

AUTOMATION OF CLARIGO – LAB VALIDATION OF THE BRAVO PROTOCOL

Le Sciellour, Christelle¹; G rault, Carole - Presenting Author²; Herv , B r n ce³; Giampaolo, Guillaume⁴; Devidts, Gilles⁵; Pirson, Maarten⁶; S razin, Val rie⁷; Vialard, Fran ois⁸

¹Christelle Le Sciellour, ²Carole G rault, ³B r n ce Herv , ⁴Guillaume Giampaolo, ⁵Gilles Devidts, ⁶Maarten Pirson, ⁷Val rie S razin, ⁸Fran ois Vialard

Abstract Body

Clarigo was designed to enable labs to implement non-invasive prenatal testing (NIPT) in a standard clinical lab facility, hence the wet lab workflow validated for this CE-IVD product comprises all manual steps.

To further standardize the procedure and increase robustness we decided to optimize and validate the automation of the test on an Agilent liquid handler BRAVO to implement an automated workflow for routine testing in our own facility.

A BRAVO instrument with specific deck set up for NGS was purchased and the Clarigo protocol optimized with support of the Agilent technical support team. Steps automated include preparation of combined index plate, multiplex and universal PCR set up, purification and pooling of libraries. In our lab we have decided to process the multiplex and universal PCR set up manually because of our lab environment and limited number of samples.

Total turn-around time is comparable with the manual workflow but the automation allows frees up time for other tasks like plasma and cfDNA isolation of the next batch of samples. Additional advantages we experienced with the automated protocol are increased robustness, reproducibility between different operators, decreased contamination, less prone to human error. Inconveniences we are trying to resolve are tracking of reagents and plate set up and lower limit of pipetting volumes for specific reagents and to implement the multiplex and universal PCR set up using the BRAVO.

So far approximately 500 routine samples were processed successfully and the automated workflow is implemented for routine use.