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Enabling continuous and real-time air microbiological monitoring with bio-fluorescent particle counter

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OBJECTIVE:
Cosmetic products are prone to biological contamination as some ingredients facilitate microorganism growth [1], affecting product safety and shelf-life. Since most of the current microbiological techniques require long time-to-result [2], alternative methods have the potential to automate environmental monitoring and prevent contamination events. Rapid-C is a fully optical automatic aerosol detector (biofluorescent optical counter). It measures viable and non-viable particles continuously and in real time, using light scattering and fluorescence analysis [3, 4]. This project evaluates Rapid-C performance in the instantaneous detection of microorganisms and is part of the validation for control of microbiological quality according to pharmacopeial guidelines [5, 6, 7], funded by the Swiss State Secretariat for Education, Research and Innovation [8].

METHODS:
Plair is using a dedicated bioaerosol testing facility (ISO 5), where Rapid-C and agar impactors are connected to measure airborne microorganisms simultaneously. Six species were selected as representatives for cleanroom environmental monitoring, and were aerosolized, and then exposed to the instruments: *Aspergillus brasiliensis, Bacillus subtilis*, *Candida albicans, Escherichia coli*, *Penicillium chrysogenum*, *Staphylococcus epidermidis*. Potential interferent particles materials simulating common consumables in cosmetic and pharmaceutical industries are also tested: poly (methyl methacrylate) (PMMA) microspheres, silica and glass microspheres, and others.

RESULTS:
Preliminary experiments with selected microorganisms proved a strong correlation between Rapid-C (auto-fluorescent units, AFU) and agar plate method (colony forming unit, CFU) in terms of linearity, accuracy, precision, and specificity. Rapid-C results are ascribed to the full analysis of scattering and fluorescence spectra and advanced intelligence algorithm embedded inside the instrument. Plair's method demonstrated the discrimination of living microorganisms, dead cells, and any other inert particles beyond 80%. Further results of a complete validation package will be presented, including the experiments on selected bacteria and fungi as well as interferant materials to enhance the discrimination between microorganisms and inert particles in cleanrooms.

CONCLUSION:
Rapid-C significantly reduces the measurement-to-result time from several days to a few minutes, minimizing human interventions and consumables. The instrument may allow a clear root cause analysis and the implementation of effective corrective actions to expedite environmental monitoring and batch release of cosmetics.

Keywords
Environmental monitoring; quality control; rapid microbiology; biofluorescence particle counter.

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