EVALUATION OF IGG AND IGM ASSAYS ON THE NEW VIDIA® INSTRUMENT AND COMPARISON WITH THE ARCHITECT® AND VIDAS® ASSAYS

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INTRODUCTION

Rubella IgG and IgM assays are especially important in the context of the pregnancy serology, since acute rubella carries a high risk of congenital rubella syndrome in the newborn. Serological status determination is mostly important for women of childbearing age in order to exclude a potential seroconversion during pregnancy. IgG false positivity must be excluded as far as possible.

The aim of the present study was to evaluate the performance of the new Vidia® (Biomerieux) Rubella IgG and IgM assays and to compare it with the performances of automates used in our laboratory (Architect® (Abbott) and Vidas® (Biomerieux) used for confirmation of Architect results).

MATERIAL AND METHODS

Samples: Rubella IgG (IU/ml) and IgM (index) concentrations were measured for 150 sera (whose rubella serology was requested by physician) with the three methods described upper.
Discrepant results in IgG and IgM: The « 2 out of 3 » statistical method was used to define the IgG serological status and IgG avidity was used for the IgM one (when there were discrepancies between results or to confirm a positive IgM status).
Data analysis: All results equal or higher to the respective tresholds were considered and classified as positive; nevertheless, interpretation of equivocal results in IgG ([treshold; 2x treshold[) is given as « uncertain immunity » in our lab.

Table 1: Summary of the results with the three instruments

	Sero status +	Sero status -
Vidia® IgG+	123	3 (b)
Vidia® IgG-	2 (a)	22

	Sero status +	Sero status -
Vidia® IgM+	11	11 (d)
Vidia® IgM-	0 (c)	126

	Sero status +	Sero status -
Vidas® IgG+	122	0 (b)
Vidas® IgG-	3 (a)	25

	Sero status +	Sero status -
Vidas® IgM+	11	23 (d)
Vidas® IgM-	0 (c)	114

	Sero status +	Sero status -
Architect® IgG+	120	2 (b)
Architect® IgG-	5 (a)	23

	Sero status +	Sero status -
Architect® IgM+	11	27 (d)
Architect® IgM-	0 (c)	110

Table 2: Inconsistent IgG Vidia® results with serological status

Sample	Vidia® (< 10IU/ml)	Vidas® (< 15 IU/ml)	Architect® (< 10 IU/ml)	Sero status	Interpretation
1	9	18	34	Positive	Equivocal
2	9	21	11	Positive	Equivocal
3	14	14	8	Negative	Negative
4	17	14	3	Negative	Negative
5	12	12	5	Negative	Negative

Table 3: Inconsistent IgM Vidia® results with avidity

Sample	Vidia® (< 1 index)	Vidas® (< 0.8 index)	Architect® (< 1.2 index)	Avidity	Interpretation
6	1.6	2.04	1.35	69	Negative
7	3.11	3.7	1.51	95	Negative
8	1.4	2.34	1.43	91	Negative
9	1.12	2.16	2.04	100	Negative
10	1.11	1.63	1.32	95	Negative
11	2.08	4.92	0.68	94	Negative
12	1.92	2.74	1.01	78	Negative
13	1.76	1.48	1.11	65	Negative
14	2.3	1.72	0.62	93	Negative
15	1.96	1.51	0.18	89	Negative
16	1.15	0.4	0.09	84	Negative

Table 4: Sensitivity, specificity, VPP and VPN

	Vidia®		Vidas®		Architect®	
	IgG	IgM	IgG	IgM	IgG	IgM
Sensitivity	98%	100%	98%	100%	96%	100%
Specificity	88%*	92%	100%	83%	92%	80%
PPV	98%	ND	100%	ND	98%	ND
PNV	92%	ND	89%	ND	82%	ND

RESULTS

Table 1
False negative results in IgG (a) and false positive results in IgG (b) were actually « equivocal » results ([treshold; 2x treshold[), meaning that their interpretation would have been “uncertain immunity”.
No false negative result (c) in IgM was found with any of the 3 methods, showing very good IgM sensitivity.
False positive results in IgM (d) were all confirmed by IgG avidity (showing at least 1 month past infection); actually, most of these false positive results had values close to the treshold of the method, showing that IgM sensitivity is prioritized to their specificity.

Table 2 and **Table 3**
IgG false negative with Vidia® are samples 1 and 2. Sample 1 shows very elevated IgM and so recent infection; no serological control was made after a few weeks in order to confirm seroconversion. This case shows that IgG sensitivity in recent infections is variable between different methods, however consequences are only of low importance while IgM are very high.
Sample 2 shows negative rate of IgG with Vidia® and positive, but equivocal, results with the 2 others methods. Serological status was then determined as « Uncertain immunity ».
IgG false positives with Vidia® are samples 3 to 5. The serological status of these samples is « Absence of immunity », whereas Vidia® gives positive results sensu stricto. But interpretation of the Vidia® results was « Uncertain immunity » since the result was < 2x treshold.
IgM false positive with Vidia® are samples 6 to 16. All but samples 7, 11 and 14 showed IgM rates < 2x treshold, meaning relatively low rates of antibodies. All samples could be confirmed by IgG avidity (IgG rates high enough).

Statement of « Absence of immunity » (IgG negative) remains of relatively low impact, since for a woman of childbearing age or a pregnant woman, serology will be repeated regularly. Concerning IgG false positive results with Vidia, the clinical impact could be heavier if distinction between « Presence of immunity » and « Uncertain immunity » was not done. Our results show that this distinction is essential.
IgM false positive results could be most of time excluded by IgG avidity determination. These false positive results could be problematic in the case of persistant low avidity.

Table 4
Predictive values for IgM could not be determined since our collective was enriched in samples with a suspicion of recent infections.
IgG sensitivity and specificity are excellent, as well as IgM performances. IgG predictive values are very good too, showing that Vidia® is a reliable system for determination of rubella serological status.

CONCLUSION

In our study, the Vidia® system presented comparable results to those obtained with our installed automates, i.e. Architect® and Vidas®. In Rubella serology, the biggest challenges remain specificity in IgG and sensitivity in IgM, in order to avoid the conclusion of seropositivity when it is not or missing seroconversion during a recent infection. IgM specificity is excellent with the 3 tested methods, sparing the laboratory potential work of confirmation. IgG sensitivity is very close to 100% when the notion of « uncertain immunity » is used in the interpretation. In addition, the Vidia® system is well adapted to automation of analyses in laboratory of medium size and its use is appreciated by laboratory technicians.