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Performance Characteristics of the ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay for the Simultaneous Qualitative Detection of HIV p24 Antigen and Antibodies to HIV-1 (Groups M and O) and HIV-2 in Human Serum or Plasma

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This Assay is not available for sale in the U.S. This assay is CE marked. ADVIA Centaur HIV Ag/Ab Combo assay is developed, manufactured, and sold by Siemens Healthcare Diagnostics Inc. for Ortho-Clinical Diagnostics Inc.

ADVIA Centaur CHIV: Principle of the Procedure

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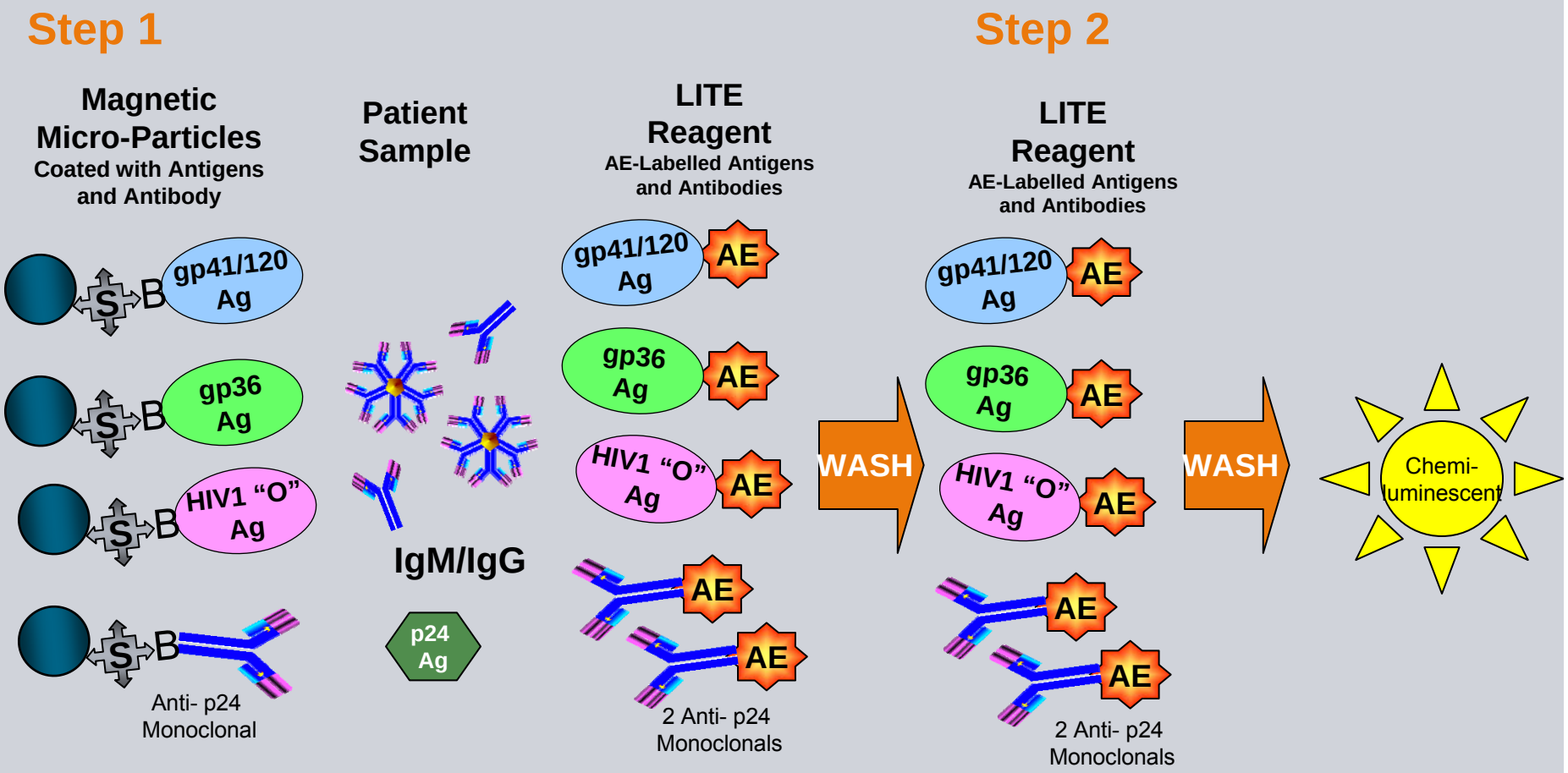

Time 18 min 18 min **56 Min**

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Sensitivity of the ADVIA Centaur CHIV Assay

Sample Classification	Number of Samples Tested	ADVIA Centaur CHIV Assay		Vendor CoA (HIV Reactive)	CHIV2 Sensitivity
		Non Reactive	Reactive		
Characterized HIV Positive Samples	538	0	538	538	100% (538/538)
p24 Core Antigen Reactive Samples	131	0	131	131	100% (131/131)
HIV Type 2 Specific Samples	54	0	54	54	100% (54/54)
HIV-1 Group O Reactive Samples	5	0	5	5	100% (5/5)
Total	**728**	**0**	**728**	**728**	**100% (728/728)**

Lysate Classification	Number of Lysates Tested	ADVIA Centaur CHIV Assay		CoA (HIV Reactive)	CHIV2 Sensitivity
		Non Reactive	Reactive		
HIV-1 Viral Lysates	47	0	47	47	100% (47/47)
HIV-2 Viral Lysates	1	0	1	1	100% (1/1)
Total	**48**	**0**	**48**	**48**	**100% (48/48)**

The 728 presumably positive samples and 48 viral particle (antigen) isolates, which included isotypes A, B, C, D, F, G, O, AE and AG as well as HIV-2 strain NHIZ, were tested by the ADVIA Centaur CHIV assay. All samples were reactive, and the observed sensitivity of the assay was 100% (Exact 95% CI 99.58%-100%).

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Resolved Specificity of the ADVIA Centaur CHIV Assay

Sample List	Number Tested	ADVIA Centaur CHIV Assay		ADVIA Centaur Assay Specificity	95% CI
		Nonreactive	Reactive		
Fresh Donors (US)	1866	1863	3	99.83% (1863/1866)	99.53%-99.6%
Fresh Donors (Finland)	1908*	1900	5	99.73% (1900/1905)	99.38%-99.91%
Frozen	5210	5201	9	99.83% (5201/5210)	99.67%-99.92%
Hospitalized Patients	207	207	0	100.00%	98.56%-100%
Total	**9191***	**9171**	**17**	**99.81% (9171/9188)**	**99.70%-99.89%**

*Three samples were confirmed to be true positives and were omitted from the calculation. The final number of negative samples for this group was 1905.

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Seroconversion Sensitivity

Results from 45 Seroconversion Panels

- Compared to HIV 1/2 Antibody Assay Results on Vendor C of A.
  - Positive on the same bleed on 10 panels
  - Positive 1 or more bleeds earlier with 35 panels

- Compared to the HIV p24 Antigen test results in the Vendor C of A the CHIV results were equivalent to, or better than, at least one of the p24 Antigen test results.

HIV-1 p24 Antigen sensitivity by NIBSC WHO Reagent (1st International Standard).

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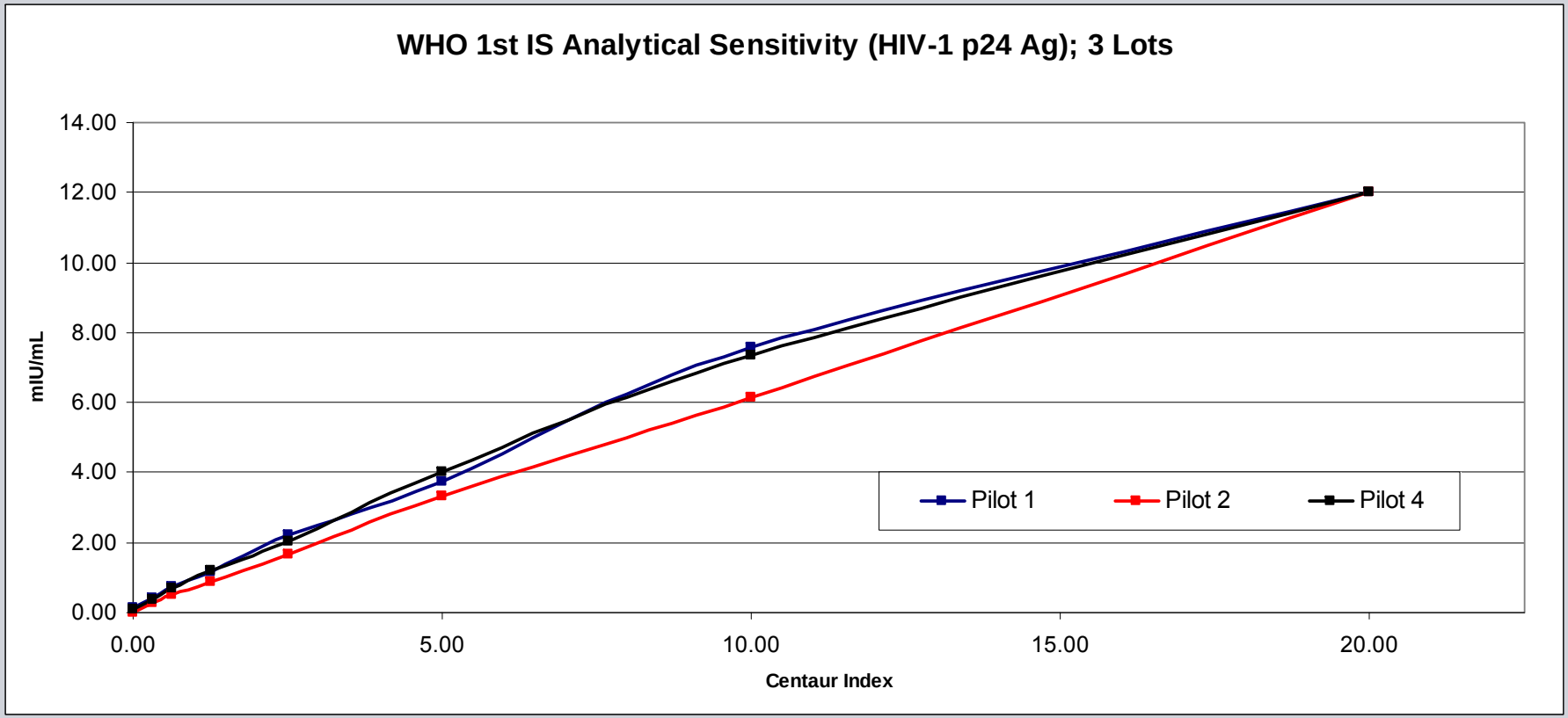

HIV1-p24 Antigen Sensitivity via NIBSC WHO Reagent (Lot 90/636) at assay index 1.0			
Centaur CHIV			
PL1	PL2	PL4	Avg
1.074 IU/mL	1.393 IU/mL	1.042 IU/mL	1.167 IU/mL

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HIV-1 p24 Antigen Sensitivity in pg/ml

HIV-1 p24 Antigen Sensitivity was measured using dilutions of the Zeptometrix HIV-1 p24 Antigen standard. Numbers in the shaded rows were omitted from the regression calculation.

	Pilot1		Pilot 2		Pilot 4		Pilot 5		Pilot 6	
Sample	**Index**	**pg/ml**	**Index**	**pg/ml**	**Index**	**pg/ml**	**Index**	**pg/ml**	**Index**	**pg/ml**
P24 Standard (pg/ml from Zepto EIA)										
125.00	**11.79**	**134.29**	**10.69**	**119.49**	**14.21**	**127.79**	**16.18**	**144.98**	**24.67**	**155.30**
62.50	**5.61**	**61.69**	**5.69**	**61.87**	**7.05**	**61.48**	**7.19**	**62.57**	**10.15**	**63.05**
31.25	**3.10**	**32.24**	**3.07**	**31.72**	**3.94**	**32.67**	**3.77**	**31.26**	**4.95**	**30.01**
15.63	**1.79**	**16.85**	**1.79**	**16.96**	**2.22**	**16.73**	**1.97**	**14.75**	**2.68**	**15.59**
7.81	**1.01**	**7.71**	**1.04**	**8.29**	**1.26**	**7.88**	**1.32**	**8.80**	**1.47**	**7.91**
3.90	**0.66**	**3.65**	**0.62**	**3.41**	**0.77**	**3.36**	**0.79**	**3.91**	**0.89**	**4.22**
1.95	**0.43**	**0.90**	**0.39**	**0.79**	**0.51**	**0.91**	**0.55**	**1.75**	**0.58**	**2.25**
0.98	**0.30**	**-0.65**	**0.28**	**-0.48**	**0.36**	**-0.47**	**0.39**	**0.25**	**0.39**	**1.04**
0.495	**0.22**	**-1.55**	**0.21**	**-1.31**	**0.27**	**-1.28**	**0.3**	**-0.66**	**0.3**	**0.35**
	1.00	**7.6**	**1.00**	**7.8**	**1.00**	**5.5**	**1.00**	**5.9**	**1.00**	**4.9**
	slope	11.74	slope	11.52	slope	9.26	slope	9.16	slope	6.35
	intercept	-4.13	intercept	-3.69	intercept	-3.79	intercept	-3.29	intercept	-1.43

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Conclusion

- The ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay is useful for the simultaneous qualitative detection of human immunodeficiency virus p24 antigen and antibodies to human immunodeficiency viruses type 1 (including group “O”) and type 2, in serum and plasma.
- This fully automated assay is accurate and reliable, comparable to existing assays, and provides excellent sensitivity and specificity to aid in the diagnosis of HIV infection.