

Blastomyces Antigen Assay Performance Statistics at MiraVista–2008

A. Intraassay Precision and Interassay Reproducibility

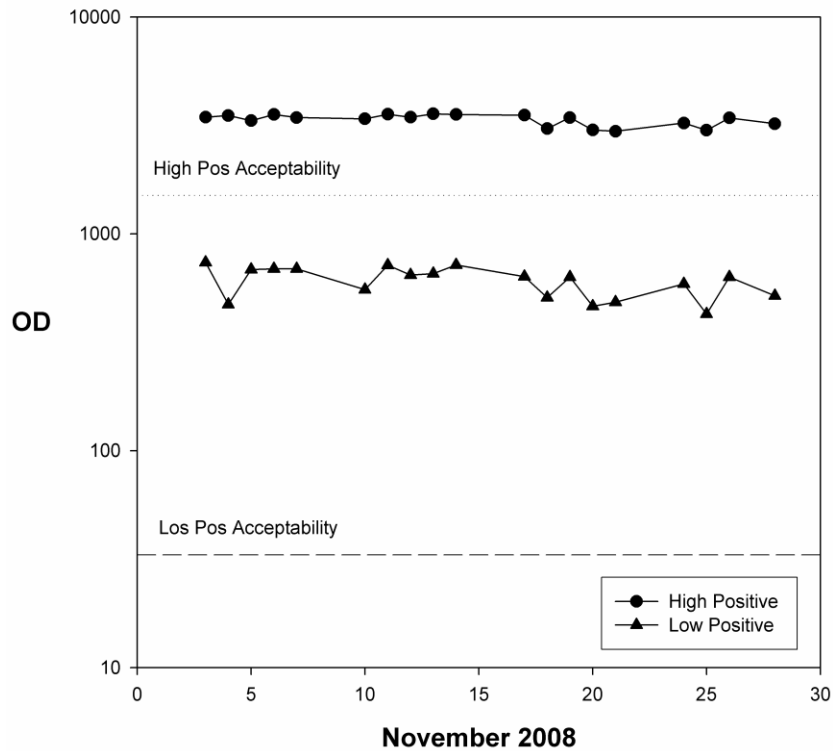
Five aliquots of assay controls are tested on two separate days.

	Test 1 [032708]	Test 2 [032808]
Control	OD* Mean \pm 1 SD (CV)	
High positive	2.956 \pm 0.091 (3.1%)	2.018 \pm 0.113 (5.6%)
Low Positive	0.826 \pm 0.065 (7.9%)	0.514 \pm 0.031 (6.0%)

*OD=optical density at 450/630 nm

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	1 st Qtr 2008	2 nd Qtr 2008	3 rd Qtr 2008	4 th Qtr 2008	2008 Totals
High Pos	2630.030 \pm 241.075 [9.2%]	2737.154 \pm 268.767 [9.8%]	3204.126 \pm 276.646 [8.6%]	3343.166 \pm 151.712 [4.5%]	3971.492 \pm 234.55 [8.03%]
Low Pos	720.265 \pm 96.426 [13.4%]	707.915 \pm 175.125 [24.7%]	527.898 \pm 92.395 [17.5%]	593.573 \pm 80.124 [13.5%]	637.413 \pm 101.018 [17.28%]
Assay accep	65/65 (100%)	64/65 (98.5%)	65/66 (98.5%)	65/66 (98.5%)	259/262 (98.9%)

C. Reproducibility of Positive Results

All positive results are verified the following test day. If the initial result is > 4 EIA units 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 1.0 and 4.0 EIA units the results are delayed until confirmation is finalized. The cutoff is the mean of the cutoff calibrators multiplied by 2.0. Data from the Bd assay in 2008 is depicted below, according to the antigen level of the first positive test.

Antigen group	1st Qtr 2008	2nd Qtr 2008	3rd Qtr 2008	4th Qtr 2008
1.0-4.0 EIA units	68/74 (91.89%)	47/59 (79.66%)	60/81 (74.07%)	85/102 (83.33%)
>4 EIA units	84/84 (100%)	92/92 (100%)	181/190 (95.26%)	196/197 (99.49%)

D. Turn-Around-Time

Day of Reporting¹	Percent
Same day	95.85
Next day	3.11
Third day	0.00
Fourth day	1.04
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