EVALUATION OF VANADIS SYSTEM AS AN ALTERNATIVE METHOD FOR CELL FREE FETAL DNA ASSAY IN MATERNAL PLASMA

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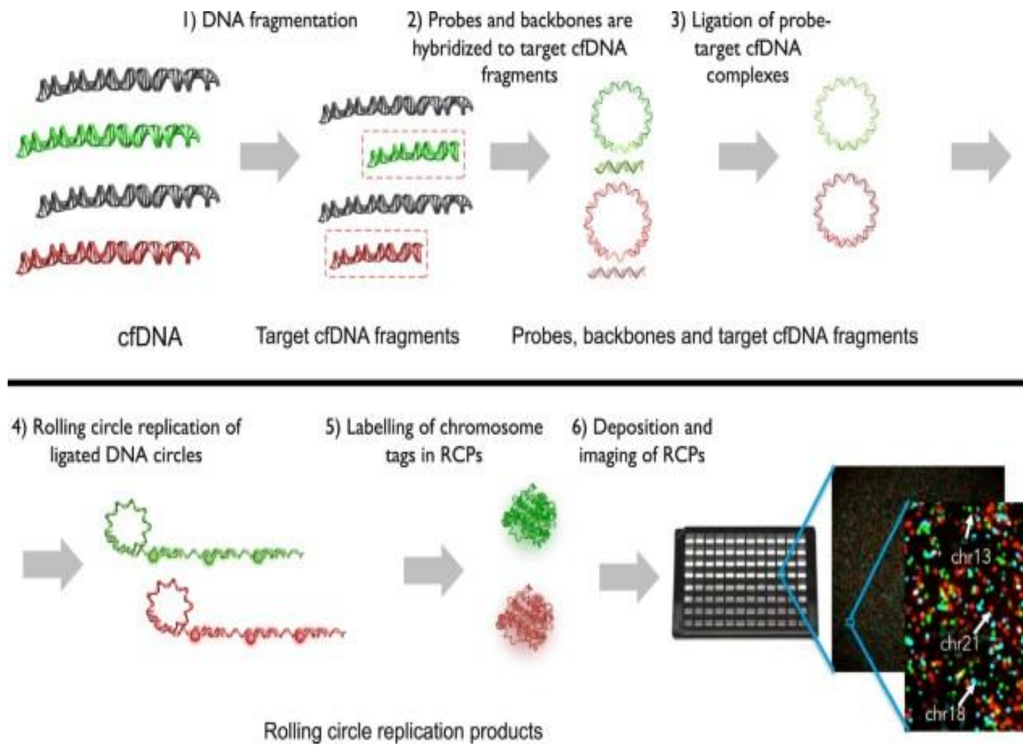
INTRODUCTION

The Vanadis® is a new automated system of free fetal DNA (cfDNA) analysis in maternal plasma. The main objective of this new system is to reduce the cost and complexity of cfDNA analysis compared to other non-invasive prenatal tests (NIPT) by avoiding PCR amplification and DNA sequencing. This leads to a greater accessibility and easier implementation of the system in national screening programs, while maintaining the improved specificities and sensitivities that NIPT tests typically have over traditional combined first trimester screening. The objective of this study was to evaluate clinical performance of the Vanadis® assay in maternal plasma screening for trisomies 21, 18, and 13, and to determine fetal sex.



MATERIALS AND METHODS

Maternal blood from 683 pregnant women was analyzed by the Vanadis® system during the period from February 2019 to February 2020, including 658 (96.3%) samples from singleton pregnancies and 25 (3.7%) from twin pregnancies (11 monozygotic and 14 dizygotic). The aneuploidy result and fetal sex obtained by the Vanadis® assay was compared with the fetal karyotype, whenever possible, or with the physical exanimation of the newborn.

RESULTS

The median age of the included women was 35 years (19 - 48 years) and the gestational age at the time of extraction was 90 days (51 - 201 days), including 622 (91.1%) first trimester samples (<99 days of gestation) and 61 (8.9%) second trimester samples (≥99 days of gestation). The study included 7 (1.0%) pathologic samples, corresponding to 6 trisomies 21 in singleton gestations and 1 trisomy 13 in a dizygotic twin pregnancy. All pathological cases were correctly identified, obtaining a sensitivity of 100%. One false positive result for trisomy 21 was detected, reaching a specificity of 99.85%. For fetal sex evaluation, only samples from singleton pregnancies (n=652) were considered (337 female fetuses and 315 male fetuses). The Vanadis® correctly classified 635 fetuses (97.4%).

	n	T 21	T13	FP
singleton	658	6		1 T21
twins	25		1	

CONCLUSIONS

Vanadis® is a new automated cfDNA analysis system in maternal plasma, with a unique and innovative design that presents certain advantages over other NIPT platforms. Although the pathological cases included in this study were limited, Vanadis® shows to be a system with great potential, showing very good sensitivities and specificities for the detection of aneuploidy as a NIPT screening test.