

USAHA IDEXX M.pt Update Johnne's Working Group

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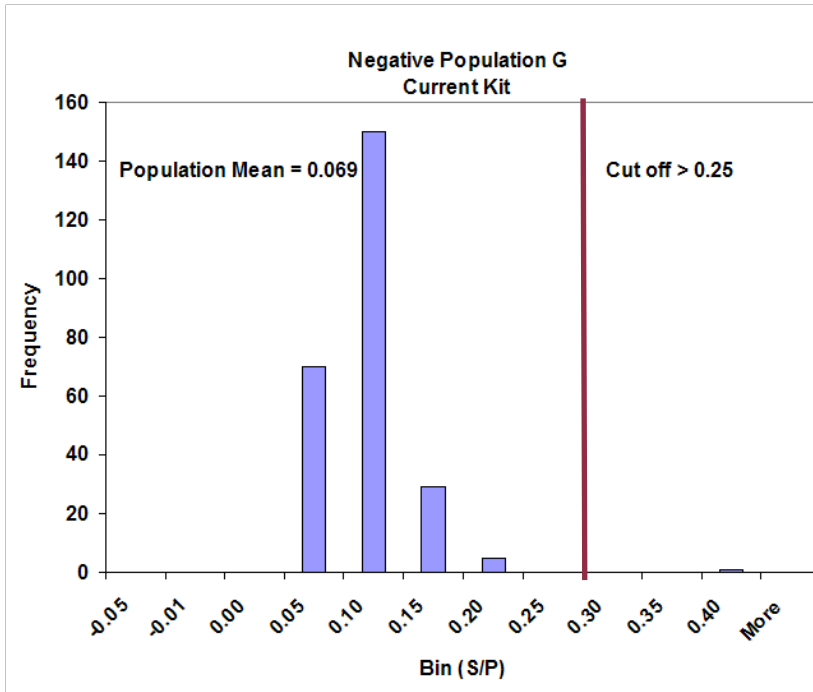
IDEXX is implementing changes to the HerdChek M.pt Antibody ELISA

- Goal to improve specificity on problem herds without impacting other areas of performance
 - Some recent studies have shown specificity challenges on certain problem herds
 - However, performance on typical populations has remained consistent

- Performance data
 - Performance on Typical Populations – Consistent
 - Performance on Problem Herds – Improved Specificity
 - Sensitivity unaffected by kit changes
 - Discrepant Results Table
 - 2X2s Performance Summary

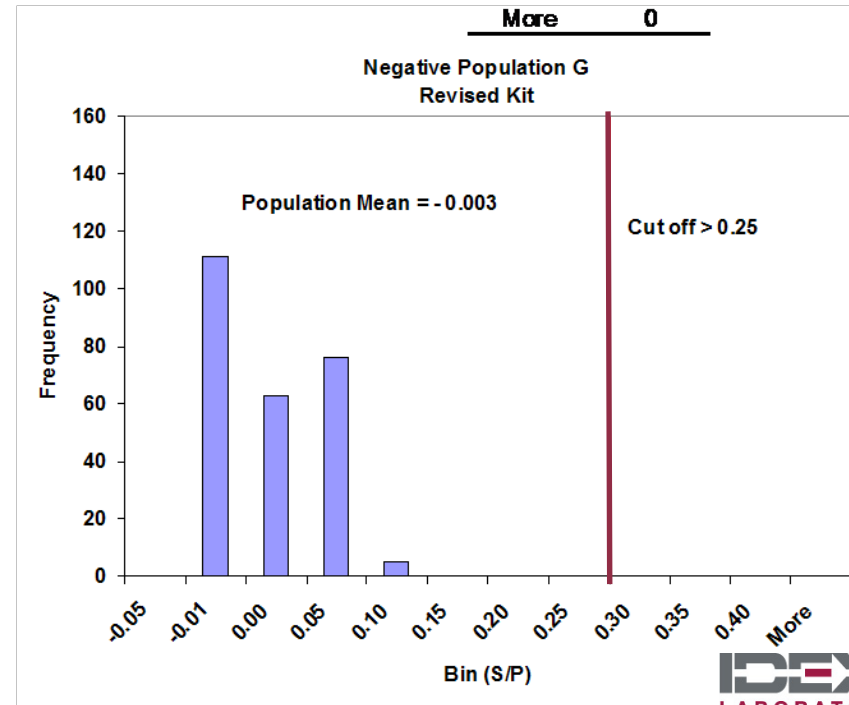
- Next Steps
 - Submission & USDA approval pending

M.pt Ab – Performance Data Typical Populations

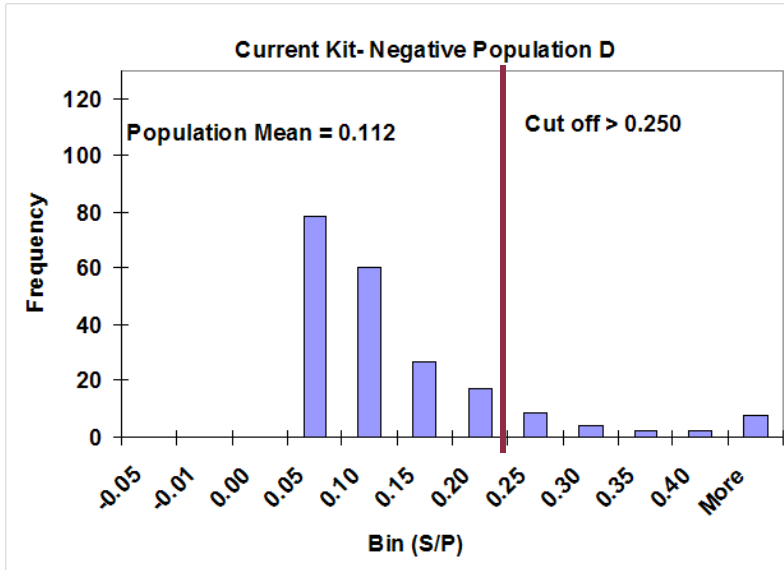


<i>Bin</i>	<i>Frequency</i>
-0.05	0
-0.01	0
0.00	0
0.05	70
0.10	150
0.15	29
0.20	5
0.25	0
0.30	0
0.35	0
0.40	1
More	0

<i>Bin</i>	<i>Frequency</i>
-0.05	0
-0.01	111
0.00	63
0.05	76
0.10	5
0.15	0
0.20	0
0.25	0
0.30	0
0.35	0
0.40	0
More	0

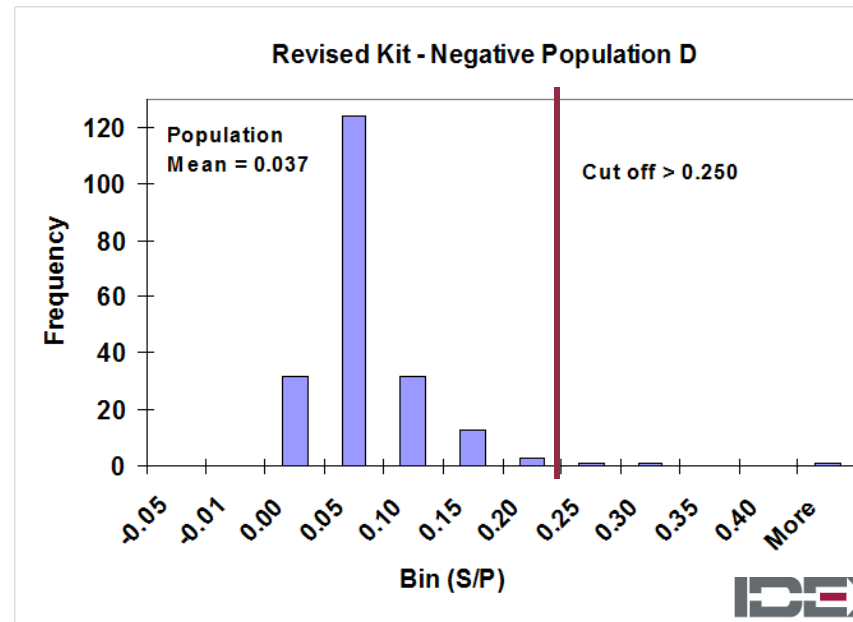


M.pt Ab – Performance Data Problem Populations



Bin	Frequency
-0.05	0
-0.01	0
0.00	32
0.05	124
0.10	32
0.15	13
0.20	3
0.25	1
0.30	1
0.35	0
0.40	0
More	1

Bin	Frequency
-0.05	0
-0.01	0
0.00	0
0.05	78
0.10	60
0.15	27
0.20	17
0.25	9
0.30	4
0.35	2
0.40	2
More	8



M.pt Ab – Performance Data

Presumed Negative Populations Tested

Population ID	n=	Current Kit			Revised Kit		
		pop mean	std dev	# std dev from cut-off	pop mean	std dev	# std dev from cut-off
A	45	0.083	0.044	3.80	-0.001	0.009	27.89
B	30	0.069	0.029	6.25	0.001	0.005	49.80
C	51	0.044	0.045	4.55	0.010	0.022	10.85
D	176	0.112	0.124	1.11	0.037	0.053	4.02
E	126	0.078	0.065	2.65	0.004	0.040	6.09
F	145	0.025	0.034	6.53	0.018	0.016	14.06
G	255	0.069	0.037	4.86	-0.003	0.017	14.48
H	15	<i>nd</i>	<i>nd</i>	<i>nd</i>	<i>nd</i>	<i>nd</i>	<i>nd</i>
I	119	0.077	0.067	2.57	0.018	0.061	3.82
962							

M.pt Ab – Performance Data

Sensitivity Unaffected by Kit Changes

Population J - Fecal Culture Positive Samples

S/P Ratios			S/P Ratios		
Sample ID	Current Kit Ref 4432:186	Revised Kit Ref 4432:186	Sample ID	Current Kit Ref 4432:186	Revised Kit Ref 4432:186
1	-0.005	-0.019	19	0.755	1.116
2	-0.001	-0.014	20	1.041	1.147
3	-0.015	-0.019	21	0.015	-0.004
4	0.035	-0.015	22	0.629	0.841
5	0.049	-0.012	23	0.045	-0.006
6	0.019	0.014	24	0.686	0.861
7	0.015	-0.004	25	1.524	1.226
8	0.064	0.006	26	0.579	0.714
9	0.262	0.128	27	0.102	0.116
10	0.064	-0.006	28	1.120	0.961
11	1.597	2.033	29	1.397	1.453
12	0.126	0.162	30	1.258	1.600
13	1.654	2.043	31	0.213	0.056
14	0.098	0.567	32	0.043	-0.017
15	0.025	0.000	33	0.985	0.656
16	0.060	0.010	34	0.037	-0.012
17	1.660	2.232	35	0.047	0.015
18	0.211	0.327	36	0.015	-0.021

M.pt Ab – Performance Data

Discrepant Results

Discrepant Test Results

Study & Sample ID	Disease Status	S/P Current Kit	S/P Revised Kit
K-3	FCpos	0.248	0.495
K-14	FCpos	0.243	0.333
J-129	FCpos	0.262	0.128
J-162	FCpos	0.098	0.567
J-169	FCpos	0.211	0.327
L-50	FCpos	0.629	0.044
L-56	FCpos	0.273	0.015
L-303	FCpos	0.280	0.204
L-101	FCpos	0.110	0.466
L-24	FCpos	0.189	0.452
M-64	FCpos	0.222	0.341

Study & Sample ID	Disease Status	S/P Current Kit	S/P Revised Kit
L-1	FCneg	0.307	0.039
L-288	FCneg	0.321	0.019
L-94	FCneg	0.255	0.240
L-73	FCneg	0.225	0.104
I-67	FCneg	0.598	0.009
C-29	PNH	0.308	0.122
D-10	PNH	0.310	0.020
D-9	PNH	0.297	0.051
D-158	PNH	0.259	0.058
D-164	PNH	0.391	0.101
D-182	PNH	0.499	0.106
D-200	PNH	0.628	0.096
D-202	PNH	0.456	0.128
D-209	PNH	0.715	0.186
D-210	PNH	0.400	0.168
D-213	PNH	0.649	0.138
D-217	PNH	0.332	0.095
D-218	PNH	0.278	0.146
D-220	PNH	0.842	0.080
D-418	PNH	0.621	0.056
E-308	PNH	0.334	-0.007
E-177	PNH	0.385	0.007

M.pt Ab – Performance Data

2X2s Performance Summary

US Populations ONLY

		Current Kit		Revised Kit	
		+	-	+	-
Disease Status	+	40	91	42	89
	-	12	648	1	659

Sensitivity: 30.53% Sensitivity: 32.06%
 Specificity: 98.18% Specificity: 99.85%

All Samples Tested To-Date

		Current Kit		Revised Kit	
		+	-	+	-
Disease Status	+	40	91	42	89
	-	30	932	5	957

Sensitivity: 30.53% Sensitivity: 32.06%
 Specificity: 96.88% Specificity: 99.48%

M.pt Ab – Next Steps

- **Currently in final stages of preparing a regulatory data package for submission to USDA**
- **Potential follow-up research & field evaluations**