EV0027
ePoster Viewing
HIV/AIDS (incl anti-retroviral drugs, treatment & susceptibility/resistance, diagnostics & epidemiology)

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

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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 Ab. The aim of this study is to compare the performance of the Geenius HIV-1/2 confirmatory assay as an alternative to the INNOLIA assay.

Material/methods: Testing sequence: Geenius HIV-1/2 assay (Biorad) and INNOLIA HIV-1/2 score line-immunoassay (Innogenetics) are carried out to confirm a positive ≥1S/CO in the initial 4th generation HIV Antigen-Antibody assay (Architect, Abbott) to all the new diagnosed cases. Viral load VIH-1 (Cobas AmpliPrep/HIV, Roche) 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, 64 out of them were positives at the initial Ag-Ab assay. In 60/64 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 INNOLIA while 1 of them was a HIV-1 infection and the other 2 were negatives by Geenius. One was indeterminate by Geenius and negative by INNOLIA. The discordant or indeterminate results were further analysed (table).

EIA (S/CO)	Confirmatory assay	Results	GP 41	P31	P24	GP36	Viral load (log)	Monitoring over time (≥ 6 months)
21.46	INNOLIA	INDETERMINATE	P	N	N	N	RNA no detected	Ongoing
	GEENIUS	INDETERMINATE	P	N	N	N		
1.95	INNOLIA	INDETERMINATE	N	N	P	N	RNA no detected	VIH-1 infection Not confirmed
	GEENIUS	NEGATIVE	N	N	N	N		
542.01	INNOLIA	INDETERMINATE	P	P	I	N	5.57	VIH-1 infection Confirmed

	GEENIUS	POSITIVE (GP160 P)	P	N	N	N		
110.03	INNOLIA	INDETERMINATE	P	N	N	N	5.03	VIH-1 infection Confirmed
	GEENIUS	NEGATIVE	N	N	N	N		
2.51	INNOLIA	NEGATIVE	N	N	N	N	ND	Ongoing
	GEENIUS	INDETERMINATE	P	N	N	N		

Conclusions: 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 INNOLIA. 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.