

Coccidioides Antigen Assay Performance Statistics at MiraVista–2008

A. Intraassay Precision and Interassay Reproducibility

- Specimens containing *Coccidioides* antigen to cover the range of detection.
 - 5 specimens run in 5 wells each for 5 testing days
 - See Table 3

Table 3		replicates - ng/ml									
		Patient 1					Patient 2				
		1	2	3	4	5	1	2	3	4	5
		7.20	8.55	7.39	7.47	8.08	2.51	2.75	2.36	2.80	2.74
		6.59	6.66	6.99	7.02	7.86	2.76	2.55	2.55	2.67	3.02
		9.65	9.64	8.76	7.81	7.62	2.77	2.33	2.63	2.57	2.68
		8.73	10.54	8.44	8.19	8.29	2.75	2.33	2.78	2.59	2.48
		6.94	8.50	6.43	7.85	8.12	2.56	2.54	2.98	2.49	2.48
avg (ng/ml)		8.04	8.85	7.90	7.63	7.96	2.70	2.49	2.58	2.66	2.73
std dev		1.403	1.672	0.839	0.498	0.288	0.123	0.205	0.174	0.102	0.223
%CV		17.4	18.9	10.6	6.5	3.6	4.6	8.2	6.7	3.9	8.2

overall	
avg (ng/ml)	7.97
std dev	1.015
%CV	12.7

overall	
avg (ng/ml)	2.62
std dev	0.191
%CV	7.3

		Patient 3					Patient 4				
		1	2	3	4	5	1	2	3	4	5
		0.57	0.72	0.62	0.70	0.65	0.13	0.09	0.12	0.13	0.15
		0.65	0.69	0.68	0.70	0.60	0.14	0.12	0.12	0.13	0.13
		0.63	0.67	0.68	0.64	0.63	0.13	0.12	0.13	0.13	0.13
		0.66	0.75	0.68	0.68	0.64	0.13	0.11	0.14	0.13	0.13
		0.68	0.75	0.68	0.72	0.66	0.14	0.13	0.14	0.11	0.12
avg (ng/ml)		0.63	0.71	0.66	0.68	0.63	0.13	0.11	0.13	0.13	0.13
std dev		0.039	0.035	0.030	0.027	0.022	0.002	0.012	0.008	0.002	0.009
%CV		6.3	4.9	4.6	4.0	3.4	1.7	11.0	5.8	1.8	6.9

overall	
avg (ng/ml)	0.67
std dev	0.043
%CV	6.4

overall	
avg (ng/ml)	0.13
std dev	0.012
%CV	9.5

Table 3	replicates - ng/ml				
	Patient 5				
	1	2	3	4	5
	0.49	0.56	0.52	0.56	0.45
	0.51	0.54	0.52	0.49	0.51
	0.42	0.47	0.46	0.51	0.43
	0.35	0.41	0.36	0.48	0.42
	0.39	0.57	0.45	0.49	0.40
avg (ng/ml)	0.44	0.49	0.46	0.51	0.45
std dev	0.076	0.070	0.077	0.036	0.039
%CV	17.3	14.1	16.6	7.2	8.6

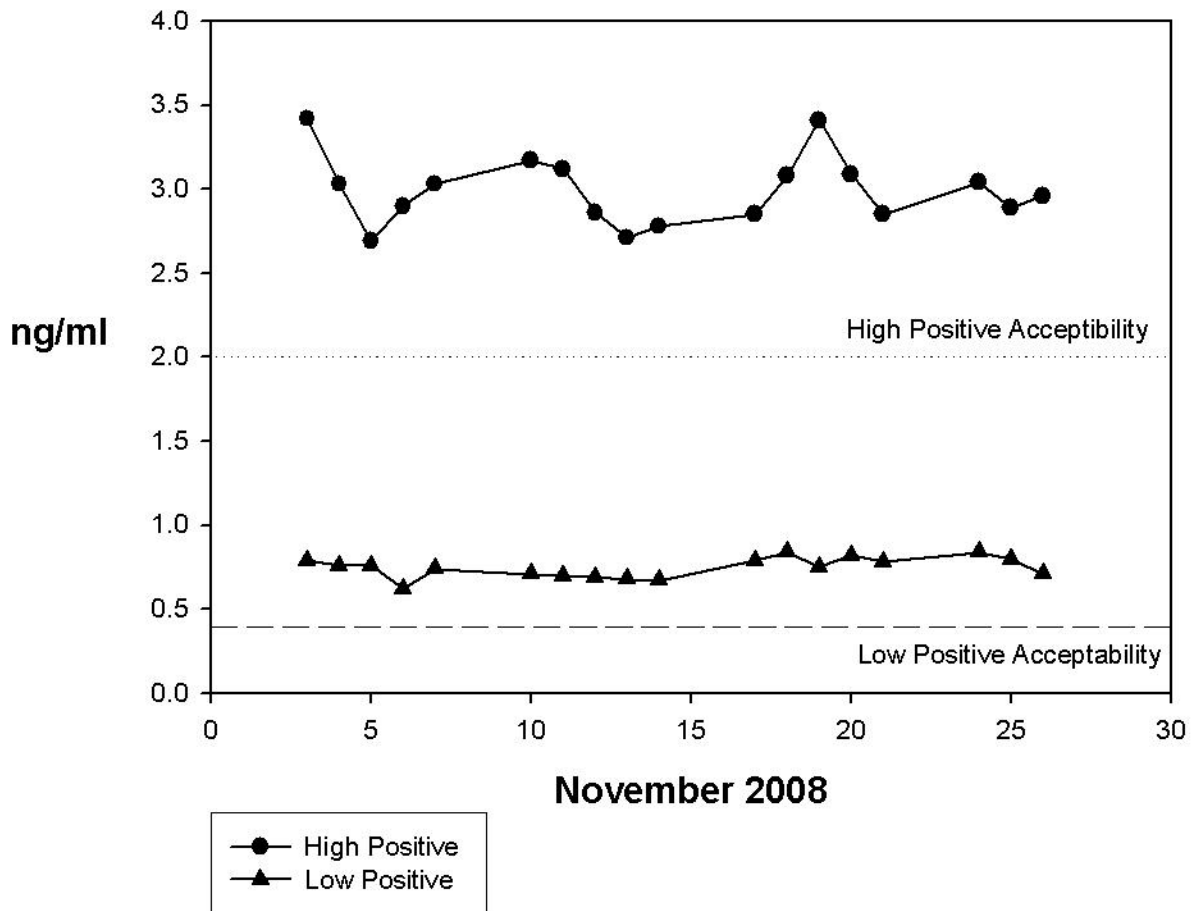
overall	
avg (ng/ml)	0.48
std dev	0.059
%CV	12.3

- Summary:
 - Inter-assay reproducibility
 - %CV ranged from 6.4-12.7
 - mean %CV 9.64
 - Intra-assay variability
 - %CV for each set of 5 replicates ranged from 1.7 to 18.9
 - Median %CV was 6.7
 - Mean %CV was 9.1

Agreement was good both between and within assays

B. Interassay Precision

Data for the assay controls for one month are shown in the figure below. The table shows data for the Blasto assay in 2008 with the mean, standard deviation and coefficient of variation.



Assay controls (mean ng/ml \pm 1 SD [CV]) and assay acceptability (number acceptable/total-%)

Std	3 rd Qtr 2008	4 th Qtr 2008	2008 Totals
High Pos	2.870 \pm 0.395 [13.8%]	3.004 \pm 0.230 [7.6%]	2.937 \pm 0.313 [10.7%]
Low Pos	0.694 \pm 0.106 [15.2%]	0.749 \pm 0.085 [11.3%]	0.722 \pm 0.096 [13.25%]
Assay accep	52/54 (96.30%)	59/60 (98.3%)	111/114 (97.4%)

C. Reproducibility of Positive Results

All positive results are verified the following test day. If the initial result is > 1.2 ng/ml the result is released to clients before confirmatory testing is complete. The result would be amended if the positive result is not confirmed. If the initial result is between 0.07 ng/ml and 1.2 ng/ml the results are delayed until confirmation is finalized. In the clinical assay results are expressed as ng/ml quantities, which are extrapolated off of a standard curve. Reactions from the linear portion of the curve are released as numeric values between 0.07 and 8.2 ng/ml. Reactions which give results above the highest point on the curve are released as >8.2 ng/ml. Data from the Quantitative assay in 2008 is depicted below, according to the antigen level of the first positive test.

Antigen group	3rd Qtr 2008	4th Qtr 2008
0.07-1.2 ng/mL	6/8 (75%)	8/11 (72.73%)
>1.2 ng/mL	3/3 (100%)	5/5 (100%)

D. Turn-Around-Time

Day of Reporting¹	Percent
Same day	100
Next day	0
Third day	0
Fourth day	0
Fifth day	0

1. Time from day received to the day reported between 111708 and 112108.

E. Monthly QC/QA

Parameter [# parameters]	% Acceptable
Assay Failures [5]	100
New lot QC [2]	100
Time frames [3]	100
Specimen processing [5]	100
Daily result sheet [4]	100
Reporting [5]	100
EIA reader QA [4]	100
Other equipment [5]	100