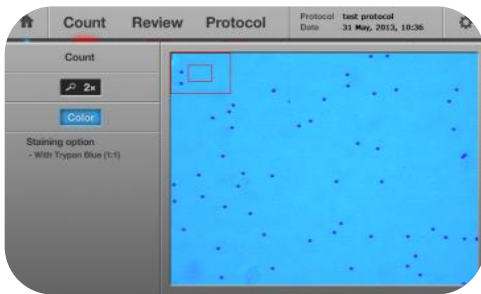
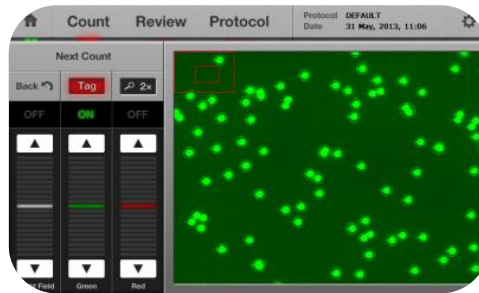


LUNA-FLTM Automated Fluorescence Cell Counter

Installation & Operation Qualification (IQ/OQ)

**IQ/OQ
Protocol
Brochure**



Installation & Operation Qualification (IQ/OQ)

1. This IQ/OQ protocol is used to verify:

- The installation and operation of a newly purchased or a previously installed instrument but not qualified LUNA-FL™ Automated Fluorescence Cell Counter.
- Updates or upgrades that may affect the instrument's performance.
- The operation of the instrument that requires regular operation qualifications.
- The requalification of a previously qualified instrument that has been reinstalled or moved to a new location.



2. This IQ/OQ protocol is required by:

- Researchers or customers who need to validate quality management systems such as GMP, GLP, GCP, or ISO standards.

**Note: Logos Biosystems makes no representation or warranties of any kinds that this IQ/OQ protocol meets or will meet any mandatory requirements of any governmental organization or other entities in any country in the world. The customer acknowledges and agrees that the customer is responsible for meeting governmental regulations and certification requirements.*

**Note: The software of the LUNA-FL™ does NOT meet 21 CFR Part 11.*

3. This IQ/OQ protocol consists of:

- 1 bound, hard copy of IQ/OQ test procedures performed by the Customer Representative (CR).

**Note: The CR is the person appointed by the customer who performs this qualification procedure. The CR may be an employee of the customer, the instrument distributor, or a third party consultant, according to the customer's SOPs.*

**Note: This protocol does NOT provide consumables necessary to perform the procedures.*

4. This IQ/OQ protocol includes the following:

Installation Qualification (IQ) Procedures	Operation Qualification (OQ) Procedures
Customer Representative (CR) Verification	Pre-Operation Verification
Environment Conditions Verification	Counting Verification
Instrument and Document Verification	Data Saving and Reporting Verification
Installation and System Verification	Warranty Verification
Operating System and Firmware Version Verification	User Training Verification

Installation & Operation Qualification (IQ/OQ)

5. Ordering Information

Cat #	Product	Quantity
L20001	LUNA-FL TM Automated Fluorescence Cell Counter	1 unit
L12005	PhotonSlide TM , 50 Slides	1 box
L12006	PhotonSlide TM , 500 Slides	10 boxes
L12007	PhotonSlide TM , 1000 Slides	20 boxes
T13001	Trypan Blue Stain, 0.4%	2 x 1 mL
L13002	Erythrosin B Stain	2 x 1 mL
F23001	Acridine Orange/Propidium Iodide Stain	2 x 0.5 mL
F23002	Acridine Orange Stain	2 x 0.5 mL
F23003	Propidium Iodide Stain	2 x 0.5 mL
F23004	Propidium Iodide Stain for Yeast	2 x 0.5 mL
F23211	Fluorescein Diacetate Stain	2 x 0.5 mL
F23212	Cell Dilution Buffer	5 x 20 mL
F23213	Fluorescence Signal Enhancer 1	2 x 0.5 mL
F23202	Yeast Viability Kit 1	1 kit
B13001	LUNA TM Standard Beads	2 x 1 mL
F23102	LUNA TM Fluorescence Calibration Beads	1 x 0.5 mL
F24004	LUNA-FL TM IQ/OQ Protocol	1 unit
P10001	LUNA TM Printer	1 unit
P12001	LUNA TM Printer Paper (Thermal, 700 prints)	3 x 2 rolls
P13001	LUNA TM Printer Cleaning Pen	1 unit

***Note:** For more information, please contact your local distributor.

For research use only.

© 2015 Logos Biosystems, Inc. All rights reserved.