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Abstract (poster session)
A comparative analysis on five different fully automated anti-rubella IgG immunoassays reporting results in IU/mL

L. Grangeot-Keros, C. Vauloup-Fellous* (Clamart, FR)

Objectives: Since the 1980s rubella IgG assays have been calibrated against the same World Health Organization (WHO) international standard and the test results reported in International Units per milliliter (IU/mL). The aim of this study was to compare in term of sensitivity and specificity five fully automated anti-rubella IgG immunoassays that report results in IU/mL: ACCESS® Rubella IgG (Beckman), LIAISON® Rubella IgG (DiaSorin), ARCHITECT® Rubella IgG (Abbott), IMMULITE® 2500 Rubella IgG (Siemens Healthcare Diagnostics) and ELECSYS® Rubella IgG (Roche Diagnostics). Methods: The study was performed in 482 selected samples from pregnant women with different level of IgG anti-rubella antibodies. Samples that showed discordant results between systems were further investigated by resolution with immunoblot (Mikrogen). Analytical performances were calculated versus expected results obtained using a combination of the consensus and immunoblot classification. Results: At first evaluation 88 samples were negative by all methods, 175 positive and 219 discordant. After immunoblot analysis on discordant samples, 217 were classified as positive and 2 as negative. The classified 90 negative and 392 positive samples were used to determine the sensitivity and specificity of each assay. When equivocal results were interpreted as positive, the sensitivity of the immunoassays ranged from 71.4% to 99.5% and the specificity ranged from 97.8% to 98.9%. When equivocal results were interpreted as negative, the sensitivity of the immunoassays ranged from 47.7% to 85.7% and the specificity ranged from 97.8% to 100%. (Table1) Conclusions: Even though all assays reported results in IU/mL this study showed only a moderate correlation, particularly in term of sensitivity. Further investigations have been performed to evaluate sensitivity and specificity of assays using a cut off with wider grey zone, which may be useful in population where vaccination is commonplace.

Assay	Sensitivity (%) (95% confidence limits [%]) with equivocal results assigned as:		Specificity (%) (95% confidence limits [%]) with equivocal results assigned as:	
	Positive	**Negative**	**Positive**	**Negative**
ACCESS®	71.4(66.7-75.9)	47.7(42.9-53.0)	97.8(92.2-99.7)	100(96.0-100)
LIAISON®	73.2(68.5-77.5)	68.9(64.0-73.4)	98.9(94.0-100)	98.9(94.0-100)
ELECSYS®	85.7(81.9-89.0)	85.7(81.9-89.0)	97.8(92.2-99.7)	97.8(92.2-99.7)
ARCHITECT®	95.2(92.5-97.1)	68.9(64.0-73.4)	97.8(92.2-99.7)	98.9(94.0-100)
IMMULITE®	99.5(92.2-99.9)	84.9(81.0-88.3)	97.8(92.2-99.7)	97.8(92.2-99.7)

Table 1.