

MEDICAL LABORATORY

EVALUATION

PARTICIPANT SUMMARY

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Immunology
2021 MLE-M2

ACP | Medical Laboratory
Evaluation 

Total Commitment to Education and Service
Provided by ACP, Inc.

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Evaluation Criteria

The evaluation criteria used in the MLE Program is in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) federal requirements for proficiency testing. The criteria are included below.

Qualitative

For qualitative/semi-quantitative procedures, evaluation is based on participant or referee consensus. A minimum percentage of participants must receive a passing score or the challenge is not evaluated due to lack of consensus. These percentages are listed below.

Anti-dsDNA	80% Participant Consensus
Anti-HIV	80% Participant Consensus
Antinuclear Antibody (ANA)	80% Participant Consensus
Anti-RNP	80% Participant Consensus
Anti-RNP/Sm	80% Participant Consensus
Anti-Sm	80% Participant Consensus
Anti-SSA	80% Participant Consensus
Anti-SSA/SSB	80% Participant Consensus
Anti-SSB	80% Participant Consensus
Anti-Streptolysin O (ASO)	80% Participant Consensus
C-Reactive Protein	80% Participant Consensus
Diagnostic Allergy	80% Participant Consensus
H. <i>pylori</i> Antibody Detection	80% Participant Consensus
Infectious Mononucleosis	80% Participant Consensus
Mycoplasma Antibody	80% Participant Consensus
Rheumatoid Factor	80% Participant Consensus
Rubella Antibody	80% Participant Consensus
SARS-CoV-2 Serology	80% Participant Consensus
Syphilis Serology	80% Participant Consensus
Viral Markers	80% Participant Consensus

Semi-Quantitative

Antinuclear Antibody (ANA) Titer	80% Participant Consensus
Anti-Streptolysin O (ASO) Titer	80% Participant Consensus
Rheumatoid Factor (Titer)	80% Participant Consensus
RPR Titer	80% Participant Consensus
VDRL Titer	80% Participant Consensus

Quantitative

For quantitative procedures, a mean and standard deviation (SD) are calculated for each peer group consisting of 10 or more laboratories. Acceptable performance is established based on a target value \pm the intervals below. An explanation on how to calculate the range of acceptability based upon these limits is also provided in your MLE Program Guide on page 37 under the heading "Acceptable Ranges for Quantitative Results."

Complement C3	\pm 3 SD
Complement C4	\pm 3 SD
C-Reactive Protein	\pm 30% or 2 SD*
High Sensitivity C-Reactive Protein	\pm 30% or 1 mg/L*
Rheumatoid Factor (International Units)	\pm 3 SD
Rubella (International Units)	\pm 3 SD
Total IgA	\pm 3 SD
Total IgE	\pm 3 SD
Total IgG	\pm 25%
Total IgM	\pm 3 SD

*Whichever is greater

Infectious Mononucleosis

<u>Method</u>	<u>Specimen IM-6</u>		<u>Specimen IM-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	117	116	2
Alere Clearview - moderate	-	1	1	-
Alere Clearview - waived	-	5	5	-
Alere Clearview Mono Plus II - moderate	-	1	1	-
Alere Clearview Mono Plus II - waived	-	3	3	-
BioStar Aceava Mono Test	-	2	2	-
BioStar Aceava Mono-whole bld	-	3	3	-
Cardinal Health SP Brand	-	1	1	-
Cardinal Health SP Brand - waived	-	4	4	-
Clarity Diagnostics	-	1	1	-
Consult Diagnostics - moderate	-	3	3	-
Consult Diagnostics - waived	-	16	15	1
Fisher HealthCare Sure-Vue	-	2	2	-
Henry Schein OneStep+ - moderate	-	1	1	-
Henry Schein OneStep+ - waived	-	10	10	-
Immunostics Inc.	-	1	1	-
LifeSign Status - waived	1	5	5	1
Other Moderate method	-	1	1	-
Other Waived method	-	7	7	-
Quidel QuickVue+	-	1	1	-
Quidel QuickVue+ - waived	-	2	2	-
Sekisui OSOM	-	4	4	-
Sekisui OSOM (waived)	-	43	43	-

Infectious Mononucleosis

<u>Method</u>	Specimen IM-8		Specimen IM-9		Specimen IM-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	26	-	26	-	26
Alere Clearview - moderate	-	1	-	1	-	1
Alere Clearview Mono Plus II - moderate	-	1	-	1	-	1
Alere Clearview Mono Plus II - waived	-	1	-	1	-	1
BioStar Aceava Mono Test	-	1	-	1	-	1
Consult Diagnostics - moderate	-	1	-	1	-	1
Consult Diagnostics - waived	-	5	-	5	-	5
Fisher HealthCare Sure-Vue	-	1	-	1	-	1
Henry Schein OneStep+ - moderate	-	1	-	1	-	1
Henry Schein OneStep+ - waived	-	2	-	2	-	2
LifeSign Status - waived	-	1	-	1	-	1
Other Moderate method	-	1	-	1	-	1
Other Waived method	-	2	-	2	-	2
Quidel QuickVue+	-	1	-	1	-	1
Quidel QuickVue+ - waived	-	1	-	1	-	1
Sekisui OSOM	-	4	-	4	-	4
Sekisui OSOM (waived)	-	2	-	2	-	2

Rheumatoid Factor—Qualitative

<u>Method</u>	Specimen RF-6		Specimen RF-7		Specimen RF-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	-	17	17	-
ASI	-	4	-	4	4	-
Biokit Rheumajet	-	1	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	-	3	3	-
Stanbio Laboratory	-	4	-	4	4	-
TheraTest	-	4	-	4	4	-
Wampole Rheumatex	-	1	-	1	1	-

<u>Method</u>	Specimen RF-9		Specimen RF-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	17	17	-
ASI	-	4	4	-
Biokit Rheumajet	-	1	1	-
Fisher HealthCare Sure-Vue	-	3	3	-
Stanbio Laboratory	-	4	4	-
TheraTest	-	4	4	-
Wampole Rheumatex	-	1	1	-

Rheumatoid Factor—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>2/4</u>	<u>8/10</u>	<u>16/20</u>	<u>32/40</u>	<u>64/80</u>	<u>128/160</u>	<u>256/320</u>	<u>512/640</u>	<u>1024/1280</u>	<u>2048/2560</u>	<u>>2560</u>
Specimen RF-6												
ALL METHODS	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-7												
ALL METHODS	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-8												
ALL METHODS	-	1	1	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	1	1	-	-	-	-	-	-	-	-	-
Specimen RF-9												
ALL METHODS	2	-	-	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	2	-	-	-	-	-	-	-	-	-	-	-
Specimen RF-10												
ALL METHODS	-	-	2	-	-	-	-	-	-	-	-	-
Fisher HealthCare Sure-Vue	-	-	2	-	-	-	-	-	-	-	-	-

Rheumatoid Factor—Quantitative (IU/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen RF-6						
All Method	16	6.1	4.3	70.6	3	0 - 20
Beckman AU	10	4.8	4.4	90.1	4	0 - 18
Specimen RF-7						
All Method	16	6.6	3.8	58.1	5	0 - 19
Beckman AU	10	5.5	3.9	71.6	5	0 - 18
Specimen RF-8						
All Method	16	62.8	4.3	6.9	63	49 - 76
Beckman AU	10	64.0	5.3	8.3	63	48 - 80
Specimen RF-9						
All Method	16	6.2	4.2	68.3	4	0 - 19
Beckman AU	10	4.7	4.5	95.5	4	0 - 19
Specimen RF-10						
All Method	16	110.9	6.7	6.1	109	90 - 132
Beckman AU	10	113.2	8.1	7.1	111	88 - 138

Anti-Streptolysin O (ASO)—Qualitative

<u>Method</u>	Specimen AS-6		Specimen AS-7		Specimen AS-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	5	-
ASI	5	-	-	5	5	-
<u>Method</u>	Specimen AS-9		Specimen AS-10			
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>		
ALL METHODS	-	5	5	-		
ASI	-	5	5	-		

Complement C3 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-6						
All Method	16	127.4	6.7	5.3	127	107 - 148
Beckman AU	10	126.7	7.9	6.2	126	102 - 151
Specimen IMP-7						
All Method	16	146.8	7.0	4.8	149	125 - 168
Beckman AU	10	144.3	7.3	5.0	146	122 - 167
Specimen IMP-8						
All Method	16	150.9	7.4	4.9	152	128 - 174
Beckman AU	10	149.0	8.2	5.5	150	124 - 174
Specimen IMP-9						
All Method	16	49.6	5.7	11.5	48	32 - 67
Beckman AU	10	51.0	6.4	12.5	50	31 - 71
Specimen IMP-10						
All Method	16	149.6	7.0	4.7	153	128 - 171
Beckman AU	10	147.8	8.1	5.5	150	123 - 173

Complement C4 (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen IMP-6						
All Method	16	21.1	1.6	7.7	21	16 - 26
Beckman AU	10	21.5	1.0	4.9	22	18 - 25
Specimen IMP-7						
All Method	16	24.9	1.8	7.1	25	19 - 31
Beckman AU	10	25.5	1.0	4.1	26	22 - 29
Specimen IMP-8						
All Method	16	25.7	2.3	8.9	27	18 - 33
Beckman AU	10	26.7	1.0	3.9	27	23 - 30
Specimen IMP-9						
All Method	16	7.9	0.9	11.8	8	5 - 11
Beckman AU	10	8.0	0.6	7.9	8	6 - 10
Specimen IMP-10						
All Method	16	26.2	1.8	6.8	27	20 - 32
Beckman AU	10	27.0	0.6	2.3	27	25 - 29

IgA (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen IMP-6

All Method	13	199.2	6.1	3.1	200	180 - 218
Beckman AU	10	199.3	6.5	3.3	199	179 - 219

Specimen IMP-7

All Method	13	233.5	6.2	2.7	236	214 - 253
Beckman AU	10	233.3	8.1	3.5	238	209 - 258

Specimen IMP-8

All Method	13	239.2	7.8	3.3	237	215 - 263
Beckman AU	10	238.0	5.0	2.1	238	223 - 253

Specimen IMP-9

All Method	13	75.3	5.7	7.6	76	58 - 93
Beckman AU	10	80.3	1.5	1.9	80	75 - 85

Specimen IMP-10

All Method	13	530.8	20.1	3.8	526	470 - 592
Beckman AU	10	535.0	30.1	5.6	528	444 - 626

IgG (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen IMP-6

All Method	13	939.8	27.6	2.9	935	704 - 1175
Beckman AU	10	940.0	9.8	1.0	937	705 - 1175

Specimen IMP-7

All Method	13	1893.5	106.2	5.6	1925	1420 - 2367
Beckman AU	10	1825.3	104.5	5.7	1766	1368 - 2282

Specimen IMP-8

All Method	13	1124.7	43.7	3.9	1131	843 - 1406
Beckman AU	10	1125.3	30.0	2.7	1124	843 - 1407

Specimen IMP-9

All Method	13	337.2	13.5	4.0	339	252 - 422
Beckman AU	10	332.3	13.7	4.1	330	249 - 416

Specimen IMP-10

All Method	13	1082.2	48.8	4.5	1075	811 - 1353
Beckman AU	10	1096.7	38.4	3.5	1083	822 - 1371

IgM (mg/dL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
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Specimen IMP-6

All Method	13	86.5	4.5	5.2	86	72 - 101
Beckman AU	10	85.0	1.0	1.2	85	82 - 88

Specimen IMP-7

All Method	13	102.5	5.8	5.6	102	85 - 120
Beckman AU	10	101.0	3.6	3.6	100	90 - 112

Specimen IMP-8

All Method	13	347.2	21.8	6.3	346	281 - 413
Beckman AU	10	335.0	14.1	4.2	333	292 - 378

Specimen IMP-9

All Method	13	32.2	1.9	6.0	32	26 - 38
Beckman AU	10	32.3	0.6	1.8	32	30 - 35

Specimen IMP-10

All Method	13	104.5	9.1	8.7	102	77 - 132
Beckman AU	10	98.0	3.0	3.1	98	89 - 107

C-Reactive Protein—Qualitative, Regular

<u>Method</u>	<u>Specimen CR-3</u>		<u>Specimen CR-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	5	-
Siemens Dimension	5	-	5	-

C-Reactive Protein—Quantitative (mg/dL or mg/L), Regular

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen CR-3						
All Method	31	14.654	13.072	89.2	3.04	0.00 - 40.80
mg/dL - units						
Beckman AU	6	2.797	0.267	9.6	2.90	1.95 - 3.64
Siemens Dimension	5	2.852	0.112	3.9	2.86	1.99 - 3.71
All Immunology Methods	16	2.726	0.234	8.6	2.75	1.90 - 3.55
mg/L - units						
All Immunology Methods	15	27.377	5.480	20.0	27.00	16.41 - 38.34

Specimen CR-4

All Method	31	8.315	7.881	94.8	1.75	0.00 - 24.08
mg/dL - units						
Beckman AU	6	1.435	0.086	6.0	1.44	1.00 - 1.87
Siemens Dimension	5	1.398	0.232	16.6	1.40	0.93 - 1.87
All Immunology Methods	16	1.389	0.149	10.7	1.40	0.97 - 1.81
mg/L - units						
All Immunology Methods	15	15.701	4.450	28.3	13.70	6.80 - 24.61

C-Reactive Protein—Quantitative (mg/L), High Sensitivity

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen HCR-3						
All Method	24	0.867	0.190	21.9	0.90	0.00 - 1.87
Beckman AU	8	0.964	0.038	4.0	0.98	0.00 - 1.97
Specimen HCR-4						
All Method	24	3.115	0.382	12.3	3.02	2.11 - 4.12
Beckman AU	9	3.157	0.414	13.1	3.00	2.15 - 4.16

Antinuclear Antibody (ANA) - Qualitative

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	10	1	10	1	-	11
ASI	-	1	-	1	-	1
Bio-Rad	1	-	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	1	-	-	1
Immuno Concepts	2	-	2	-	-	2
INOVA Diagnostics	2	-	2	-	-	2
TheraTest	4	-	4	-	-	4

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	11	-	-	11
ASI	1	-	-	1
Bio-Rad	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1
Immuno Concepts	2	-	-	2
INOVA Diagnostics	2	-	-	2
TheraTest	4	-	-	4

Antinuclear Antibody (ANA)—Semi-Quantitative (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>8/ 10</u>	<u>16/ 20</u>	<u>32/ 40</u>	<u>64/ 80</u>	<u>128/ 160</u>	<u>256/ 320</u>	<u>512/ 640</u>	<u>>640</u>	<u>1024/ 1280</u>	<u>2048/ 2560</u>	<u>≥2560</u>
Specimen AE-6												
ALL METHODS	-	-	-	-	-	1	-	2	-	1	1	-
Bio-Rad	-	-	-	-	-	-	-	1	-	-	1	-
Immuno Concepts	-	-	-	-	-	1	-	1	-	-	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-7												
ALL METHODS	-	-	-	-	-	-	2	1	-	2	-	-
Bio-Rad	-	-	-	-	-	-	1	1	-	-	-	-
Immuno Concepts	-	-	-	-	-	-	1	-	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	-	-	1	-	-
Specimen AE-8												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-
Specimen AE-9												
ALL METHODS	-	-	-	-	1	-	-	2	1	1	-	-
Bio-Rad	-	-	-	-	-	-	-	1	1	-	-	-
Immuno Concepts	-	-	-	-	1	-	-	-	-	1	-	-
INOVA Diagnostics	-	-	-	-	-	-	-	1	-	-	-	-
Specimen AE-10												
ALL METHODS	5	-	-	-	-	-	-	-	-	-	-	-
Bio-Rad	2	-	-	-	-	-	-	-	-	-	-	-
Immuno Concepts	2	-	-	-	-	-	-	-	-	-	-	-
INOVA Diagnostics	1	-	-	-	-	-	-	-	-	-	-	-

Anti-dsDNA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	6	1	6	-	7
GenBio ImmunoDOT Panel 1	-	1	1	-	-	1
Immuno Concepts	1	-	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	-	4	-	4	-	4

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	7	-	7
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Anti-RNP

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	1	-	2	-	2
Immuno Concepts	1	-	-	1	-	1
Phadia EliA	-	1	-	1	-	1

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	2	-	2
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1

Anti-RNP/Sm

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	-	6	-	6
GenBio ImmunoDOT Panel 1	1	-	-	1	-	1
Immuno Concepts	1	-	-	1	-	1
TheraTest	4	-	-	4	-	4

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6
GenBio ImmunoDOT Panel 1	-	1	-	1
Immuno Concepts	-	1	-	1
TheraTest	-	4	-	4

Anti-SSA

<u>Method</u>	Specimen AE-6		Specimen AE-7		Specimen AE-8	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	6	-	-	6
Immuno Concepts	1	-	1	-	-	1
Phadia EliA	1	-	1	-	-	1
TheraTest	4	-	4	-	-	4

<u>Method</u>	Specimen AE-9		Specimen AE-10	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	6	-	-	6
Immuno Concepts	1	-	-	1
Phadia EliA	1	-	-	1
TheraTest	4	-	-	4

Anti-SSB

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	3	3	5	1	-	6
Immuno Concepts	-	1	1	-	-	1
Phadia EliA	-	1	1	-	-	1
TheraTest	3	1	3	1	-	4

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	1	-	6
Immuno Concepts	1	-	-	1
Phadia EliA	1	-	-	1
TheraTest	3	1	-	4

Anti-SSA/SSB

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	1	-	-	1

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	1	-	-	1
GenBio ImmunoDOT Panel 1	1	-	-	1

Anti-Sm

<u>Method</u>	<u>Specimen AE-6</u>		<u>Specimen AE-7</u>		<u>Specimen AE-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	1	-	6	-	6
Immuno Concepts	1	-	-	1	-	1
Phadia EliA	-	1	-	1	-	1
TheraTest	4	-	-	4	-	4

<u>Method</u>	<u>Specimen AE-9</u>		<u>Specimen AE-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	6	-	6
Immuno Concepts	-	1	-	1
Phadia EliA	-	1	-	1
TheraTest	-	4	-	4

Rubella—Qualitative

<u>Method</u>	<u>Specimen RU-6</u>		<u>Specimen RU-7</u>		<u>Specimen RU-8</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	5	-
Siemens ADVIA Centaur	5	-	-	5	5	-

<u>Method</u>	<u>Specimen RU-9</u>		<u>Specimen RU-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	-	5	5	-
Siemens ADVIA Centaur	-	5	5	-

Rubella—Quantitative (IU/mL)

One lab reported results for Rubella – Quantitative (IU/mL). The vendor assay values on a Beckman Access 2 for specimens RU-6 through RU-10 are: 65.2 IU/mL, <10.0 IU/mL, 41.2 IU/mL, <10.0 IU/mL, and 41.2 IU/mL, respectively.

Anti-HIV

<u>Method</u>	<u>Specimen HIV-6</u>		<u>Specimen HIV-7</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	22	43	64	1
Alere Clearview HIV1/2 STAT-PAK	1	-	1	-
Alere Determine - moderate	2	-	2	-
Alere Determine - waived	15	-	15	-
bioLytical Labs INSTI HIV - moderate	-	2	2	-
bioLytical Labs INSTI HIV - waived	-	11	11	-
Chembio HIV 1/2 Assay - waived	-	16	16	-
Orasure OraQuick Advance Rapid HIV-1/2 - waived	1	14	14	1
Other Waived method	3	-	3	-

<u>Method</u>	<u>Specimen HIV-8</u>		<u>Specimen HIV-9</u>		<u>Specimen HIV-10</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	-	5	-	5
bioLytical Labs INSTI HIV - moderate	5	-	-	5	-	5

Note: Specimen HIV-6 was by Peer Group. This sample contained the p24 Antigen.

Allergen Specific IgE Antibodies

Specimen AL-6

<u>Method</u>	Maple (Box Elder) (t1) Allergen CLASS RESULT								Grey Alder (t2) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	2	-	-	-	-	-	-	-	1	1	-	-	-
Hitachi CLA-1	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	1	-	-	-	-	-	-	-	1	1	-	-	-

	Dog Dander (e5) Allergen CLASS RESULT								Horse Dander (e3) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	1	1	2	-	-	-	-	-	1	1	-	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	1	-	1	-	-	-	-	-	1	1	-	-	-

	Penicilloyl G (c1) Allergen CLASS RESULT								Bermuda Grass (g2) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	2	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-
Hitachi CLA-1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	1	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-

	Perennial Rye (g5) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	-	-	2	2	-	-
Hitachi CLA-1	-	-	-	-	1	1	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	-	1	1	-	-

Allergen Specific IgE Antibodies

Specimen AL-7

<u>Method</u>	Common (Short) Ragweed (w1) Allergen CLASS RESULT								Russian Thistle (w11) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	1	-	-	2	2	-	-	-	-	1	1	-	-	-	-	-
Hitachi CLA-1	1	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	-	2	1	-	-	-	-	1	1	-	-	-	-	-
	Bermuda Grass (g2) Allergen CLASS RESULT								House Dust Mite (D. pteronyssinus) (d1) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	1	1	-	-	-	-	-	-	-	2	1	-	-	-
Hitachi CLA-1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	1	-	-	-	-	-	-	-	2	1	-	-	-
	Maple (Sycamore) (t11) Allergen CLASS RESULT								Soybean (f14) Allergen CLASS RESULT							
	0	0/1	1	2	3	4	5	6	0	0/1	1	2	3	4	5	6
ALL METHODS	-	-	2	1	-	-	-	-	-	1	-	-	1	-	-	-
Hitachi CLA-1	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-
Phadia ImmunoCAP System (KU/L)	-	-	1	1	-	-	-	-	-	1	-	-	1	-	-	-
	Egg White (f1) Allergen CLASS RESULT															
	0	0/1	1	2	3	4	5	6								
ALL METHODS	-	-	3	-	-	1	-	-								
Hitachi CLA-1	-	-	1	-	-	1	-	-								
Phadia ImmunoCAP System (KU/L)	-	-	2	1	-	-	-	-								

Total IgE—Quantitative (U/mL)

<u>Specimen/Method</u>	<u>Labs</u>	<u>Mean</u>	<u>SD</u>	<u>CV</u>	<u>Median</u>	<u>Range</u>
Specimen AL-6						
All Method	6	214.3	14.5	6.8	207	170 - 258
Specimen AL-7						
All Method	6	125.7	4.2	3.3	127	113 - 139
Specimen AL-8						
All Method	3	17.0	2.0	11.8	17	11 - 23
Specimen AL-9						
All Method	6	7.0	0.1	0.0	7	6 - 8
Specimen AL-10						
All Method	6	18.0	1.0	5.6	18	15 - 21

Syphilis Serology—Qualitative: MHA-TP

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	4	4	-	-	4
Serodia	-	4	4	-	-	4

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	4	-	4	-
Serodia	4	-	4	-

Syphilis Serology—Qualitative: Treponema pallidum antibodies

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	9	9	-	-	9
Abbott Architect	-	1	1	-	-	1
diagnostics direct Syphilis Health	-	6	6	-	-	6
Check	-	2	2	-	-	2
Siemens ADVIA	-	2	2	-	-	2

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	9	-	9	-
Abbott Architect	1	-	1	-
diagnostics direct Syphilis Health	6	-	6	-
Check	2	-	2	-
Siemens ADVIA Centaur	2	-	2	-

Syphilis Serology—Qualitative: RPR

<u>Method</u>	Specimen SY-6		Specimen SY-7		Specimen SY-8	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	-	13	12	1	-	13
ASI	-	5	4	1	-	5
Becton Dickinson	-	5	5	-	-	5
Fisher HealthCare Sure-Vue	-	3	3	-	-	3

<u>Method</u>	Specimen SY-9		Specimen SY-10	
	<u>Reactive</u>	<u>Non-Reactive</u>	<u>Reactive</u>	<u>Non-Reactive</u>
ALL METHODS	13	-	13	-
ASI	5	-	5	-
Becton Dickinson	5	-	5	-
Fisher HealthCare Sure-Vue	3	-	3	-

Syphilis Serology—Semi-Quantitative: RPR (Titer)

<u>Specimen/Method</u>	<u>N/A (Neg)</u>	<u>1:1</u>	<u>1:2</u>	<u>1:4</u>	<u>1:8</u>	<u>1:16</u>	<u>1:32</u>	<u>1:64</u>	<u>1:>64</u>
Specimen SY-6									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-7									
ALL METHODS	1	-	2	4	-	-	-	-	-
ASI	1	-	1	-	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-8									
ALL METHODS	7	-	-	-	-	-	-	-	-
ASI	2	-	-	-	-	-	-	-	-
Becton Dickinson	4	-	-	-	-	-	-	-	-
Specimen SY-9									
ALL METHODS	-	-	2	5	-	-	-	-	-
ASI	-	-	1	1	-	-	-	-	-
Becton Dickinson	-	-	-	4	-	-	-	-	-
Specimen SY-10									
ALL METHODS	-	-	-	2	5	-	-	-	-
ASI	-	-	-	2	-	-	-	-	-
Becton Dickinson	-	-	-	-	4	-	-	-	-

H. pylori Antibody Detection

<u>Method</u>	<u>Specimen HP-3</u>		<u>Specimen HP-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	36	-	-	36
Alere Clearview - moderate	2	-	-	2
Alere Clearview - waived	1	-	-	1
Alfa Scientific Instant-View	2	-	-	2
Consult Diagnostics - moderate	5	-	-	5
Consult Diagnostics - waived	6	-	-	6
Fisher HealthCare Sure-View	1	-	-	1
Henry Schein OneStep+ - moderate	1	-	-	1
Henry Schein OneStep+ - waived	8	-	-	8
McKesson Medi-Lab Performance - waived	3	-	-	3
NDC Pro Advantage	1	-	-	1
Polymedco Poly stat	1	-	-	1
Quidel QuickVue	5	-	-	5

Mycoplasma Antibody

<u>Method</u>	<u>Specimen MY-3</u>		<u>Specimen MY-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	5	-	1	4
Meridian ImmunoCard	4	-	1	4

SARS-CoV-2 Serology

<u>Method</u>	<u>Specimen SAB-3</u>		<u>Specimen SAB-4</u>	
	<u>Positive</u>	<u>Negative</u>	<u>Positive</u>	<u>Negative</u>
ALL METHODS	19	-	-	19
Abbott Architect	4	-	-	4
Beckman ACCESS / 2 / Dxl	4	-	-	4
Healgen Scientific	2	-	-	2
Other EUA method	2	-	-	2
Roche cobas 6000 / e 601	2	-	-	2
Roche cobas e 411	2	-	-	2
Siemens ADVIA	1	-	-	1
VITROS Eci	1	-	-	1

Viral Markers – Anti-HBc (IgM)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-	-	7	1
Abbott Architect	-	5	-	-	5	-	-	4	1
VITROS 5600	-	2	-	-	2	-	-	2	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-
Abbott Architect	-	5	-	-	5	-
VITROS 5600	-	2	-	-	2	-

Viral Markers – Anti-HBc (Total/IgG)

<u>Method</u>	Specimen VM-6			Specimen VM-7			Specimen VM-8		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	-	-	-	6	-	6	-	-
Abbott Alinity	1	-	-	-	1	-	1	-	-
Abbott Architect	4	-	-	-	4	-	4	-	-
Roche cobas 6000 / e 601	1	-	-	-	1	-	1	-	-

<u>Method</u>	Specimen VM-9			Specimen VM-10		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	6	-	-	-	6	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	4	-	-	-	4	-
Roche cobas 6000 / e 601	1	-	-	-	1	-

Viral Markers – Anti-HIV

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	10	-	-	10	-	-	10	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	5	-	-	5	-	-	5	-
bioLytical Labs INSTI									
HIV - moderate	-	1	-	-	1	-	-	1	-
Orasure OraQuick									
Advance Rapid HIV-1/2 - waived	-	2	-	-	2	-	-	2	-
Siemens ADVIA	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	10	-	10	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	5	-	5	-	-
bioLytical Labs INSTI						
HIV - moderate	-	1	-	1	-	-
Orasure OraQuick						
Advance Rapid HIV-1/2 - waived	-	2	-	2	-	-
Siemens ADVIA	-	1	-	1	-	-

Viral Markers – Anti-HAV (IgM)

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	7	-	-	7	-	-	7	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	4	-	-	4	-	-	4	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	-	1	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	7	-	-	-	7	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	4	-	-	-	4	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
VITROS 5600	1	-	-	-	1	-

Viral Markers – Anti-HAV (Total/IgG)

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	4	-	4	-	-	4	-	-
Abbott Architect	-	3	-	3	-	-	3	-	-
Siemens ADVIA	-	1	-	1	-	-	1	-	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	4	-	-	4	-	-
Abbott Architect	3	-	-	3	-	-
Siemens ADVIA	1	-	-	1	-	-

Viral Markers – HBeAg

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	5	-	-	5	-	5	-	-
Abbott Architect	-	5	-	-	5	-	5	-	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	1	4	-	-	5	-
Abbott Architect	1	4	-	-	5	-

Viral Markers – Anti-HBs

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	6	-	6	-	-	-	6	-
Abbott Alinity	-	1	-	1	-	-	-	1	-
Abbott Architect	-	3	-	3	-	-	-	3	-
Roche cobas 6000 / e 601	-	1	-	1	-	-	-	1	-
Siemens ADVIA	-	1	-	1	-	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	6	-	6	-	-
Abbott Alinity	-	1	-	1	-	-
Abbott Architect	-	3	-	3	-	-
Roche cobas 6000 / e 601	-	1	-	1	-	-
Siemens ADVIA	-	1	-	1	-	-

Viral Markers – HBsAg

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	9	-	-	9	-	9	-	-
Abbott Alinity	-	1	-	-	1	-	1	-	-
Abbott Architect	-	4	-	-	4	-	4	-	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	1	-	-
Siemens ADVIA	-	2	-	-	2	-	2	-	-
VITROS 5600	-	1	-	-	1	-	1	-	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	8	-	1	-	9	-
Abbott Alinity	1	-	-	-	1	-
Abbott Architect	4	-	-	-	4	-
Roche cobas 6000 / e 601	1	-	-	-	1	-
Siemens ADVIA	2	-	-	-	2	-
VITROS 5600	-	-	1	-	1	-

Viral Markers – Anti-HCV

<u>Method</u>	<u>Specimen VM-6</u>			<u>Specimen VM-7</u>			<u>Specimen VM-8</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	14	-	-	14	-	2	12	-
Abbott Alinity	-	1	-	-	1	-	-	1	-
Abbott Architect	-	5	-	-	5	-	-	5	-
OraSure OraQuick HCV	-	2	-	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-	1	-	-
Roche cobas e 411	-	1	-	-	1	-	1	-	-
Siemens ADVIA	-	3	-	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-	-	1	-

<u>Method</u>	<u>Specimen VM-9</u>			<u>Specimen VM-10</u>		
	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>	<u>Positive</u>	<u>Negative</u>	<u>Equivocal</u>
ALL METHODS	-	14	-	-	14	-
Abbott Alinity	-	1	-	-	1	-
Abbott Architect	-	5	-	-	5	-
OraSure OraQuick HCV	-	2	-	-	2	-
Roche cobas 6000 / e 601	-	1	-	-	1	-
Roche cobas e 411	-	1	-	-	1	-
Siemens ADVIA	-	3	-	-	3	-
VITROS 5600	-	1	-	-	1	-

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