Bio-Rad Geenius HIV-1/2 assay as an alternative to the INNO-LIA HIV-1/2 assay for CLSI M53 algorithm

Aitziber Aguinaga Pérez[1], Ana Navascués Ortega[1,2], Isabel Polo Vigas[1,2], Xabier Beristain Rementería[1,2], Carmen Ezpeleta Baquedano[1,2]

[1]Servicio de Microbiología Clínica. Complejo Hospitalario de Navarra. [2] Instituto de Investigación Sanitaria de Navarra, IdiSNA, Pamplona, Navarra, Spain

Background: The CDC and CLSI published the updated recommendations for laboratory testing for HIV Infection. They include tests for HIV antigens and nucleic acid because antibody testing alone might miss a considerable percentage of HIV infections detectable by virologic tests. The Western blot is no longer part of the algorithm. This new algorithm, specifically the second stage addresses the need to detect and differentiate HIV-2 from HIV-1 antibodies. The aim of this study is to compare the performance of the Geenius HIV-1/2 confirmatory assay as an alternative to the INNO-LIA assay.

Methods: Testing sequence: Geenius HIV-1/2 assay (Bio-rad Laboratories, Marnes-la-Coquette, France) and INNO-LIA HIV-1/2 score line-immunoassay (Innogenetics®, Gent, Belgium) are carried out to confirm a positive ≥ 1 S/CO in the initial 4th generation HIV Antigen-Antibody assay (Architect, Abbott, Wiesbaden, Germany) to all the new diagnosed cases. Viral load HIV-1 (Cobas AmpliPrep/HIV, Roche, Mannheim, Germany) is carried out in all negative and indeterminate cases, to rule out false-negative results early in the course of HIV infection. Study period: 1/1/2015 to 30/9/2015.

Results: 19.591 samples were tested during study period. 64 out of them were positives at the initial antigen-antibody assay. The mean age of patients was 37 years (12-63 years). Forty of them were male. In 60 of 64 samples, the results were concordant in the two confirmatory assays: 40 were HIV-1 infection, 1 HIV-2, 18 negatives and 1 indeterminate. Discordant results were obtained in 4 samples: 3 were indeterminate by INNO-LIA while 1 of them was an HIV-1 infection and the other 2 were negatives by Geenius. One was indeterminate by Geenius and negative by INNO-LIA.

Table 1: Discordant results of confirmatory assays nd indeterminate result

Patient	EIA (S/Co)	Confirmatory assay	Results	GP 41	p31	p24	GP36	Viral load (log)	Monitoring over time (≥ 6 months)
5	21.46	INNOLIA	IND	P	N	N	N	RNA no detected	
		GEENIUS	IND	P	N	N	N		Ongoing
6	1.95	INNOLIA	IND	N	N	P	N	RNA no detected	VIH-1 infection Not confirmed
		GEENIUS	N	N	N	N	N		
10	542.01	INNOLIA	IND	P	P	I	N	5.57	
		GEENIUS	P GP160 P	P	N	N	N		VIH-1 infection Confirmed
61	110.03	INNOLIA	IND	P	N	N	N	5.03	VIH-1 infection Confirmed
		GEENIUS	N	N	N	N	N		
78	2.51	INNOLIA	N	N	N	N	N	RNA no detected	VIH-1 infection Not confirmed
		GEENIUS	IND	P	N	N	N		

Results: Index of concordance or agreement was measured between the results of INNO-LIA and Geenius. Cohen's kappa coefficient was 0.87; shown almost perfect agreement between result of both confirmatory test.
INNO-LIA assay shown more indeterminate results than Geenius. Geenius assay fell to diagnose acute HIV (patient number 61).
The discordant results between antigen lines are shown in Table 2. Discrepancies were mainly observed among antigens p24 and p31.

Table 2: Discordant lines at detail

Patiens	VIH Status	INNO-LIA Results	GEENIUS Results	Specific antibody and different results between confirmatory test		
				Antibody	INNO-LIA	GEENIUS
6	N	IND	N	p24	P	N
10	P	IND	P	P31	P	N
				P24	IND	N
11, 96	P	P	P	P31	P	N
				P24	P	N
13, 14, 37, 38, 41, 77, 91, 96	P	P	P	P31	P	N
15, 24, 45, 47, 79, 83, 87, 88, 65	P	P	P	P24	P	N
36	P	P	P	P31	IND	N
				P24	P	N
61	P	IND	N	GP41	P	N
68	P	P	P	GP36	N	P
71	P	P	P	P31	N	P
78	N	N	IND	GP41	N	P
81	N	N	IND	GP41	N	P

Conclusions:

1. There is good agreement between the two confirmatory assays. The Geenius test requires less skill and training of technical staff, less time to get the results and has an automatic reading. The number of indeterminate results with Geenius is lesser than that obtained with INNO-LIA.
2. More samples are required to assess the accuracy to diagnose early infection. Viral load is necessary to confirm the diagnosis, mainly in case with indeterminate or discordant results.
3. Patients with high-risk exposure and suspicion of acute HIV infection new determinations of serology and viral load three weeks later are recommended.

Reference:
http://www.cdc.gov/hiv/testing/laboratorytests.html
Diagnosis and management of acute HIV infection. New York State Department of Health AIDS Institute: www.hivguidelines.org. 2015.
Hawthorne Halle A, Samuelson A, Nordin M, Albert J, Bogdanovic G. Evaluation of Bio-Rad Geenis HIV-1 and-2 assay as confirmatory assay for detection of HIV-1 and -2 antibodies. Clinical and vaccine Immunology. 2014;21(8):1192-1194.