
**BLOG**
ISO 20391

# Validation Slide and LUNA QC Mode

## Bringing ISO Standards into Daily Practice

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## Introduction : Why is Daily QC separately needed?

In a previous article, we looked at the international standards and principles defined in ISO 20391-1 and 20391-2. These ISO standards are an important foundation for ensuring the reliability of cell counting data. However, in real laboratory environments, applying ISO procedures to daily instrument performance checks (Daily QC) is often too complex and burdensome.

What researchers truly need is a practical verification tool that, while not as strict as ISO regulations, is simple, reproducible, and easy to use on a daily basis.

This is where the Validation Slide (BF, FL) comes in, together with the QC Mode built into Logos Biosystems' LUNA-FX7™ and LUNA-BX7™ cell counters. The Validation Slide provides a straightforward way to verify the accuracy of instrument counts against the labeled concentration and viability values, while QC Mode allows results to be automatically logged, tracked through cumulative graphs, and exported as CSV files for management.

In short, when used together, these two tools enable researchers to implement the data reliability required by ISO standards in a simple, systematic way as part of their daily lab routine.

## Strengths and Limitations of ISO Standards

The greatest strength of ISO 20391-2 is that researchers validate their methods by directly measuring the actual cells they use, and then compiling statistical data. This makes it one of the most accurate and valid approaches available.
However, there are also several practical challenges:

A sufficient number of replicates (N) and repeated measurements are required, which demands significant effort and time for sampling and data processing.
Results obtained from one specific cell type cannot be directly applied to another; each new cell type requires the same validation procedure.
Therefore, while the ISO approach is excellent for method validation, it is too lengthy and complex to be realistically applied to daily instrument checks (Daily QC).

The specific requirements and practical applications of ISO 20391 were covered in detail in previous posts. For a deeper dive into the ISO standards, please refer to:

*"Understanding Cell Counting Standards : ISO 20391 – 1"*
*"Understanding Cell Counting Standards : ISO 20391 – 2"*

In this article, we will focus on how these principles can be applied in everyday lab practice — specifically through the use of the Validation Slide and LUNA QC Mode.

## The Need for Standard Materials in Daily QC

For this reason, researchers often look for simple standard materials that can be used for Daily QC instead of real cells.

Of course, these materials cannot perfectly replicate the results of measuring live cells. Nevertheless, they are far more suitable for quickly confirming whether the instrument is maintaining stable performance.

Commonly used examples include NIST-traceable beads with known concentrations or fixed cells prepared for quality control purposes. However, these also have drawbacks—such as pipetting errors or uneven cell distribution within the counting chamber—which means multiple repeated measurements are still necessary.

## Validation Slide: A Simple but Powerful QC Tool

The Validation Slide (BF/FL) is a standardized tool designed to verify instrument performance using the labeled concentration and viability values, instead of real cells. Since no sample preparation or pipetting is required, measurements are always performed under identical conditions, minimizing loading and distribution errors. This makes it highly advantageous for repeated QC checks.


*Validation Slide (BF/FL): FL is a slide with fixed fluorescent beads, while BF is a semi-permanent slide with printed patterns—both can be used for instrument QC.*

**1. Validation Slide BF (Brightfield)**
A glass slide with a circular pattern printed on its surface, designed for semi-permanent use.
Can be used in QC Mode on LUNA-FX7™ and LUNA-BX7™, or in basic measurement mode on other brightfield counters as a quick sanity check

**2. Validation Slide FL (Fluorescence)**
Contains pre-fixed fluorescent beads, with a limited shelf life.
Compatible with QC Mode on LUNA-FX7™ (not supported by LUNA-BX7™, which lacks fluorescence imaging).
On other fluorescence-based instruments without QC Mode, it can still be used in standard FL measurement mode for performance checks.

### Why is it useful?

Compared with other reference materials, Validation Slides have lower cost and storage requirements, while making it easy to implement the QC concepts emphasized in ISO standards directly in the laboratory. They are particularly useful for:

· Verifying instrument performance after new installation
· Performing regular QC checks
· Confirming performance after lot changes
· User training and competency assessment

## QC Mode of LUNA-FX7™ & BX7™

**What is QC Mode?**

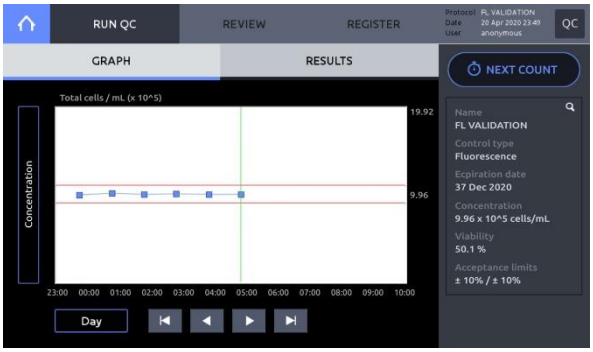
A feature that enables easy, in-instrument QC using Validation Slides (BF/FL).
Compares the measured concentration and viability directly against the labeled reference values to check for deviations. Simplifies the core principles of ISO 20391-1/2 (accuracy, precision, documentation) into a practical daily QC routine. If needed, Validation Slides can also be measured in basic (standard) mode for a quick status check.

**Automated Reporting & Traceability**

QC results are automatically stored as cumulative graphs, allowing easy visualization of variability or drift.
Results can be exported as CSV files for archiving, sharing, or secondary analysis, ensuring long-term traceability.
Comprehensive record-keeping makes it highly suitable for GMP environments and regulatory compliance.

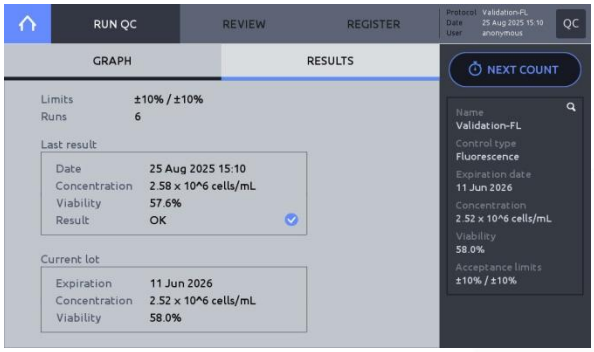
**Regular QC Scheduling**

Define acceptable deviation ranges and check frequencies (e.g., weekly or at the start of each project) in the lab SOP, making audits and performance tracking much easier. If deviations increase consistently or spike suddenly, prioritize checking for instrument or operational issues.




***Cumulative QC Result Graph***

*: Repeated measurements remain consistently within the defined reference range.*




***QC Result Screen***

*: Validation Slide measurement falls within the reference range (±10 %), resulting in an OK judgment.*

## Combining ISO Standards with Validation Slides: A Practical Lab Workflow

ISO 20391-2 is the most valid standard for verifying your method using the actual cells you work with. However, the procedure is complex and burdensome for daily QC. In contrast, the Validation Slide (BF/FL) is a simple and reproducible QC tool, well-suited for routine checks of instrument status.

The most efficient approach is:

**1. Perform Method Validation with ISO 20391-2.**

→ When introducing a new cell type or counting method, statistically verify accuracy and precision according to ISO procedures.

**2. Run Daily QC with the Validation Slide + QC Mode.**

→ Check deviations against the labeled reference values, and track instrument performance over time using cumulative graphs/CSV export.


By combining these two approaches, you can secure both the data reliability expected by ISO and the operational efficiency provided by the Validation Slide.

## Conclusion: Bringing ISO Standards into Everyday Lab Practice

Validation Slides and QC Mode bridge the gap between the rigor of ISO standards and the practical efficiency of daily laboratory work.
· ISO standards provide essential international criteria and reliability for method validation.
· Validation Slide + QC Mode simplify the repetitive daily QC process into a straightforward and reproducible routine.

By applying both together, researchers can ensure data reliability (accuracy, precision, traceability) while also gaining operational efficiency (time savings, reduced human error, regulatory readiness).

Beyond routine checks, Validation Slides and QC Mode are also highly valuable for:
· Verifying instrument performance after new installations
· Regular instrument maintenance
· User training and competency assessment
· Ensuring compliance in GMP environments and external audits

Ultimately, the goal is not to follow ISO procedures in their full complexity every single day, but rather to embed ISO principles into simple, daily routines. Validation Slides and QC Mode make this possible, providing researchers with a realistic and powerful solution—one that sets the foundation for QC management to become a new standard approach in the lab.

## Frequently Asked Questions (FAQ)

### Q1. How often should I use the Validation Slide?

**A.** It is recommended to use the Validation Slide before starting an experiment, after the instrument has not been used for an extended period, and whenever unexpected variability in results is suspected. The frequency can be adjusted depending on the research setting and project size.

### Q2. Can the QC Mode acceptance criteria (±10%) be changed?

**A.** The default tolerance is set to ±10%, but this can be modified by the researcher when entering the Validation Slide information for the first time. Once the slide information is saved, the acceptance range cannot be changed, so it is important to set the criteria appropriately in advance.

### Q3. Is the Validation Slide disposable?

**A.** The Validation Slide BF has no expiration date and can be reused as long as it is properly handled to avoid damage or contamination. The Validation Slide FL, on the other hand, has a specified expiration period, and it is recommended to replace it once that period has passed.

### Q4. How are QC results managed?

**A.** All QC results are automatically saved in the instrument and displayed as cumulative trend graphs to monitor long-term performance. The results can also be exported, providing both graph images and CSV data files. This allows researchers to check performance trends visually and organize QC records or perform statistical analysis with the raw data. When needed, these results can also serve as objective evidence of reliability in research reports or publications.