

US EPA ARCHIVE DOCUMENT



**US Environmental Protection Agency
Office of Pesticide Programs**

UDM Performance Standard Revision Document

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Revisions to the Performance Standard for the AOAC Use-dilution Methods for *Staphylococcus aureus* (955.15) and *Pseudomonas aeruginosa* (964.02)

Background:

The AOAC Use-dilution methods (UDM) 955.15 (*Staphylococcus aureus*) and 964.02 (*Pseudomonas aeruginosa*) are laboratory assays used to measure the antimicrobial efficacy of liquid disinfectants on inanimate surfaces. Products must pass tests of both microbes for a hospital disinfectant claim. The UDM's performance standard is defined by the maximum number of positive carriers out of 60 per test per microbe to achieve a passing outcome for a product. Historically, up to one positive carrier out of 60 tested has been the performance standard for both microbes. A reassessment of the method's performance standard was conducted utilizing the best available data and statistical methodology to analyze the UDM's variability. To support revisions to the AOAC International (AOAC) standard methods, the EPA submitted three manuscripts to the Journal of AOAC International (JAOAC) for technical review and approval. The manuscripts described: 1) the outcome of a 2009 UDM collaborative study, 2) a statistical model for assessing performance standards of disinfectant test methods, and 3) the use of statistical modeling to reassess the UDM performance standard. All three manuscripts have been accepted for publication. On August 23, 2013, AOAC approved the new performance criteria for methods 955.15 and 964.02 as first action revisions to the AOAC standards. The revised AOAC methods are posted online at: http://www.aoac.org/imis15_prod/AOAC/Default.aspx.

Reassessment Methodology:

Using the statistical model, the published variability of the UDM (based on a 2009 study) was used to reassess the performance standard. The analysis focused on an assessment of error rates, both *pass-error* and *fail-error* rates. A *pass-error* occurs when the disinfectant being tested has low efficacy, but is deemed a pass by the performance standard, while a *fail-error* occurs when the disinfectant is of acceptable efficacy, but is deemed a fail by the performance standard. The goal was to reduce error rates while maintaining a practical level of testing. The variability exhibited by *P. aeruginosa* was higher compared to *S. aureus*, thus the performance standards are different for each microbe. The Agency will monitor the outcome of the new performance standard criteria as data are generated, and if necessary, adjust the performance standard at a later date.

New Performance Standard Criteria:

The current version of AOAC Methods 955.15 and 964.02 posted by AOAC on September 19, 2013 should be used for testing. Refer to the Product Performance Test Guidelines (810.2200) for efficacy testing recommendations. For a hospital disinfectant product to be deemed effective, the following criteria apply:

- Each microbe should be tested three times. Each test should be conducted against a separate batch of product for a total of three batches. All three batches should be at the lower certified limit (LCL) of the active ingredient(s). Each of the three tests

should be conducted on a different day. Testing at a single lab is acceptable. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media.

- The performance standard for *S. aureus* is 0-3 positive carriers out of sixty.
- The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty.
- To be deemed an effective product, the product must pass all tests for both microbes.

Applicability:

The new performance standard criteria only apply to liquid products tested with the UDM against *S. aureus* and *P. aeruginosa*. For limited and broad spectrum disinfectant claims, the new performance standard for *S. aureus* applies. UDM requirements for testing *Salmonella enterica* are not impacted. The new performance standard criteria are applicable to data used to support new registrations, label amendments, data call-ins issued by the Agency, and in post registration testing.

References:

1. Official Methods of Analysis (2013) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, AOAC Use-dilution Method 955.15
2. Official Methods of Analysis (2013) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, AOAC Use-dilution method 964.02
3. Office of Chemical Safety and Pollution Prevention Test Guidelines: Series 810 – Product Performance Test Guidelines. See: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm
4. Tomasino, S.F., Parker, A.E., Hamilton, M.A., & Hamilton, G.C. (2012) Performance of the AOAC Use-dilution method with Targeted Modifications: Collaborative Study. *J. AOAC Int.* **95** (6), 1618-1628
5. Parker, A.E., Hamilton, M.A., & Tomasino, S.F. (2013) A Statistical Model for Assessing Performance Standards for Quantitative and Semi-quantitative Disinfectant Test Methods. *J. AOAC Int.* (accepted for publication)
6. Tomasino, S.F., Parker, A.E., & Hamilton, M.A. (2013) Use of Statistical Modeling to Reassess the Performance Standard for the AOAC Use-dilution Methods (955.15 and 964.02). *J. AOAC Int.* (accepted for publication)
7. *Standard Operating Procedure for AOAC Use Dilution Method for Testing Disinfectants (MB-05)*, EPA Office of Pesticide Programs, Microbiology Laboratory, Environmental Science Center, Ft. Meade, MD, <http://www.epa.gov/pesticides/methods/atmpa2z.htm>