



Bio-Plex™ Validation Kit 3.0

Catalog Number 171-203000

Product Insert

The Bio-Plex validation kit is used for the operational qualification (OQ) of the Bio-Plex protein array system. The validation kit is designed to validate the operation of all of the primary components of the system and is a valuable tool that allows the user to discriminate between assay and instrument problems.

Each of the bead sets making up the Bio-Plex validation kit has specifications that may vary by lot number. Following are acceptable specifications for this specific lot of validation kit beads for reference. See the Bio-Plex validation kit manual for specific definitions of each parameter, the impact on Bio-Plex assay performance, and instructions on performing a validation. These values can also be found in the Bio-Plex Manager 3.0 Validation Log specifications window or in the Bio-Plex Manager™ 2.0 Excel spreadsheet provided on the CD with the version 2.0 software.

Optical Validation

Parameter	Specification
DD median	4774–6593
CL1 median	3383–4135
CL1 CV%	3.0–7.0%
CL2 median	3520–4302
CL2 CV%	4.0–8.0%
RP1 median	15205–18583
RP1 CV%	5.0–10.0%

Fluidics Validation

Parameter	Specification
Carryover	< or = 4.0%

Reporter Validation

Parameter	Specification
Dynamic range	4.5–4.28
Linearity	>0.995
Slope	0.0593–0.0799
Accuracy	>90%
Sensitivity	<200 MESF

Classify Validation

Region	Specification
Region 34	>80.0%
Region 38	>80.0%
Region 54	>80.0%
Region 73	>80.0%
Region 77	>80.0%

Parameter	Specification
DD efficiency	> or = 75.0%

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For technical service, call your local Bio-Rad office, or in the US, call 1-800-4BIORAD (1-800-424-6723)