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First comparison of 3 syphilis antibodies confirmation tools: two automated immunoblot and one ELISA spot test

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PURPOSE

Congenital syphilis (CS) is very rare but extremely severe: fetal loss/neonatal death (50%), prematurity (25%) and major long-term sequelae in other surviving children (20%) (1). It then requires careful diagnosis.

⇒ Interest of immunoblot :

- Confirmation of IgG in pregnant women (numerous false-positives)
- Detection of IgM in case of suspicion of CS in the newborn

OBJECTIVES

Compare the specificity and practicability of three confirmatory techniques for the diagnosis of CS

MATERIAL & METHODS

- Retrospective and monocentric study
- Conducted at the Institute of Infectious Agents (CHU Lyon, France) in 2020

Clinical diagnosis		Syphilis serological profile: Treponemal test (Abbott ARCHITECT Syphilis TP)	Syphilis serological profile: Non-treponemal test (RPR, Biorad®)	Number of patients
Syphilis (n=67)	Active syphilis	+	+	39
	Serological scar	+	-	25
	Pregnant women	+	+/-	3
Non syphilis (n=37) (main cross reactions described in literature)	Primary infection EBV			9
	Lyme disease			1
	ANCA autoantibodies			6
	Primary infection VIH			10
	Leptospirosis			1
	Pregnant women			10
Total				104

Table 1. Study population

- Sera analyzed by the three methods; detection of antibodies directed against four membrane protein specific for *Treponema pallidum*: TmpA,

Kit	Virotech Tp IgG / IgM LINE	RecomLine® IgG / IgM	SeraSpot® Anti-*Treponema* IgG/IgM
Company	Eurobio®	Biosynex®	R-Biopharm®
Technique	Immunoblot	Immunoblot	ELISA spot array
Automaton	Dynablot	Carl®	SeraSpot®
			 

RESULTS

Evaluation of sensitivity in a population with active syphilis or serological scar is good on the different methods analyzed (Table 2). Evaluation of the different cross-reactions through specificity shows 2 sera Epstein-Barr virus primary infection positive with Eurobio® or Biosynex® immunoblots. No cross reaction was detected in the other

	Specificity (%) [IC_{95} (%)]		Sensitivity (%) [IC_{95} (%)]
	IgG	IgM	IgG
Virotech *T. pallidum* IgG/IgM LINE Eurobio®	97 [85.5 – 100]	100 [90,3 – 100]	99 [92,0 – 99,9]
RecomLine® IgG/IgM Biosynex®	100 [90.3 – 100]	97.0 [85.5 – 100]	100 [94,6 – 100]
Seraspot® Anti-*Treponema* IgG/IgM R-biopharm®	100 [90,3 – 100]	100 [90.3 – 100]	99 [92,0 – 99,9]

Table 2. Performance summary

	Percentage of failures requiring serum re-testing (%) IgG + IgM
Virotech *T. pallidum* IgG/IgM LINE Eurobio®	1
RecomLine® IgG/IgM Biosynex®	16
Seraspot® Anti-Treponema IgG/IgM R-biopharm®	1

Table 3. Percentage of failures requiring serum re-testing

	RecomLine® IgG/IgM Biosynex®	Virotech *T. pallidum* IgG/IgM Eurobio®	SeraSpot® IgG/IgM R-Biopharm®
Technical characteristics of the automaton, reagents and consumables (/4)			
Ergonomics	2	3	3
Reagent management	2	4	3
Waste management	3	4	4
Strip drying	3	3	not assessable
Strip handling	2	4	not assessable
Software features (/4)			
Proposed features	2	3	3
Launching of the analyses	3	3	3
Results	2	4	4
Report creation	3	4	4
Percentage score	**61%**	**89%**	**86%**

Table 4. Technical evaluation grid

Excellent and comparable performances

Specificities (IgM and IgG) 99 – 100%

Sensitivities (IgG) 97 – 100%

Praticability and ergonomics are in favor of Eurobio® Immunoblot and the Seraspot®

SUMMARY / CONCLUSION

- First study to assess the diagnostic performance and practicability of syphilis immunoblots
- Performances comparable and excellent:
  - IgG specificities close to 100% → reliable clinician response for pregnant women
  - IgM specificities close to 100% → reliable response to the clinician in case of suspicion of CS in a newborn.

By combining performance and practicality, Eurobio® immunoblot and the Seraspot® method could thus be positioned as confirmatory tests in our laboratory. Subsequently, an evaluation on a larger cohort, in particular for cross-reactions and sera from women/children with suspected congenital syphilis, will confirm the performance of these automats in this indication.

REFERENCES

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