

Complete Luminometer Validation Solutions

IQ/OQ/PQ

Berthold Detection Systems provides complete validation solutions for today's cGMP/GLP regulated laboratories. This includes reference light sources, evaluation software, and complete manuals for the performance and documentation of IQ/OQ/PQ validation.



Concept

The Berthold Detection Systems single tube and microplate luminometers are known for their exceptional performance and high reliability. These instruments are popular in many laboratories, including highly regulated pharmaceutical R&D labs and product QC labs. Berthold Detection Systems is pleased to offer sophisticated and proven validation tools for luminometers.

Stable light sources for Single Tube Luminometers



The Luminescence TestTube

The light source for our single tube luminometers provides stable light of approximately 450 nm maximum wavelength. The source is encased in a sealed glass tube. The light emission simulates single photon events typical for bio- and chemiluminescence reactions. The light source will be stable for many years.

Stable light sources for Microplate Luminometers



The Luminescence TestPlate

The Luminescence TestPlate utilizes 14 highly stable light sources, which simulate luminescence samples with various levels of light emission. All light sources emit in the 540–590 nm range (green light). The intensities of the light sources are spread over 6 orders of magnitude. The TestPlate has the outer dimensions of a standard 96 well microplate. A built-in rechargeable battery with smart charge management ensures reliable function of the device. The surfaces of the TestPlate are chemical resistant and easy-to-clean. The closed exterior surface eliminates the risk of contamination. A yearly manufacturer recertification service is available and recommended.

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Performance Check

TestPlate Ser. No.: 25
Instr. Type & Ser. No.: MPL1 - 1994
Date: 14.10.04

Bigd Min: 170
Bigd Max: 182

Bigd Variation (RL/UL): Pass
Bigd Variation (max 100 RL/ULs): Pass

	Target Mean	Lower Limit	Upper Limit	Actual	Act. Dev (%)	Status
B2	8	0	89.8	8	0.00	Pass
E2	18	0	89.8	18	0.00	Pass
F2	34	0	87.4	36	5.88	Pass
Q2	72	14.8	129.2	76	6.39	Pass
D6	666	540.2	771.8	662	-0.61	Pass
A6	26660	26662	329280	289030	-3.27	Pass
C8	43968	38759.4	41422.6	41416	-0.01	Pass
E8	85936	59159.8	72511.2	63891	-3.07	Pass
A10	85685.3	77117.7	94258.9	82096	-2.89	Pass
C10	169370.6	85362.1	116848.5	102914.1	-2.97	Pass
E10	174524	112118.8	137045.4	131285.1	-2.86	Pass
D12	168778	143848.4	1788703.8	168424	-2.48	Pass
	212200	191987.2	235258.8	207097.9	-2.45	Pass
	206814	2018136.8	3187811.4	284425	-2.48	Pass

Report of successful luminometer validation

Automated Instrument Validation

The regular evaluation is completed in just five minutes. The Evaluation PC Software validates the luminometer by reading the individual light sources of the TestTube or TestPlate as well as the instrument background. A report is generated automatically. The report will clearly state if the luminometer performance is within the specified range, and will show „pass“ or „fail“ for background as well as for each of the light sources. When the Evaluation PC software is initially installed, the reference values are taken. This process is fully automated. User guidance is provided for each step of the procedure.

IQ/OQ/PQ Qualification Procedures

The principle of qualifying laboratory equipment is established. However, every type of equipment requires specific Know-How. Having supported all types of luminometers in different laboratory environments for many years, Berthold Detection Systems is in a unique position to offer reliable guidance in regards to validation processes.

The new IQ/OQ/PQ documentation packages reflect this:

They include IQ/OQ/PQ procedures, guidelines for periodic maintenance, as well as several types of checklists, schedules and logbooks.



IQ/OQ/PQ documentation package



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