Testing Surface Disinfectants

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Testing surface disinfectants: Method development phases

[*Key words*: standard operating procedure, optimization, pre-collaborative study, collaborative study, surveillance]

The process for developing and evaluating a disinfectant test method can be partitioned into five phases. **Phase 1** is crafting a method, **Phase 2** is optimizing the method, **Phase 3** is a pre-collaborative study, **Phase 4** is the full collaborative study, and **Phase 5** is surveillance of the method after it has been accepted and is in use. These phases for developing a test method are different from the phases, tiers, or levels suggested for testing a specific disinfectant (e.g., Bloomfield et al., 1994; Springthorpe and Sattar, 2005)

Phase 1

Phases 1 and 2, which provide a solid foundation for the disinfectant test method, are usually the work of one research group and the experiments are usually performed in only one laboratory. The goals of Phase 1 are to (i) prepare a protocol that is reasonable, relevant, and valid and (ii) demonstrate its feasibility by conducting preliminary laboratory runs of the protocol. This work requires knowledge and experience in disinfectant testing methods and in laboratory technology.

Phase 2

The goal of Phase 2 is to create a standard operating procedure (**SOP**) that specifies settings for key operational factors. The SOP should be developed to optimize the protocol so that the method produces the most information for the least time and effort. This phase should include a set of designed experiments within one laboratory to produce statistical assessments of resemblance, repeatability, responsiveness, and ruggedness of the optimized method. Experience indicates that Phases 1 and 2 require many months of effort.

Phase 3

The goals of Phase 3 are to check that the protocol can be run successfully in other laboratories and to demonstrate that the method is sufficiently reliable that it merits a full collaborative study. A pre-collaborative study typically consists of 3 laboratories and a narrow spectrum of tests. The statistical design and analysis guidelines for a full collaborative study apply, except that there are fewer laboratories and test scenarios. Pre-collaborative study results may show that the method possesses deficiencies that make it unsuitable for a full collaborative study. Usually, the information from the pre-collaborative study leads to some modifications of the protocol and refinement of study

management and of the quality control system, prior to the full collaborative study. The pre-collaborative study should produce the same statistical evaluations as a full collaborative, except the results are subject to more uncertainty and cover fewer scenarios than expected of a full collaborative study. The pre-collaborative study serves as a feasibility trial for the statistical design and analysis methods intended for use in the full collaborative study.

Phase 4

The goals of Phase 4 are to provide convincing assessments of the resemblance, responsiveness, repeatability, and reproducibility of the disinfectant test. Based on the results of the collaborative study, expert panels will decide whether the disinfectant test method merits acceptance as a standard method and government authorities will decide whether it produces data suitable for regulatory use. The collaborative study provides information necessary to set a performance standard and to determine the most efficient test protocol for generating a suitably reliable efficacy estimate.

Phase 5

The goal of Phase 5 is to monitor an accepted disinfectant test method as it is applied routinely. Phase 5 surveillance data can be used to refine knowledge about the attributes of the test. Phase 5 studies are not yet included in disinfectant evaluation programs. Instead, occasional literature review articles provide updated information for selected disinfectant tests.

References

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