

## Histoplasma Antigen Assay Performance Statistics at MiraVista–2008

### A. Intraassay Precision and Interassay Reproducibility

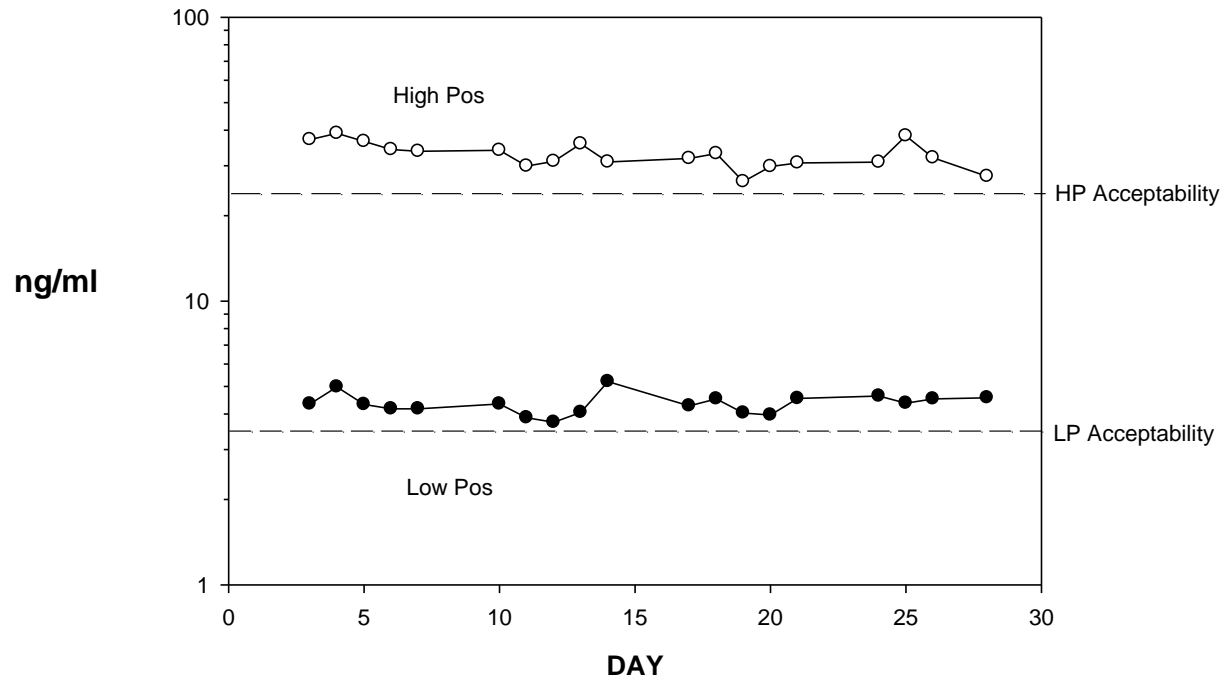
Five aliquots of assay controls are tested on two separate days.

	Test 1 [032708]	Test 2 [032808]
<b>Control</b>	<b>OD* Mean <math>\pm</math> 1 SD (CV)</b>	
High positive	1952 $\pm$ 106 (5.4%)	1782 $\pm$ 113 (6.3%)
Low Positive	349 $\pm$ 17 (4.9%)	323 $\pm$ 16 (5.1%)

\*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 Quantitative 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 <sup>st</sup> Qtr 2008	2 <sup>nd</sup> Qtr 2008	3 <sup>rd</sup> Qtr 2008	4 <sup>th</sup> Qtr 2008	2008 Totals
<b>High Pos</b>	30.567 $\pm$ 2.899 [9.5%]	32.481 $\pm$ 3.143 [9.7%]	34.055 $\pm$ 3.559 [10.4%]	32.543 $\pm$ 3.646 [11.2%]	32.412 $\pm$ 3.31 [10.2%]
<b>Low Pos</b>	4.436 $\pm$ 0.479 [10.8%]	4.520 $\pm$ 0.401 [8.9%]	4.380 $\pm$ 0.386 [8.8%]	4.383 $\pm$ 0.398 [9.1%]	4.430 $\pm$ 0.416 [9.4%]
<b>Assay accep</b>	66/66 (100%)	65/67 (97.0%)	63/65 (96.9%)	65/66 (98.5%)	259/264 (98.1%)

### **C. Reproducibility of Positive Results**

All positive results are verified the following test day. If the initial result is > 3.9 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 <0.6 and 3.9 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 0.6 and 39.0 ng/ml. Reactions which give results above the highest point on the curve are released as >39 ng/ml. Positive reactions above the cutoff but below the lowest standard on the curve are released as <0.6 ng/ml. The cutoff is the mean of the cutoff calibrators multiplied by 3.0. Data from the Quantitative assay in 2008 is depicted below, according to the antigen level of the first positive test.

<b>Antigen group</b>	<b>1<sup>st</sup> Qtr 2008</b>	<b>2<sup>nd</sup> Qtr 2008</b>	<b>3<sup>rd</sup> Qtr 2008</b>	<b>4<sup>th</sup> Qtr 2008</b>
<b>&lt;0.6-3.9 ng/ml</b>	341/390 (87%)	297/313 (95%)	277/320 (87%)	310/347 (89%)
<b>4.0-19.9 ng/ml</b>	269/269 (100%)	237/239 (99%)	235/235 (100%)	252/252 (100%)
<b>20.0-&gt;39 ng/ml</b>	161/161 (100%)	133/134 (99%)	132/132 (100%)	123/124 (99%)

### **D. Turn-Around-Time**

<b>Day of Reporting<sup>1</sup></b>	<b>Percent</b>
Same day	96.94
Next day	2.26
Third day	0.63
Fourth day	0.17
Fifth day	0

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

### **E. Monthly QC/QA**

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