P0048

A SEVEN YEAR EXPERIENCE OF EXTERNAL QUALITY ASSESSMENT PROGRAM FOR *RHD* FETAL GENOTYPING

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Today, non-invasive fetal *RHD* genotype helps the practitioners to greatly improve patient monitoring in RH1 negative women. A positive *RHD* fetal genotyping diagnoses a RH1 feto-maternal incompatibility for the anti-RH1 allo-immunized 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. In 2010, it appeared essential for the CNRHP, and part of its missions, to propose to laboratories an external quality assessment.The CNRHP can rely on more than twenty years experience in the fetal *RHD* genotyping to establish such control. In 2015, we transfered EQC program conducted by the CNRHP to ASQUALAB. The aim of this presentation is to review the EQC program seven years after its launch.

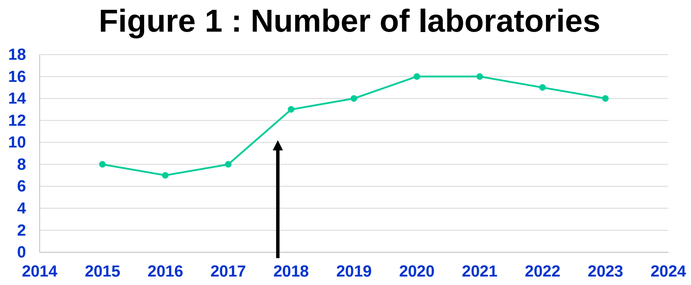
METHODS

Positive control specimen were prepared from RH1 negative plasma donors spiked with various concentration of RH1 positive plasma in order to reflect RH1 positive fetuses at different gestational ages. Negative control specimen, made also from RH1 negative plasma donors. After the initial CNRHP analysis, the samples were conveyed to the participating laboratories with a feedback form where they had to state 1) the material and methods used and 2) the results and the clinical biological interpretation in the context of a clinical case.

RESULTS

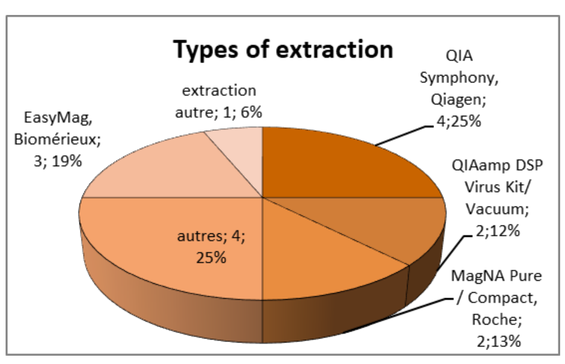
14 assessments were conducted since 2015 with an increasing number of laboratories from 7 to 16 in 2022 (figure 1). Each year, we achieved a 100 % response rate. The EQC results were most of the time conform to those expected, 90% with note A (table 1) although the laboratories use different extraction and amplification protocols (figure 2, 3). Some laboratories (4% of results) made unsuitable clinical interpretations despite right analytical results (note B).

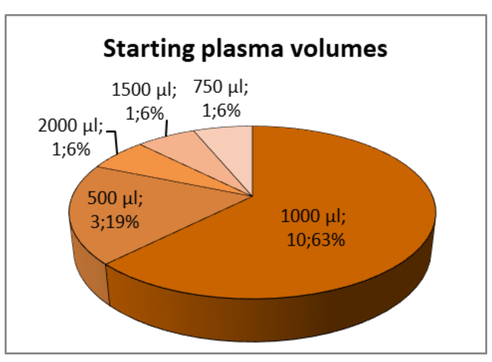
Figure 1 : Number of laboratories



Reimbursement of genotyping by health insurance in July 2017
Generalization of the use of this test in pregnant women

Figures 2 : Different types of extraction used and volumes of plasma extracted

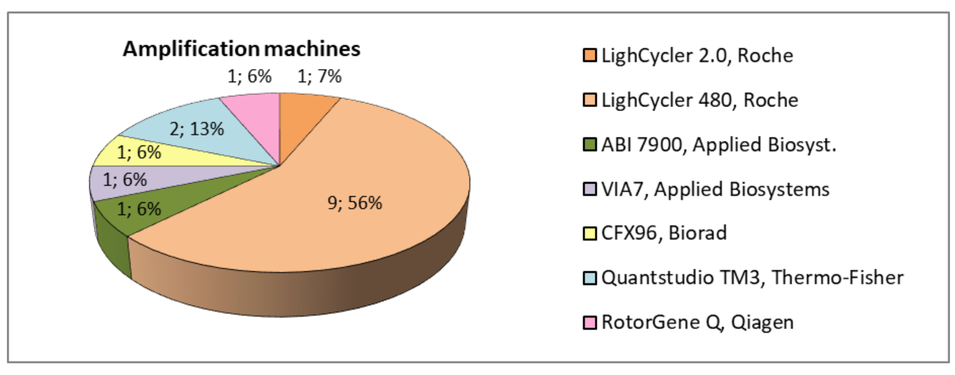




LAB CODE	2015				2016				2017				2018				2019				2020				2021				2022			
	15P1	15P2	15P3	15P4	16P1	16P2	16P3	16P4	17P1	17P2	17P3	17P4	18P1	18P2	18P3	18P4	19P1	19P2	19P3	19P4	20P1	20P2	20P3	20P4	21P1	21P2	21P3	21P4	22P1	22P2	22P3	22P4
	Inint.	RHD-	RHD+	RHD+	RHD-	RHD-	RHD+	RHD+	Inint.	RHD+	RHD-	RHD+	RHD-	RHD+	RHD+	RHD-	Inint.	RHD+	RHD+	RHD+	Inint.	RHD-	Inint.	RHD+	RHD-	RHD+	RHD-	RHD+	RHD + Inint.	RHD+	Inint.	RHD-
1	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
2	A	A							A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	A	A
3																					A	A	D	A								
4															A	B	A	A	A	A	A	A	D	A								
5													A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
6																			A	A	A	A	A	A	A	A	A	A	A	A	D	A
7																					AT	B	D	A	A	A	B	B	A	B	A	A
8	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	AT	AT	AT	A	A	A	A	A	A	A	A	A	A	A	A
9	A	A	A	A	A	A	A	A	A	A	A	A	B	A	A	A	D	B	A	A	D	A	A	B	A	A	A	A				
10	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	AT	AT	AT	A	A	A	A	A	A	A	A	B	A	A	A
11	A	A																														
12													A	A	A	A	A	A	A	A	A	A	A	A								
13																									A	A	A	A	A	A	A	A
14													B	A																		
15																	A	A	A	A	A	A	A	A	A	A	A	D	A	A	A	A
16																																
17																													A	A	A	A
18																													A	A	D	D
19	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	A	A	A	A	A	A	A	A
20															A	A	A	A	A	A	A	A	A	A	A	A	A	B	A	A	A	A
21	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	D	A	B	A	A	A	D	A
22							A	A	A	A	A	A	B	A	A	A	D	A	A	A	D	A	D	B	A	A	B	A	D	A	D	A
Total attendees	8	8	6	6	6	6	7	7	8	8	8	8	11	11	12	12	13	13	13	13	15	15	15	15	13	13	13	13	14	14	14	14
Total registered	8				7				8				13				14				16				16				15			
% participation	100%	100%	75%	75%	86%	86%	100%	100%	100%	100%	100%	100%	85%	85%	92%	92%	93%	93%	93%	93%	94%	94%	94%	94%	81%	81%	81%	81%	93%	93%	93%	93%
A -notes	8	8	6	6	6	6	7	7	8	8	8	8	8	11	12	11	11	12	14	14	14	15	12	13	13	14	11	11	13	13	11	14
	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	73%	100%	100%	92%	85%	92%	100%	100%	88%	94%	75%	81%	93%	100%	79%	79%	87%	87%	73%	93%
B-notes	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	1	0	1	0	0	0	1	0	3	0	0	3	2	1	2	0	0
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	27%	0%	0%	8%	0%	8%	0%	0%	0%	6%	0%	19%	0%	0%	21%	14%	7%	13%	0%	0%
C-Notes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
D-notes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	4	0	1	0	0	1	1	0	4	1
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	15%	0%	0%	0%	13%	0%	25%	0%	7%	0%	0%	7%	7%	0%	27%	7%

Table 1 : Evaluation of results

Figure 3: Amplification systems used



The letters A, B, C or D are assigned according to:
- the expected qualitative response of the test
- the difference between the laboratory result and the average of all the participating laboratories clinical -biological advice

- **A : Correct answer, difference between 0-10%, appropriate clinical -biological advice**
- **B : Correct answer, difference between 0-10%, unsuitable clinical -biological advice**
- **C : Correct answer, difference > 10%, adapted clinical -biological advice**
- **D : Wrong answer**

Notes A	90%
Notes B	4%
Notes C	3%
Notes D	3%

Global Results

3% of the results correspond to wrong answers corresponding to a grade D. The grade D is observed for uninterpretable RHD genotyping due to the presence of maternal or fetal variants. Two laboratories give false positive results in this case because the techniques used do not detect variants. This problem is not limited to EQAs and these laboratories also return false positive results for patients.

CONCLUSION

The presented EQC meets the criteria required to evaluate the practices of laboratories performing noninvasive fetal *RHD* genotyping. The extension of the field from analytical process to postanalytical process including results interpretation and biological advices was important to improve national harmonization of the results of this specialized examination and to highlight the labs giving clinical advices to help prevention of fetal or newborn anemia.