Microbiology meets molecular diagnostics evolving in flexible sample to result workflow

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Background

Beneficial interactions between traditional culture methods and molecular diagnostic can significantly improve current management of Carbapenem-Resistant Enterobacteriaceae (CRE) positive patients in health care facilities. According to CDC guidelines CRE-colonized patients should be placed on contact precaution to prevent transmission of resistant bacteria reducing mortality rates[1]. An innovative approach integrates WASP® and ELITe InGenius® systems to contemporaneously support culture and molecular diagnostic methods in a standardized, traceable and time-saving automated workflow for CRE analysis simultaneously performed from the same collection device: **Copan FecalSwab™**. Aim of the study was to compare MANUAL versus WASP® automated liquid handling for the preparation of **ready-to-process primary tubes** for molecular diagnostics testing.

Material & Methods

Workflow analysis was carried out through detailed measurement of the multiple steps performed by a skilled technician to process a complete run of 12 FecalSwab™ samples using ELITe InGenius® sample-to-result molecular platform. Analytical approach has evaluated two phases: **the baseline** where all the pre-analytical steps were manually performed and **after the integration of WASP® liquid handling module.** For each FecalSwab™ sample, WASP® has performed the streaking on chromogenic media **(**dual plate CHROMID™ CARBA SMART bioMérieux Italia) and the transfer of 500 µL of Cary Blair media in eNAT® tube for molecular analysis (Fig.1).

After the samples selection, the complete molecular diagnostic workflow consists of the following automated steps: **Sample Preparation (SP), Instruments Set up (IS)**, **Instrument Loading (IL), Extraction and Amplification (EA)** and **Data Analysis (DA).** Technician hands on time (HOT), risk of errors and total number of analytical steps were compared before and after the integration. In addition, the performance of **WASP® liquid handling module** has been evaluated considering three parameters: 1) cross contamination between a group of positive and negative alternating samples (24 positive and 24 negative), 2) the accuracy of aspiration volume (Ct value of each eNAT® tube inoculated with 500 µL of positive FecalSwab™ media spiked with stools contaminated with *Klebsiella pneumoniae* KPC resistant and *E.coli* OXA 48 clinical strains) and 3) the time to perform dual plate streaking plus eNAT® inoculation.

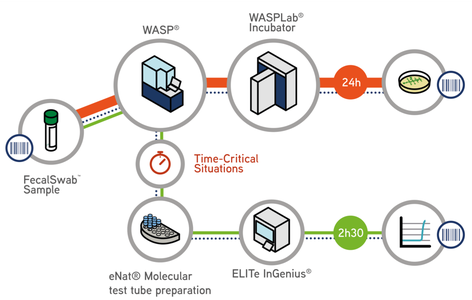
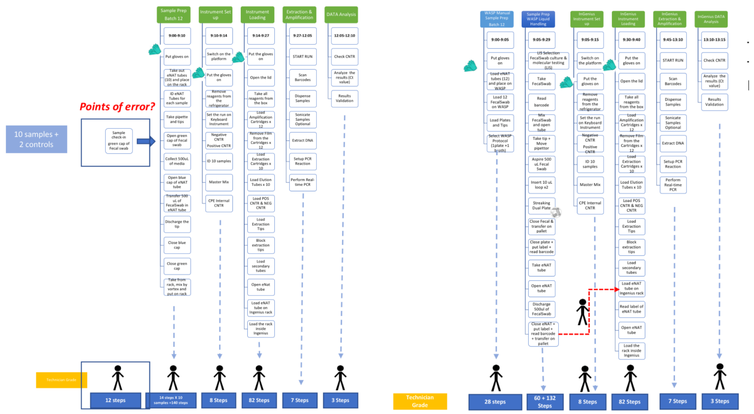


Figure 1 – Sample Workflow

Workflow Results

For baseline, a total of **252 steps** from samples to results were identified: **152 manual SP, 8 IS**, **82 IL**, **7 EA** and **3 DA**. The total HOT was 23 mins with **17** points of error risks while the total laboratory lead time was 3 h and 10 min. After the integration of WASP® liquid handling module a total of **320 steps** were identified with a total HOT of 20 mins. The major simplification was observed in the primary tube **selection and preparation** phase: **28 steps** versus **152 steps**, with a reduction of **81,6% of manual handling (Figure 2).**



Only Molecular Total Steps: 252
Manual Sample prep: 152 steps
Total Laboratory Lead Time: 3 h 10
HOT samples & reagents: 23 mins

Microbiology + Molecular Total Steps: 320
Manual Sample prep: 28 steps
Total Laboratory Lead Time: 4 h 10
HOT samples & reagents: 20 mins

Figure 2 – Steps

Performance Results

Regarding the performance of **WASP® liquid handling module: no cross contamination** between positive and negative alternating samples has been detected. The ΔCt value of the samples inoculated with the same bacterial load was between 1 and 1,5. The total time to perform one run of 12 FecalSwab™ with a protocol of dual plate streaking (10µL) and eNAT® inoculation was 23 mins and 44 sec (Fig. 3).

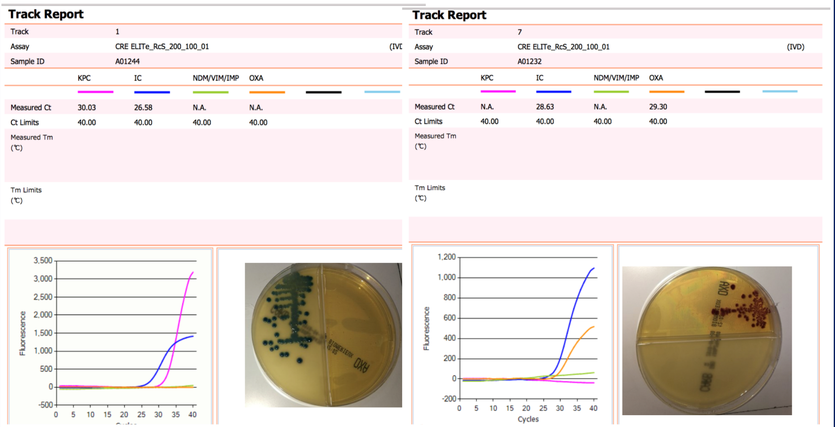


Figure 3 WASP® liquid handling performance

Conclusions

COPAN WASP® liquid handling module and ELITe InGenius® sample-to-result systems provide an innovative solution to integrate molecular diagnostics and automated bacteriology processing for CRE Screening and allow **to improve standardization, traceability and reduce sample-hands on time (HOT)** to support clinical decisions and patient management.

1 CDC Laboratory Protocol for Detection of Carbapenem-Resistant or Carbapenemase-Producing, Klebsiella spp. and E. coli from Rectal Swabs.

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