

Changing Swabs: To Validate or Not To Validate?

J. Michael Miller,^a Sheldon Campbell,^b Michael Loeffelholz^c

Microbiology Technical Services, LLC, Dunwoody, Georgia, USA^a; Yale University School of Medicine, New Haven, Connecticut, USA^b; University of Texas Medical Branch, Galveston, Texas, USA^c

A widely perceived requirement for validation of all new specimen collection swabs by the laboratory appears to be the result of misinformation. Neither the College of American Pathologists (CAP) nor regulations through the Clinical Laboratory Improvement Amendments (CLIA) address specifically the issue of swab validation for general specimen collection (1–4). While both regulatory agencies require the validation of newly incorporated “test systems,” the specimen collection swab, which is not a component of the test system, is neither a “test” nor a “system.” It is in fact more like a scalpel or urine cup, neither of which requires validation before use.

Swabs for general specimen collection. There appear to be no CAP or CLIA requirements to validate collection swabs except those specifically recommended in FDA-approved tests or kits. Upon careful review of the CAP Microbiology, All Common, and Laboratory General checklists, there appears to be nothing specific that addresses a specimen collection device (swab or otherwise). A search under “swab” finds nothing relevant; searching on “collection device” finds only the material under “Molecular Microbiology.” A review of the sections regarding specimen collection, general microbiology, and test validation and verification find nothing that speaks to the specific question of swab validation. CAP and CLIA laboratory surveyors have no grounds to suggest that validation of swabs is necessary. The literature contains many reviews on different types of swabs for the recovery of microorganisms from specific specimens, but no in-house validation is required by CAP or CLIA for swabs being used for collection of general specimens, such as for eyes, wounds, skin, etc.

Swabs recommended by the manufacturer for FDA-approved test kits. The question of how a change in the collection device or sample impacts the verification or validation of molecular tests is part of the molecular microbiology section of the CAP microbiology checklist. If a test kit manufacturer has indicated in its package insert a specific swab for use in their kit or test (molecular or otherwise) and that test system has been FDA cleared or approved for use of that specific swab, then switching to a different

swab will require in-house validation of the new swab. Changing to a new swab in this case would be considered a modification to the FDA clearance and would require a validation to ensure that the new collection swab works at least as well as the swab recommended by the manufacturer.

The Clinical and Laboratory Standards Institute (CLSI), formerly NCCLS, has published a specimen transport document that outlines how to validate a swab (5). CLSI, while authoritative, is not regulatory and therefore does not require swab validation for licensure activities but offers guidelines should a validation be necessary.

It would be prudent to look at the data provided by the manufacturer on organism survival and verify any use that seems outside that which is described. In addition, one can have a reasonable expectation that specimen collection swabs produced under good manufacturing practices should perform as the swab manufacturer describes.

REFERENCES

1. Clinical Laboratory Improvement Amendment 42. CFR 493.1253 (b) (2).
2. College of American Pathologists. 2013. Microbiology checklist. CAP Laboratory Accreditation Program. College of American Pathologists, Northfield, IL.
3. College of American Pathologists. 2013. Laboratory general checklist. CAP Laboratory Accreditation Program. College of American Pathologists, Northfield, IL.
4. College of American Pathologists. 2013. All common checklist. CAP Laboratory Accreditation Program. College of American Pathologists, Northfield, IL.
5. NCCLS. 2003. Quality control of microbiological transport systems. approved standard. NCCLS document M40-A. NCCLS, Wayne, PA.

Published ahead of print 11 September 2013

Address correspondence to J. Michael Miller, jmm8@comcast.net.

Copyright © 2013, American Society for Microbiology. All Rights Reserved.

doi:10.1128/JCM.02023-13