T265

A TWO-YEAR EXPERIENCE OF IMPLEMENTING GENETICAL EXTERNAL QUALITY CONTROL FOR *RHD* FETAL GENOTYPING IN CNRHP

Da Silva,N.R. (1), Huguet-Jacquot,S. (1), Toly-Ndour,C. (1), Cortey A. (2), B. Carbonne (2), A. Mailloux (1)

(1) Centre National de Référence en Hémobiologie Périnatale (CNRHP), Hôpital Saint-Antoine, pôle biologie médicale et pathologie, GHU Est Parisien, AP-HP, Paris
(2) Centre National de Référence en Hémobiologie Périnatale (CNRHP), Hôpital Trousseau, pôle périnatalité, GHU Est Parisien, AP-HP, Paris

Background

Today, non-invasive fetal *RHD* genotype helps the practitioners to greatly improve the accuracy follow-up in RH1 negative women. A positive *RHD* fetal genotyping diagnoses a RH1 feto-maternal incompatibility for the anti-RH1 alloimmunized pregnant women. For the non-immunized ones, a negative test will avoid injection of IgRH. Since the *RHD* fetal genotyping became a key to the monitoring of RH1 negative pregnant women, an increasing number of laboratories performed such test. It appeared essential for the CNRHP and it is part of its missions, to offer a quality assessment program based on an external quality control (EQC). The CNRHP can rely on more than ten year experience in the fetal *RHD* genotyping by PCR from maternal blood and its EN ISO 15189 accreditation to establish such control.

The aim of this presentation is to review the EQC program two years after its launch.

Methods

Positive control specimen were prepared from RH1 negative plasma donors spiked with various concentrations of RH1 positive plasma in order to reflect RH1 positive fetuses of different gestational ages. Negative control specimen, made from RH1 negative plasma donors, remained unspiked. Once tested, the samples were conveyed to the laboratories with a feedback form where they had to state the material and methods used, the results and the clinical interpretation. The control samples were sent twice a year.

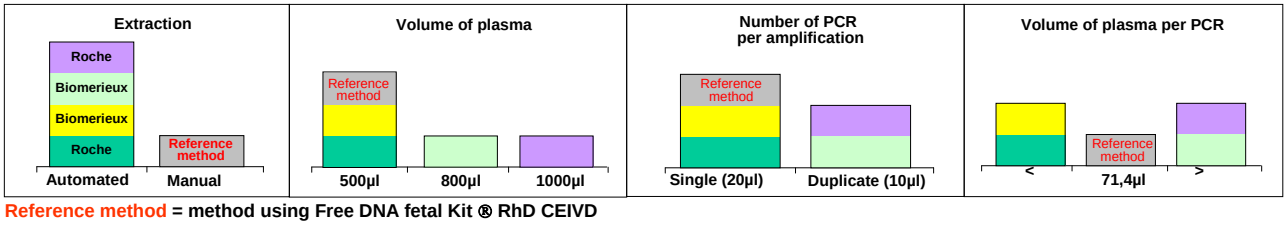
Results

YEAR	2010	2011		2012
EXERCICE	10-06/01	11-02/01	11-12/02	12-06/01
DATE	16/06/2010	24/02/2011	01/12/2011	19/06/2012
NUMBER OF LABORATORIES	5	7	6	6
CONTROL SPECIMEN	10P1 : positive *RHD (28GW)* 10P2 : positive *RHD (18GW)* 10P3 : negative *RHD*	11P1 : positive *RHD (18GW)* 11P2 : negative *RHD*	11P3 : negative or ininterpretable (24GW) 11P4 : negative or ininterpretable (26GW)	12P1 : positive *RHD (12GW)* 12P2 : positive *RHD (12GW)*
CORRECT RESULT	5/5	7/7	6/6	12P1 : 4/6 12P2 : 4/6
CORRECT CLINICAL INTERPRETATION	Non done	11P1 : 7/7 11P2 : 5/7	11P3 : 5/6 11P4 : 5/6	12P1 : 2/6 12P2 : 3/6

GW : gestation weeks

Over these two years, 9 series of samples were prepared and sent to 6 laboratories (3 in 2010, 4 in 2011, 2 in 2012) reaching each year a 100% response rate. In 2010, the EQC results were consistent with those expected although the laboratories use different extraction and amplification protocols (figure1). In 2011, two laboratories made erroneous clinical interpretations despite right analytical results. In 2012, the EQC concluded to 2 analytical and 4 interpretation errors. Only a single laboratory returned the right analysis together with the good clinical interpretation.

Figure 1 : Extraction and amplification protocols used by the laboratories



Reference method = method using Free DNA fetal Kit ® RhD CEIVD

Conclusion

The presented EQC meets the criteria required to evaluate the practices of laboratories performing fetal RHD genotyping. The ideal EQC should be prepared from maternal plasma from a single pregnant woman containing a predetermined quantity of fetal DNA but the collection is impossible in practice. The next step is the transfer of EQC program conducted by the CNRHP to an EN ISO / IEC 17043 certified entity.