NON-INVASIVE PRENATAL TEST FOR TWINS WITH CLARIGO

Gouas, Laetitia[1]; Vago, Philippe[1]

[1]Service de Cytogénétique Médicale, CHU Estaing, Clermont-Ferrand

Abstract Body

Like all Non-Invasive Prenatal Tests, Clarigo is analyzing fetal cfDNA in maternal blood originating from the placenta. The test screens for trisomy 21 (T21), 18 (T18) and 13 (T13) and the dedicated data analysis tool Clarigo Reporter provides a positive (POS), negative (NEG) or a not automatically called result.

Clarigo has been initially validated on maternal blood samples of singleton pregnancies and no samples for twin pregnancy were included. An evaluation of the test performances was performed based on twin samples analyzed in routine, within five centers from the French Clarigo Consortium. A total of 187 twin samples were included, 91 bichorionic (BC) and 69 monochorionic (MC). Two samples of each BC twins, invasive results showed that 1 fetus gave a T21 result and also gave a POS result for Clarigo. In addition, Clarigo gave a T18 result in one of the BC twins which was not confirmed by invasive testing due to natural demise, which in its turn is supportive of a correct call. Observed sensitivity and specificity in this local validation for T21 and T18 was >99.9%. Observed specificity for T13 was >99.3%. Observed sensitivity for T13 could not be calculated due to absence of a confirmed T13 twin sample. Further routine testing will provide better insights in the actual sensitivity and specificity for twin samples. Due to the higher complexity of the sample composition it is expected that numbers will be comparable or lower than the numbers reported for screening of singleton pregnancies.

NIPT results should always be complemented with additional clinical information and follow up invasive testing for positive and inconclusive results in order to make a decision on patient management. This is especially true for twins.