



AOAC Official MethodsSM Program

TECHNICAL BULLETIN

AOAC TB 2021-001 – Sample Size and Dilution Ratio (Microbiology)

OMB Approval Date: 10-2021

Effective Date: 11-2021

Subject/Title: Sample Size and Dilution Ratio (Microbiology)

Intended Use: Validation Guidance for Methods – Microbiology for Food and Environmental Surfaces

1. If there is any change in the dilution ratio, that change shall be validated¹.
2. If a method has an approved validation with a certain test portion size, then the validated claim for that method may include portions up to that test portion size. To claim a test portion size above higher than the approved validated test portion size, then validation is required².

¹ **Note:** Methods cannot claim a different test portion to the enrichment broth ratio of a given matrix than that of the ratio of the approved validation. Any such change must be validated. A smaller test portion size of the same matrix may be claimed if the portion to broth ratio is the same as the larger portion to broth that was validated.

² **Note:** AOAC reserves the right to require validation data to support any deviation in test portion size that is not equal to the test portion size in the approved validation. The smallest acceptable test portion size claimed must be greater than or equal to the smallest portion for the reference method used as part of the approved validation study.