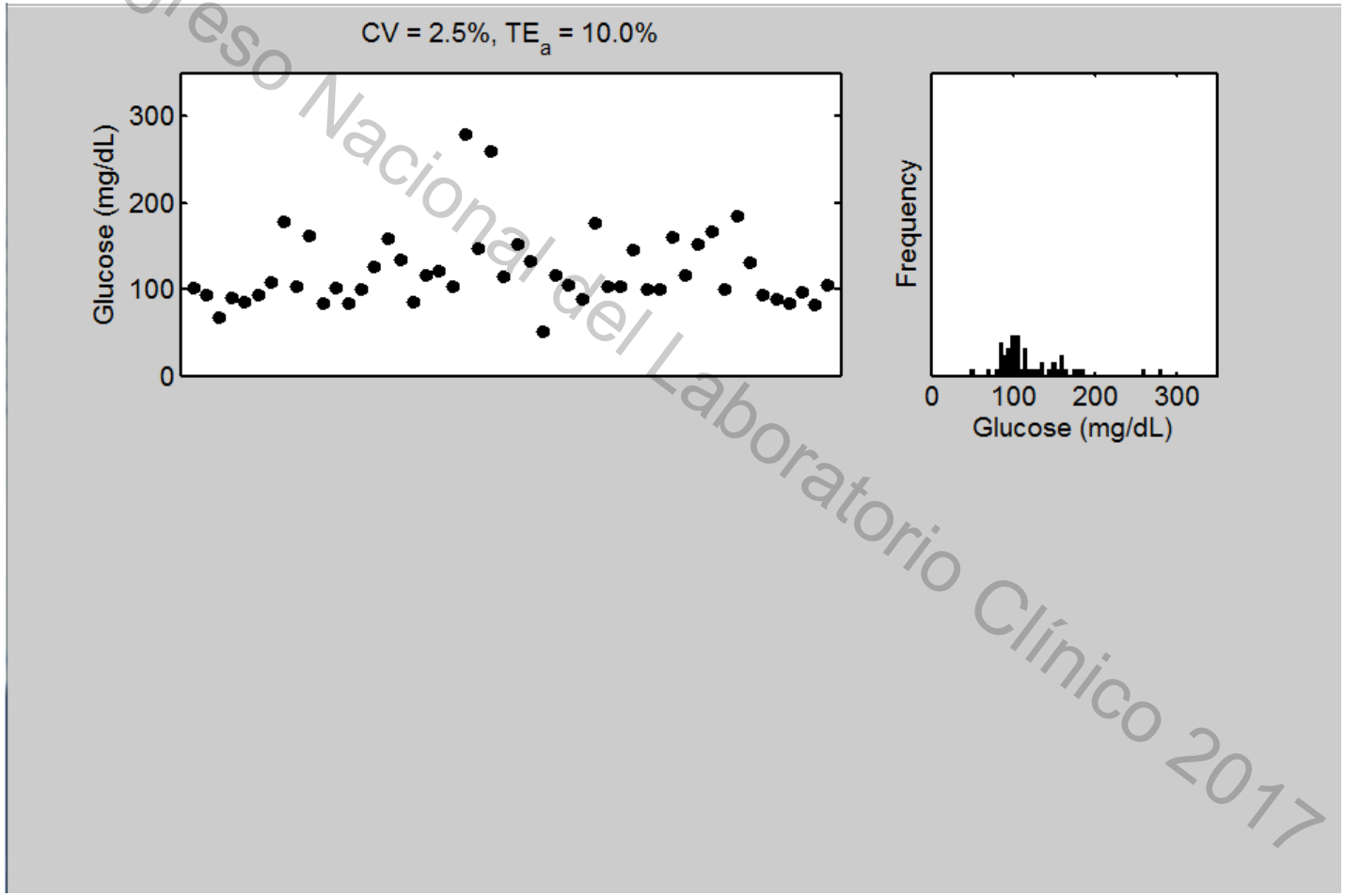
A simulation of the risk of producing incorrect patient results during a malfunction

Displaying Patient Specimen Results



Patient glucose results are displayed along with a histogram of their distribution

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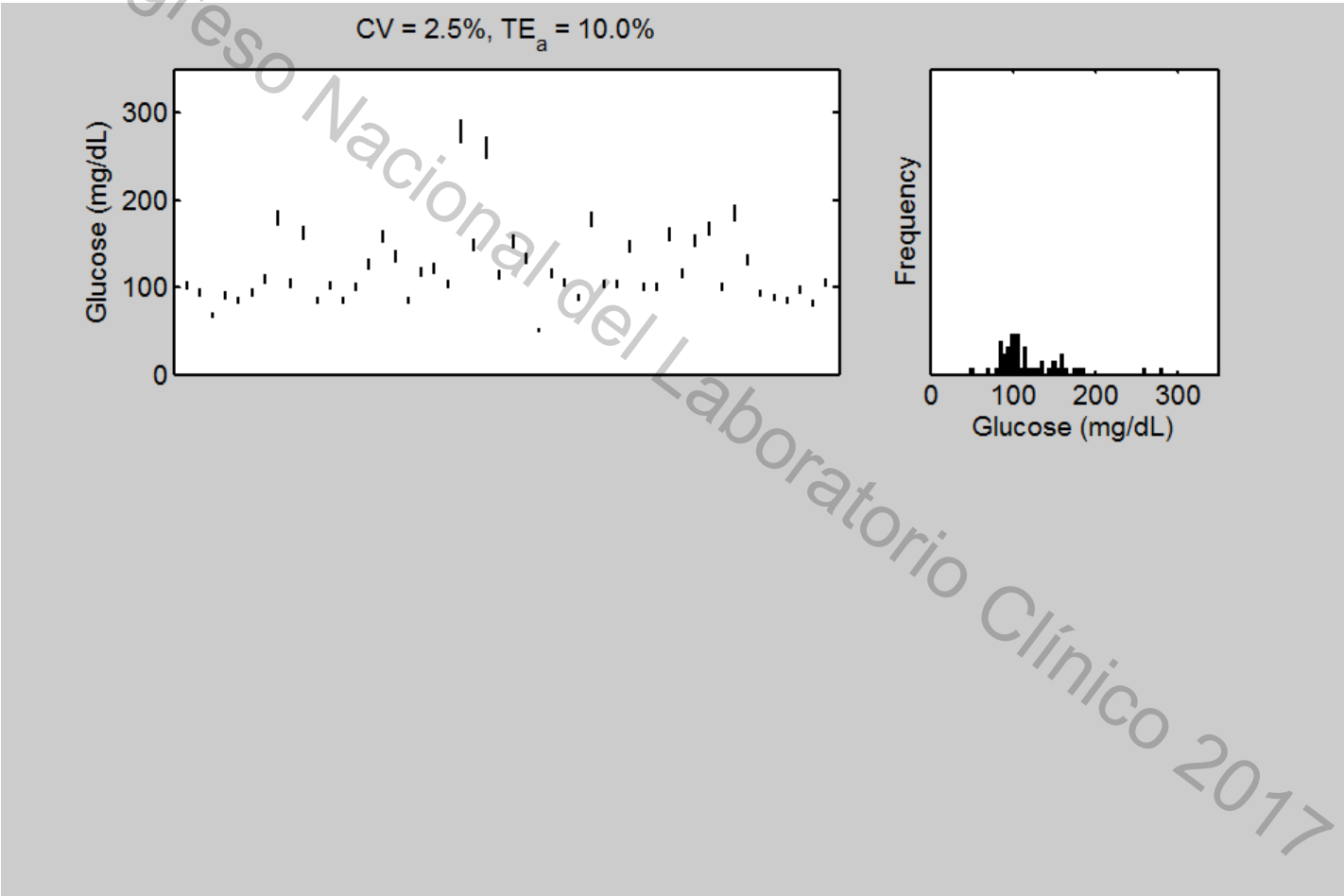
Simulating Measurement Error



Patient glucose results are displayed as error bars as a reminder that all results have measurement error.

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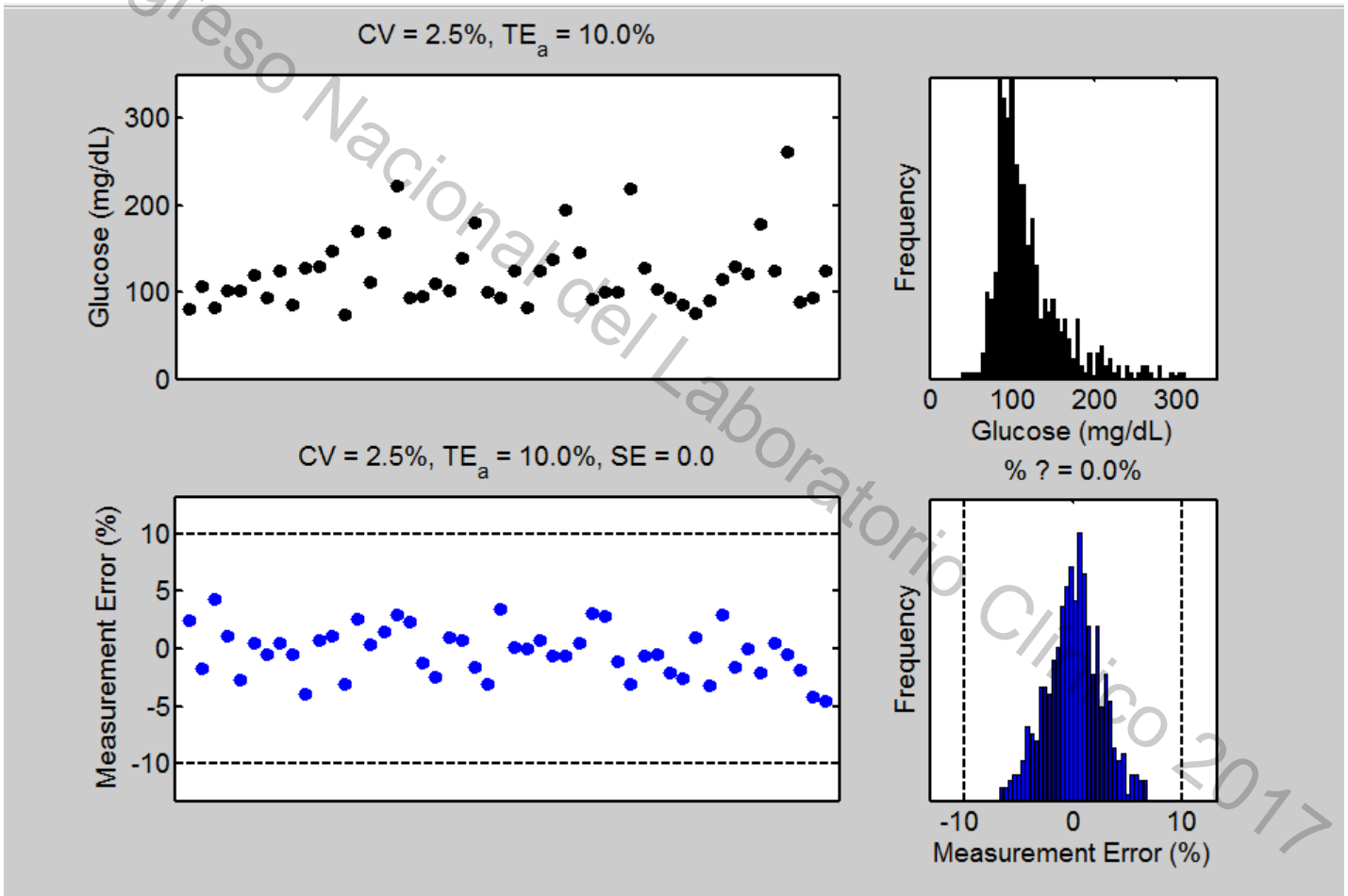
Display of Patient Results with Errors (1/2)



Measurement errors are simulated and displayed along with patient results. Their distribution has a known form.

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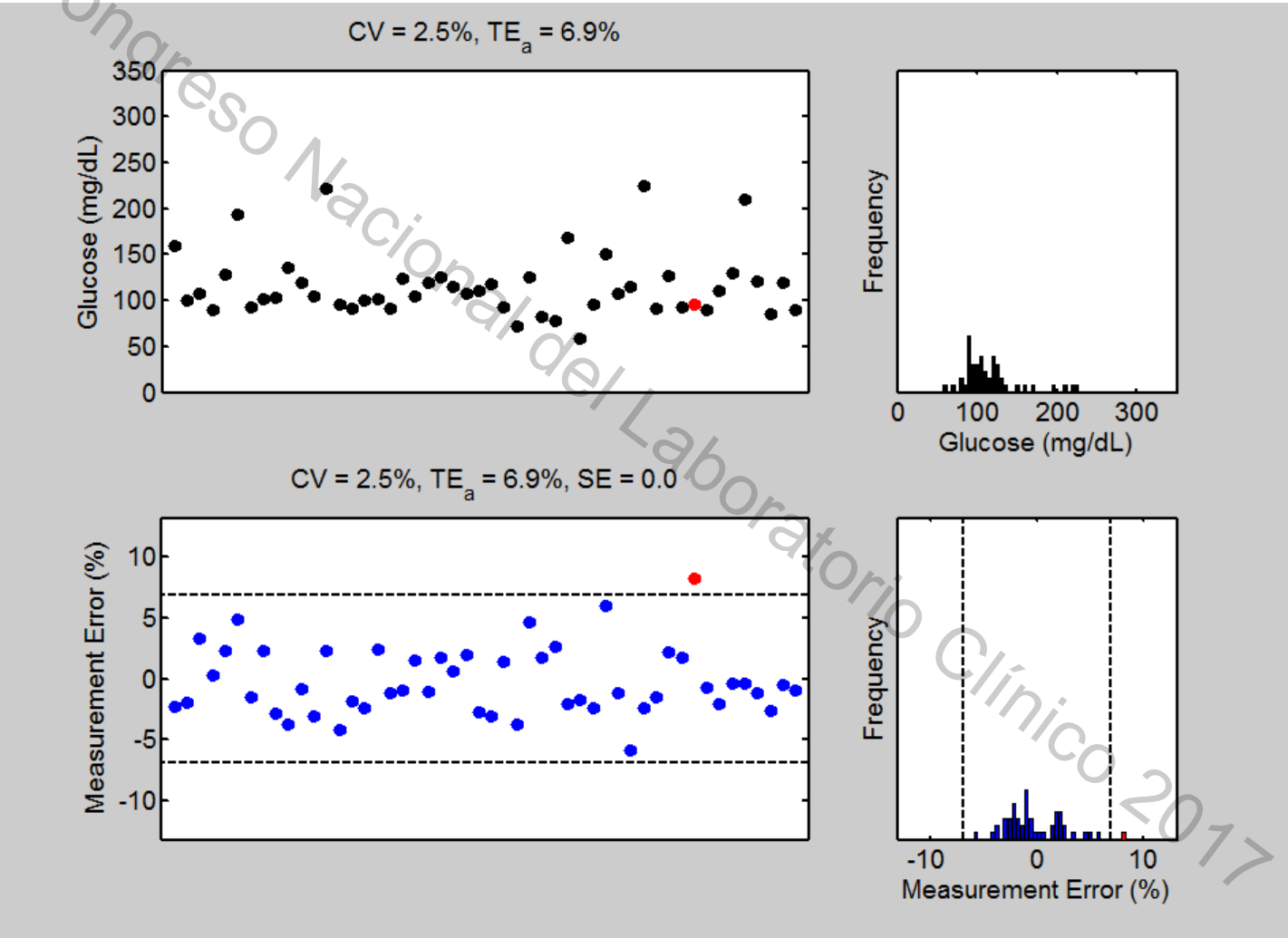
Display of Patient Results with Errors (2/2)



Patient results with too much error cannot be easily distinguished when only looking at the patient data.

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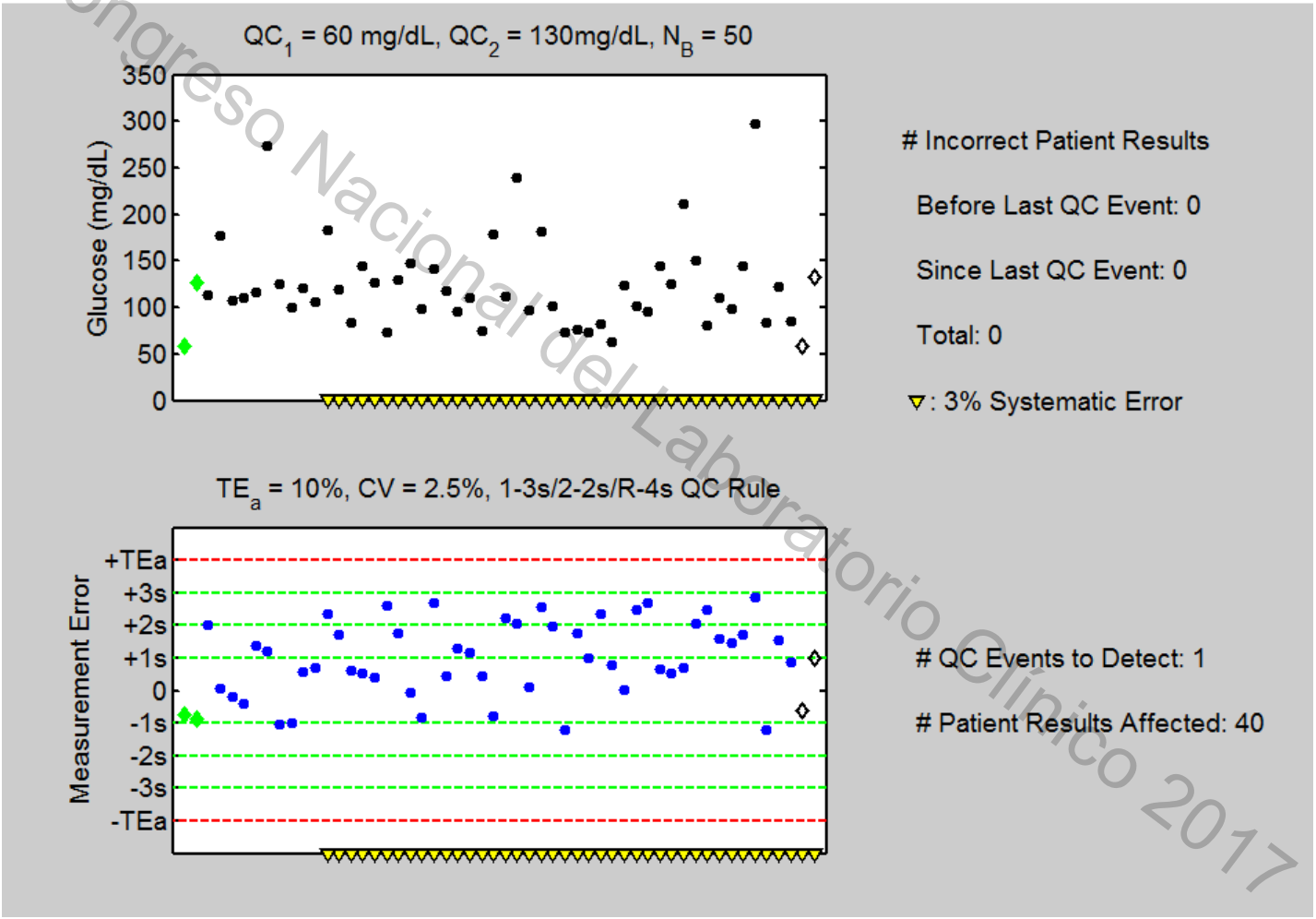
Simulating a QC Strategy (1/2)



A specified error condition is started at a random position in the first batch. The error condition affects controls and patients – testing continues until the QC detects the error condition.

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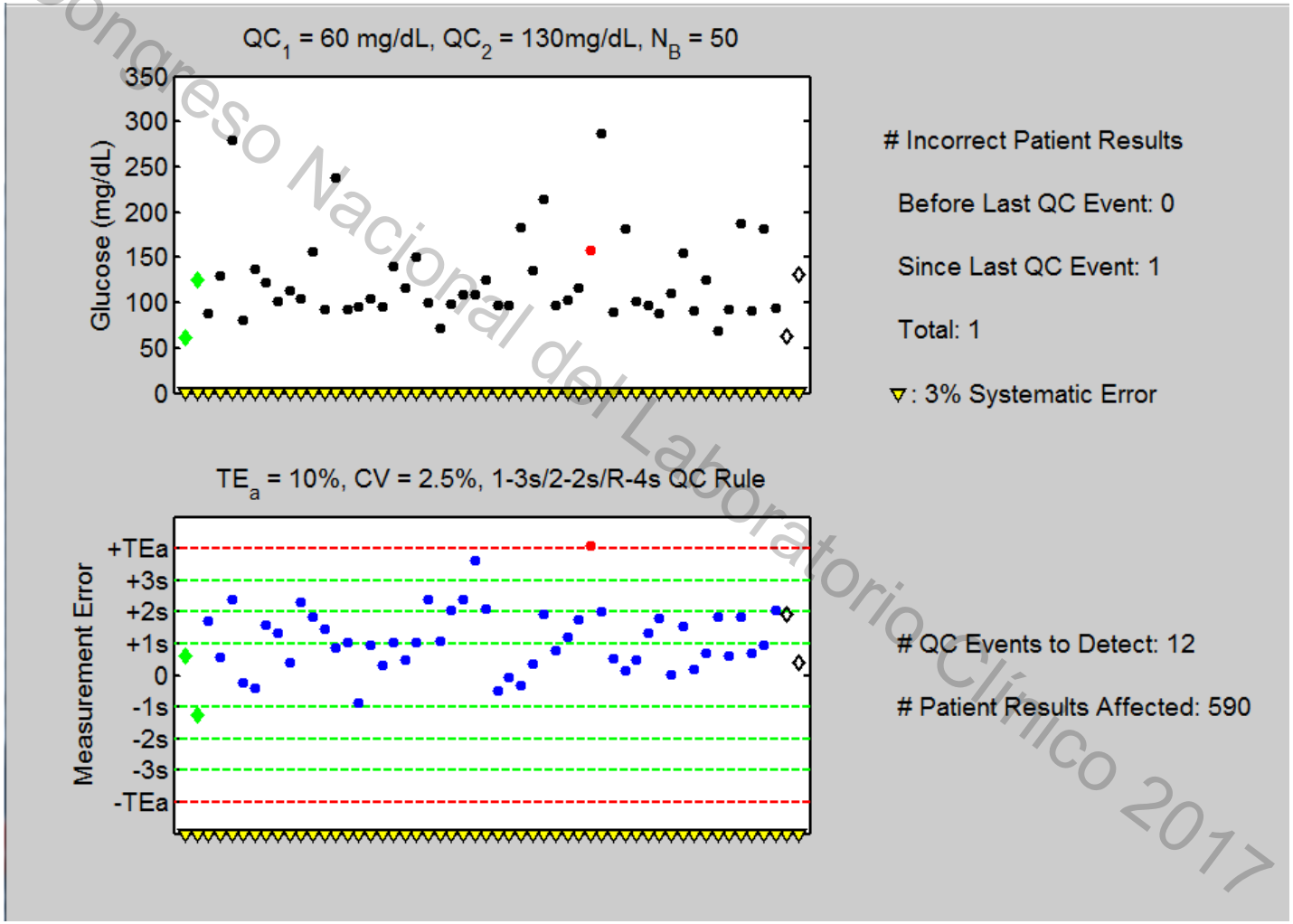
Simulating a QC Strategy (2/2)



As patient specimens are adversely affected, those with an unacceptable amount of error are indicated in red and tabulated on the right.

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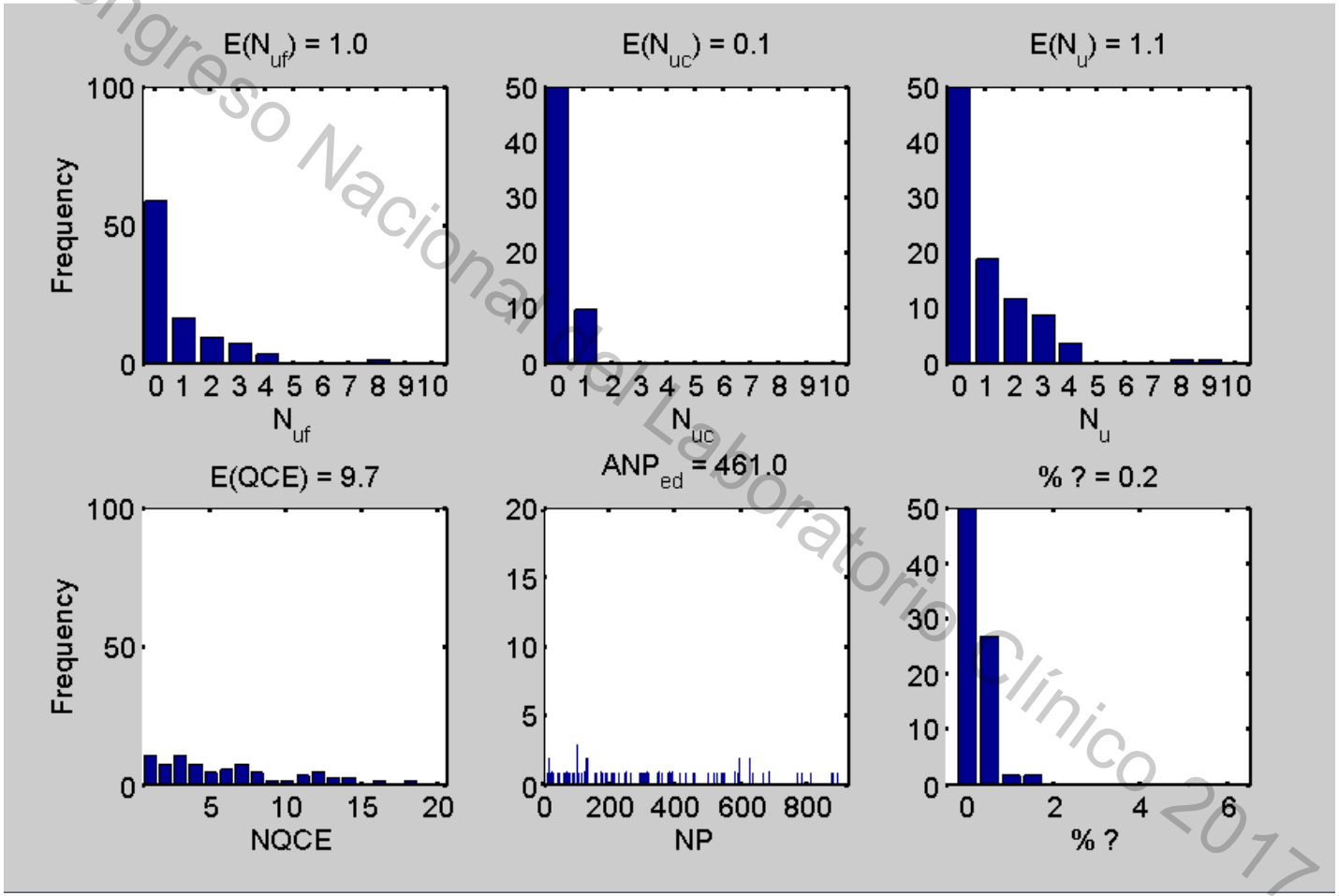
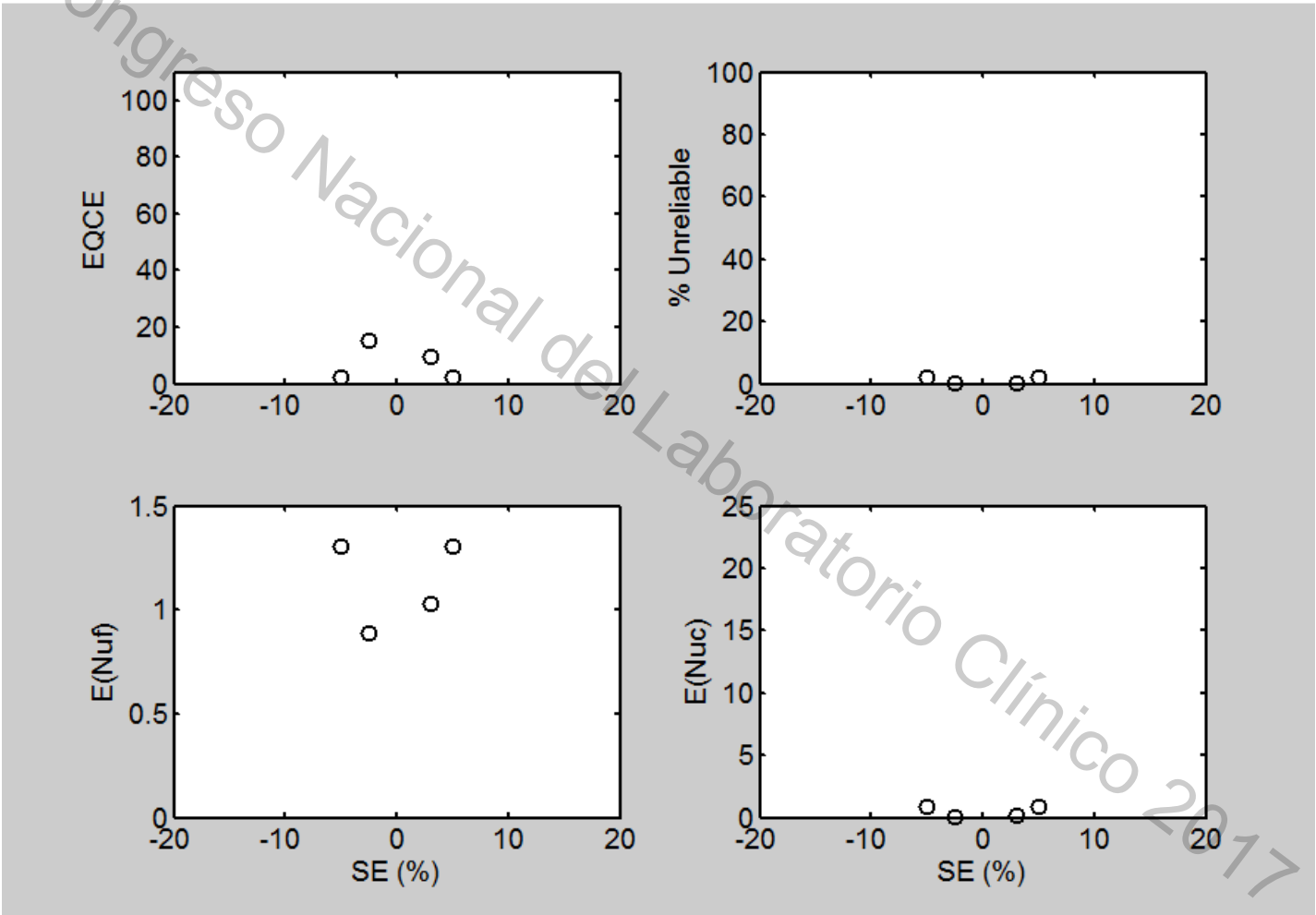
Simulating a QC Strategy 100 Times



As the simulation is modeling probablistic processes (like QC), each execution will be different. It is necessary to repeat multiple times to derive an expectation of the outcomes.

Simulating Different Error Conditions



As different error conditions are simulated, the most important metrics are recorded and summarized.

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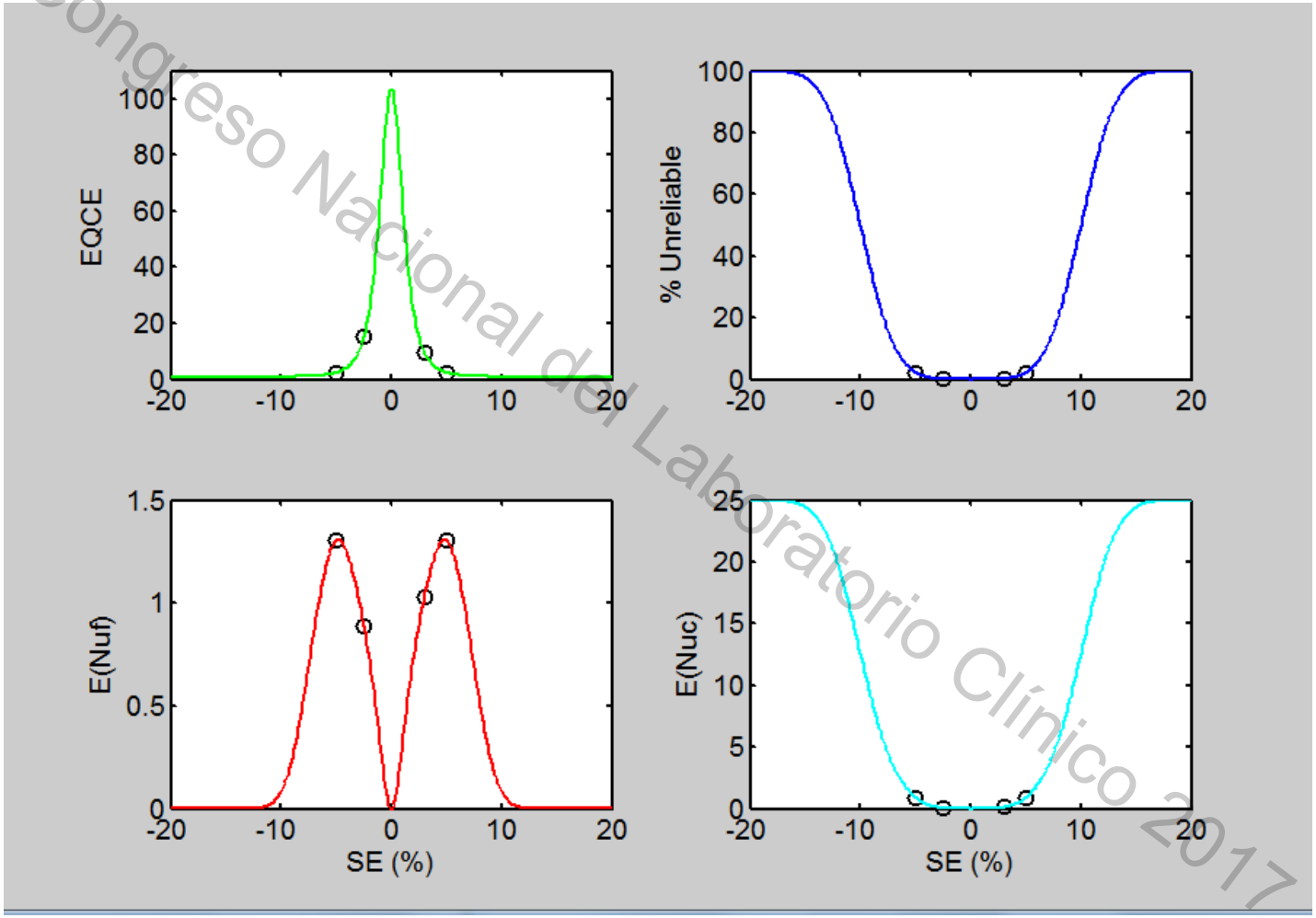
Evaluating a Range of Error Conditions



While simulation could be used to evaluate a range of error conditions, the mathematical solution is much faster and more precise.

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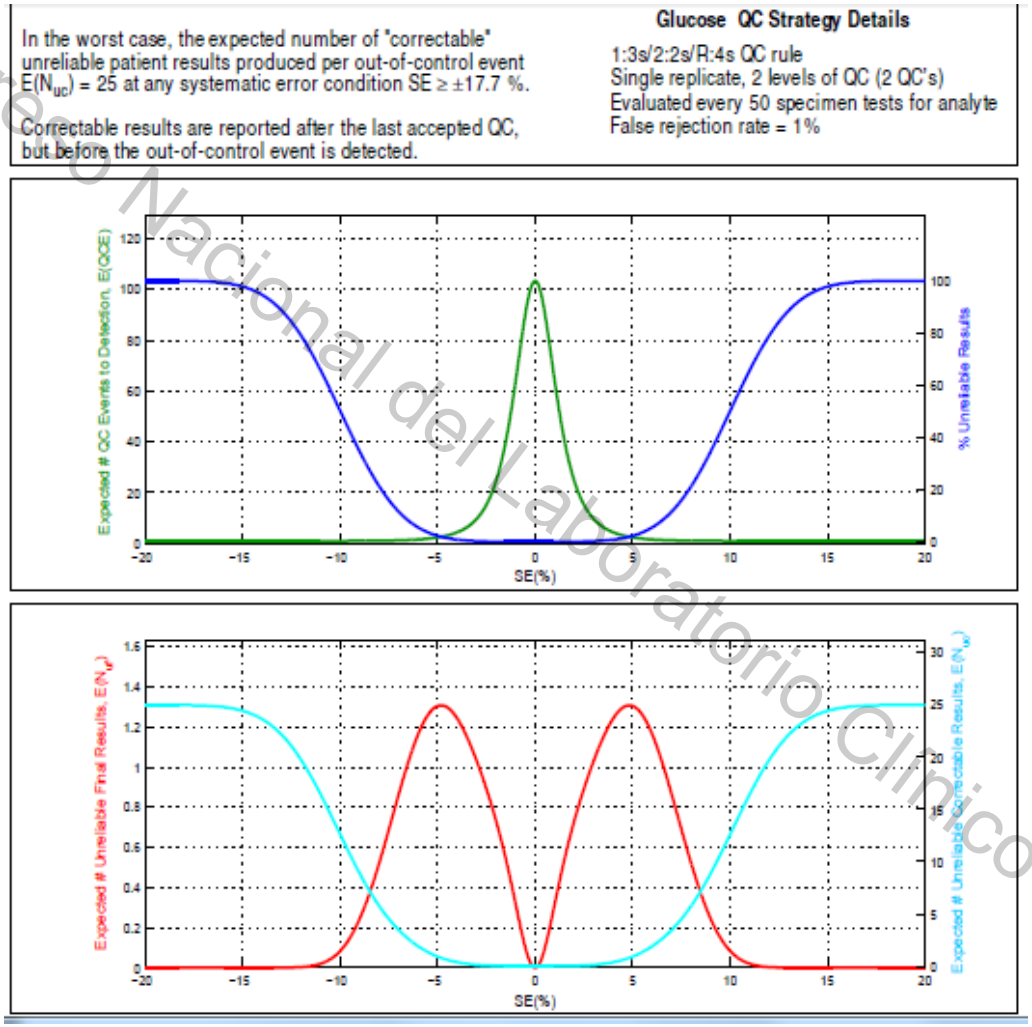
Mission:Control Risk Analysis Output



The Simulation Scenario can be evaluated in Mission:Control to see what the complete risk analysis of the test method is.

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Conclusion

- The first step of Risk Management is risk evaluation.
- The risk of producing an incorrect patient specimen result is a function of the QC strategy and can be evaluated by either simulation or computation.

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Thank you!