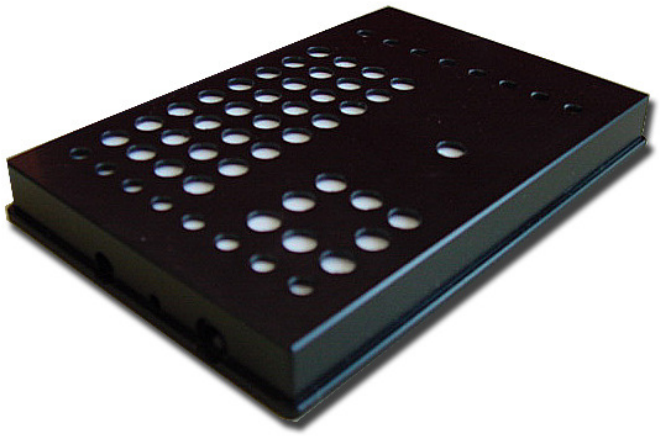
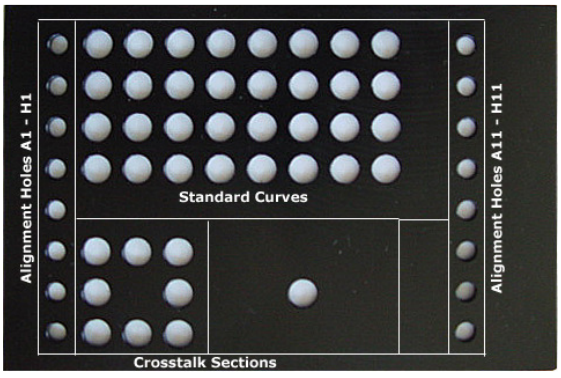
innovative instruments inc.

Luminescence QC-PAK ™



Comprehensive Validation of Microplate Luminometers

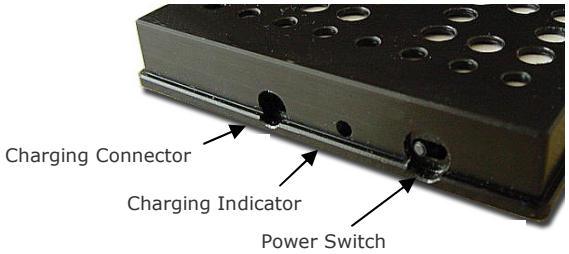
- Alignment of Plate Transport
- Reproducibility
- Linearity
- Cross Talk
- Standard Curve Over 7 Decades
- 24 Hour Battery Powered LED's with Overcharge Safety
- Statistical Software with Factory Calibrated Nominal Values



III's **Luminescence QC-PAK™** is the perfect tool for verification testing of all brands of Microplate Luminometers.

A **QC-Pak™** consists of as SBS standard plate with an array of light intensities covering 7 decades. Small wells are used to analyze plate alignment and "cross talk" wells measure light spill over.

The plate body is made of anodized aluminum containing a battery, a charging circuit, 2 light-emitting diodes (LED's), a mesh of fiber optics woven into a screen, and pattern of masks and filters to regulate the light.



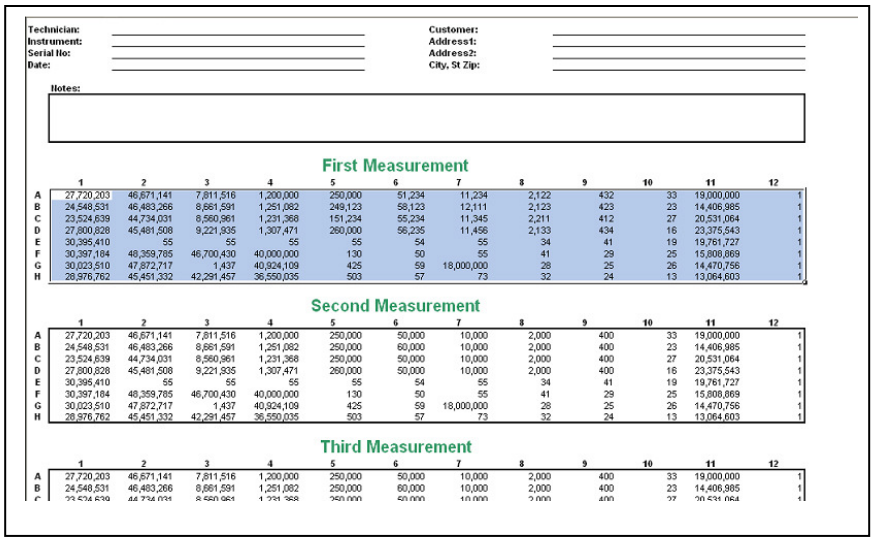
leading laboratory innovation

Luminescence QC-PAK ™

Reproducibility

The plate is measured 5 times for 0.1 to 1 seconds per well, depending on the Gain factor. The data is copied into the Statistical Evaluation Template and scripts calculate the mean and standard deviations.

If the CV of any well is outside the defined limit, the reader fails the reproducibility test.



Technician: Customer:
Instrument: Address1:
Serial No: Address2:
Date: City, St Zip:

Notes:

First Measurement

	1	2	3	4	5	6	7	8	9	10	11	12
A	27,720,203	46,671,141	7,811,516	1,200,000	250,000	51,234	11,234	2,122	432	33	19,000,000	1
B	24,548,531	46,483,266	8,661,591	1,251,082	249,123	58,123	12,111	2,123	423	23	14,406,985	1
C	23,524,639	44,734,031	8,560,961	1,231,368	151,234	55,234	11,345	2,211	412	27	20,531,064	1
D	27,800,828	45,481,508	9,221,935	1,307,471	260,000	56,235	11,456	2,133	434	16	23,375,543	1
E	30,395,410	55	55	55	55	54	55	34	41	19	19,761,727	1
F	30,397,184	48,359,785	46,700,430	40,000,000	130	50	55	41	29	25	15,808,869	1
G	30,023,510	47,872,717	1,437	40,924,109	425	59	18,000,000	28	25	26	14,470,756	1
H	28,976,762	45,451,332	42,291,457	36,550,035	503	57	73	32	24	13	13,064,603	1

Second Measurement

	1	2	3	4	5	6	7	8	9	10	11	12
A	27,720,203	46,671,141	7,811,516	1,200,000	250,000	50,000	10,000	2,000	400	33	19,000,000	1
B	24,548,531	46,483,266	8,661,591	1,251,082	250,000	60,000	10,000	2,000	400	23	14,406,985	1
C	23,524,639	44,734,031	8,560,961	1,231,368	250,000	50,000	10,000	2,000	400	27	20,531,064	1
D	27,800,828	45,481,508	9,221,935	1,307,471	260,000	50,000	10,000	2,000	400	16	23,375,543	1
E	30,395,410	55	55	55	55	54	55	34	41	19	19,761,727	1
F	30,397,184	48,359,785	46,700,430	40,000,000	130	50	55	41	29	25	15,808,869	1
G	30,023,510	47,872,717	1,437	40,924,109	425	59	18,000,000	28	25	26	14,470,756	1
H	28,976,762	45,451,332	42,291,457	36,550,035	503	57	73	32	24	13	13,064,603	1

Third Measurement

	1	2	3	4	5	6	7	8	9	10	11	12
A	27,720,203	46,671,141	7,811,516	1,200,000	250,000	50,000	10,000	2,000	400	33	19,000,000	1
B	24,548,531	46,483,266	8,661,591	1,251,082	250,000	60,000	10,000	2,000	400	23	14,406,985	1

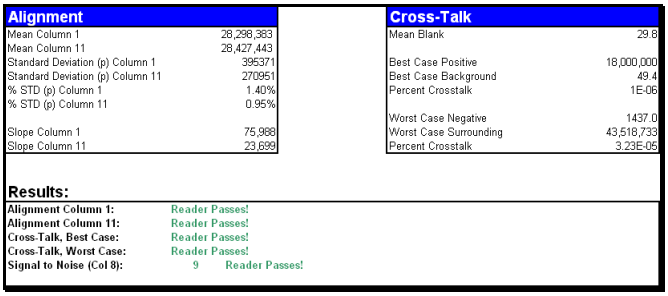
Cross Talk

A positive well is surrounded by blank wells, and blank well is surrounded by positive wells, and ratios are taken to determine "spill over" or "cross talk" between wells. III calls these tests "best case" and "worst case" cross talk, respectively. "Best case" cross talk higher than 3 x 10^{-5} is considered "out of specification."

Alignment

The plate has narrow wells of uniform intensity in columns 1 and 12 to measure alignment.

The software evaluates the linearity and consistency of these wells, and flags readers outside defined limits as "out of alignment."

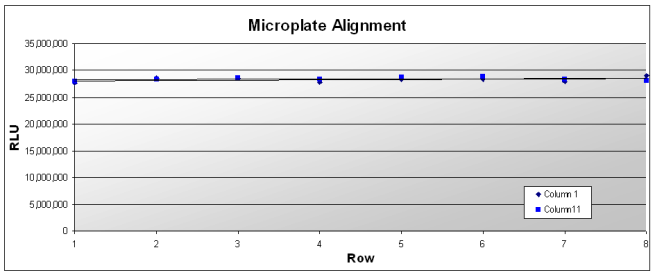


Alignment	
Mean Column 1	28,298,383
Mean Column 11	28,427,443
Standard Deviation (p) Column 1	395371
Standard Deviation (p) Column 11	270951
% STD (p) Column 1	1.40%
% STD (p) Column 11	0.95%
Slope Column 1	75,988
Slope Column 11	23,699

Cross-Talk	
Mean Blank	29.8
Best Case Positive	18,000,000
Best Case Background	49.4
Percent Crosstalk	1E-06
Worst Case Negative	1437.0
Worst Case Surrounding	43,518,733
Percent Crosstalk	3.23E-05

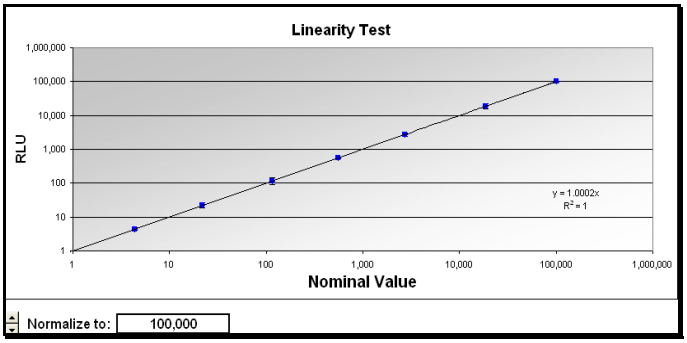
Results:

Alignment Column 1:	Reader Passes!	
Alignment Column 11:	Reader Passes!	
Cross-Talk, Best Case:	Reader Passes!	
Cross-Talk, Worst Case:	Reader Passes!	
Signal to Noise (Col 8):	9	Reader Passes!



Linearity

The Linearity Plot charts the regression line of the measured RLU values (Y axis) against the factory calibrated "gold standard" RLU (X axis), for each of the 8 luminescence intensity standards. The data is plotted on logarithmic scale over 7 decades of intensity. "Signal to noise" and r-squared are evaluated.



Analytical Data Summary

Gives a summary of all analyzed data:

"**QC Pak Mean**": averages of the raw RLU measurements

"**QC Pak Std Dev**": Population Standard Deviations

"**Normal Mean**": raw RLU averages, normalized

"**Nominal Mean**": factory calibrated "gold standard" RLU averages

"**Normal Std Dev**": QC Pak Std Dev on normalized scale

3 x Std Dev" shows the "Normal Std Dev" multiplied by 3

QC Pak Mean	QC Pak Std Dev	Normal Mean	Nominal Value	Normal Std Dev	3 x Std Dev
45892487	742102	100,000	100,000	1617.0	4851.1
8614001	473722	18,770	18,681	1032.2	3096.7
1247480	39134	2,718	2,721	85.3	255.8
252518	4333	550	551	9.4	28.3
53041	4176	116	115	9.1	27.3
10307	633	22	22	1.4	4.1
2029	61	4	4	0.1	0.4
405	11	0.9	0.9	0.0	0.1

y = mx + b	
Slope =	1.0000
Y int. =	10
r^2 =	1.00000

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