Adequate Performance Evaluation Data of

Getein1100 Immunofluorescence Quantitative Analyzer

1. Performance claim to be validated

1.1 Performance of Getein 1100

The background voltage range: <100 mV

Linear correlation coefficient (r): ≥0.95 in the range of 0 ~3200 mV

Repeatability: CV ≤2.00%.

Stability: P≤±2.0%.

1.2 Performance characteristics of Getein1100 with matching test devices

Table 1 Performance Characteristics

Performance Characteristics					
Biomarkers	Abbr.	Sample Mode	Measurement range	Linear range	Intra-assay precision
Cardiac Troponin I	cTnI	Serum/Plasma/Whole Blood	0.10~50.00 ng/ml	0.20-40.00 ng/ml	≤ 10%
N-terminal B-type natriuretic peptide precursor	NT-proBNP	Serum/Plasma/Whole Blood	100~35000 pg/ml	100-20000 pg/ml	≤ 10%
High sensitivity C-reactive protein	hs-CRP + CRP	Serum/Plasma/Whole Blood	0.50~200.00 mg/L	1.00-150.00 mg/L	≤ 10%
D-Dimer	D-Dimer	Serum/Plasma/Whole Blood	0.10~10.00 mg/L	0.10-10.00 mg/L	≤ 10%
Myohemoglobin	Myo	Serum/Plasma/Whole Blood	30.0~600.0 ng/ml	50.0-400.0 ng/ml	≤ 10%
Creatine Kinase - MB	CK-MB	Serum/Plasma/Whole Blood	2.50~80.00 ng/ml	2.50-80.00 ng/ml	≤ 10%
Procalcitonin	PCT	Serum/Plasma/Whole Blood	0.10~50.00 ng/ml	0.10-40.00 ng/ml	≤ 10%
Microalbumin	mAlb	Urine	10.0~200.0 mg/L	10.0-200.0 mg/L	≤ 10%

CystatinC	CysC	Serum/Plasma/Whole Blood	0.50 -10.00 mg/L	0.50 -10.00 mg/L	≤ 10%
β_2-microglobulin	β_2-MG	Serum/Plasma/Whole Blood	0.50 -20.00 mg/L	0.50 -20.00 mg/L	≤ 10%
Neutrophils gelatinases associated apolipoprotein	NGAL	Serum/Plasma/Whole Blood/Urine	50~5000 ng/ml	50.0 -1500.0 ng/ml	≤ 10%
Human Chorionic	HCG+β	Serum/Plasma	25~100000 mIU/ml	25~10000 0 mIU/ml	≤ 10%
Glycohemoglobin	HbA1c	Whole blood	2%~14%	2%~14%	≤ 10%

2. Performance evaluation method

2.1 Experiment procedure for instrument

2.1.1 Background voltage check

Test the background voltage three times using background debug card, the voltage of which is "-". Check if the maximum and minimum of three values are in the range of <100mV.

2.1.2 Linear relationship

Collect five debug cards. The concentrations are "+-", "+", "++", "+++", "++++" respectively. Test the five debug cards two times with the instrument to be checked. Record the voltage value and calculate the average of the two as test value. Take the debug card concentration as x-axis, the test value as y-axis, and then calculate the liner equation and correlation coefficient (r) of Getein 1100 respectively.

2.1.3 Repeatability

Test the debug card "++" 10 times. Remove the maximum and minimum value, then the coefficient variation (*CV*) as following formula:

$$CV = s / \bar{x} \times 100\%$$

In this formula, S means "standard deviation", and $\bar{x}$ means "average".

2.1.4 Stability

Test the voltage of debug card with the concentration of "++" from 0th min to 60th min every 5 min. Then Record the results (13 numbers) and calculate the maximum deviation (P-value) as following formula:

$$P = (Vmax-Vmin) / Vcon$$

In this formula, Vmax, Vmin is the maximum and minimum of test values, Vcon is the true voltage value of the debug card.

3. Performance evaluation records and analysis

3.1 Background voltage

Table 2 background voltage data and results

Date	Evaluation project			Serial No.
2012.3.12	Background voltage:			GT0368F8
Test results (mV)	1	2	3	Vmax =58
	86	87	78	Vmin=92
	Amplification factor: 25			
Analysis of the results	Vmax and Vmin are in the range of<100mV, the amplification factor is 25 (≥ 10).			
Performance claim	The background voltage should be in the range of <100mV. The amplification factor should be ≥ 10.			
Conclusion	Evaluation result is in accordance with the performance claim.			

3.2 Linear relationship

Table 3 linear relationship data and results

Date		Evaluation project		Serial No.		
2012.3.12		Linear relationship		GT0368F8		
Voltage of debug cards (mV)		+-	+	++	+++	++++
		125	250	500	1000	3000
Evaluation data (mV)	result 1	123	268	418	977	2577
	result 2	107	280	509	1045	2752

	average	115	274	463.5	1011	2664.5
Analysis of the results	Liner equation y = 0.8797x +47.8930.0523 Correlation coefficient r = 0.9988					
Performance claim	Linear range: 0 mV~3200 mV, r≥0.950					
Conclusion	Evaluation result is in accordance with the performance claim.					

3.3 Repeatability

Table 4 repeatability data and results

Date	Evaluation project				Serial No.					
2012.03.12	CV-value				GT0368F8					
Item	1	2	3	4	5	6	7	8	9	10
Evaluation data	509	492	498	503	491	503	501	493	505	505
Analysis of the results	Remove the maximum 0.339 and the minimum 0.334 $\bar{x}$ =500 S=6.218 CV = $S/\bar{x}$ =1.24%									
Performance claim	Repeatability: CV≤2.0%									
Conclusion	Evaluation result is in accordance with the performance claim.									

3.4 Stability

Table 5 Stability data and results

Date	Evaluation project						Serial No.						
2012.03.12	P-value						IA0DE444023A						
Item	1	2	3	4	5	6	7	8	9	10	11	12	13
Evaluation data	498	499	504	498	497	501	504	503	497	499	497	502	502
Analysis of the results	P-value = (504-497)/497=1.4%												

Performance claim	Stability: P≤±2.0%
Conclusion	Evaluation result is in accordance with the performance claim.

4. Summary of Performance evaluation

The result of performance evaluation of Getein 1100 Immunofluorescence Quantitative Analyzer shows that the performance parameters (Background voltage, Linear relationship, Repeatability, Stability) are all in accordance with the performance claim supplied by the manufacturer.