EVALUATION OF THE GALILEO® AUTOMATED INSTRUMENT (IMMUCOR®) FOR SCREENING IRREGULAR RED BLOOD CELL ANTIBODIES IN PREGNANT WOMEN: EXPERIENCE OF FRENCH NATIONAL REFERENCE CENTER FOR PERINATAL HEMOBIOLOGY

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Background: In France all women during their pregnancies, regardless of their RhD type, should be tested for clinically significant antibodies. If they are RhD positive they must be screened at the first trimester and then at the third trimester.Whereas if they are RhD negative they must be screened at the first trimester and then at 6 months (before IgRH injection) and 8 months. The screening for antibodies followed by their identification serve to determine the need for additional analysis to monitor the risk of haemolytic disease of the fetus and newborn (HDFN). It is essential for our lab, as a reference center in France, to detect antibodies at very low titres, because the monitoring of the pregnancy as well as the care of the newborn both depend on this result. This is not only for anti-RH1 antibodies (although there are still 150 new RH1 immunizations in France per year) but also for other antibodies (anti-RH4 or Anti-KEL1…)

The aim of this study is to evaluate antibody screening and the sensitivity of detection of irregular red blood cell antibodies in pregnant women on the Galileo® automated instrument in our reference center. .

Materials and methods: 85 samples of pregnant women were analysed. The Capture-R (4 cell) technology used on the Galileo® for screening was compared with the gel test method performed routinely and manually in our lab (LISS Coombs gel, DIAMED®).

To evaluate the sensitivity of detection of anti-RH1 we used 6 dilutions of the NISBC (National Institute for Biological Standards and Control) anti-RH1 standard: from 0.75 ng/ml to 24 ng/ml.

Results: For the 50 negative samples tested we found 50 negative results with Galileo®. The 14 specificities of allo-antibodies tested were: 5 anti-RH3, 4 anti-RH4, 1 anti-RH5, 5 Anti-KEL1, 4 anti-RH8, 3 anti-FY1, 2 anti-JK1 3 anti-MNS3, 1 anti-MNS4, 1 anti-LU1, 1 anti-LU2, 2 anti-JK1, 3 anti-MNS1, 1 anti-MNS5. Galileo® detected 30 of the 35 positive samples and the 5 antibodies not detected were: 2 anti-RH8 and 3 anti-MNS1. Another assay was performed to test positive results with serial dilution of sera (in albumin medium) and we observed a better sensitivity with the Capture-R Immucor® Technology than with the gel test method for all antibodies detected by Galileo®.

The sensitivity of detection of anti-RH1 was found between 0.75 and 1.5 ng/ml for Galileo (versus 6 ng/ml for gel test method).

Conclusion:, Galileo® offers a high sensitivity for the 14 specificities of antibodies tested during this evaluation to monitor clinically significant antibodies in pregnant women. The Capture-R (4 cell) screening method is a satisfactory technology with a better sensitivity for anti-RH1 detection than the gel method. Furthermore, the 5 antibodies not detected (2 anti-RH8 and 3 anti-MNS1) were IgM antibodies that cannot cross the placenta and therefore would not be the cause of HDFN.