



## 方法确认及验证研究

方法确认与验证是实验室通过实验对标准方法、非标方法、内部方法提供提供客观证据以确认或验证该实验方法的准确性、精密性、与稳定性能达到特定的需求。

包含但不限于以下这些情况：

- 分析一种或多种样本基质
- 运用一种或多种仪器或平台
- 多种方法之间的比较
- 不同实验室, 不同区域实验室之间的比较
- 通过确认实验可以摸索出实验的特征性和关键步骤, 以确保有足够胜任方法的实施经验

### 为什么要确认/验证你的方法？

- 基于企业过程监控, 快速放行的需要, 需要使用更加快速的方法
- 新研发产品, 无国家国际标准方法, 需要制定企业内部方法
- ISO 17025实验室认证要求使用确认过的实验方法
- 和其他实验室结果有可比性
- 避免假阴性结果

### 我们的方法验证程序基于：

依据灵敏性、准确性、精密性、重复性、再现性、特异性等参数信息来评价方法的可接受性。

基于以下参考依据：

- AOAC Microbiological Guidelines
- ISO 16140-2:2016
- FDA's Guidelines for Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods
- RB/T 033-2020 微生物检测方法确认与验证指南评价

### 联系我们

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# Method Validation Studies

Method validation is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses of a method are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes.

- In one or more matrices to be analyzed
- In one or more instruments or platforms
- With a demonstrated sensitivity, specificity, accuracy, trueness, reproducibility, ruggedness and precision to ensure that results are meaningful and appropriate to make a decision.
- Reliably for its intended purpose. Intended purpose categories include, but may not be limited to emergency / contingency operations; rapid screening and high throughput testing; and, confirmatory analyses.
- After the method developer has conducted experiments to determine or verify a number of specific performance characteristics that serve to define and / or quantify method performance.

## Why validate your test methods?

- Benefits public health and world trade
- False negative results are unacceptable
- ISO 17025 lab accreditation demands the use of validated methods

## Our Method Validation Studies

With a long history in method validations, Mérieux NutriSciences confirms your methods are suitable for their intended use. We analyze for accuracy, precision and reproducibility in quantitative methods, and sensitivity and specificity in qualitative methods.

Adhering to recognize industry protocols, Mérieux NutriSciences researchers bring years of experience to each method validation study. At each stage of our custom-designed projects, our research team will keep you informed and engaged. Our method validation studies can help:

- Assist kit manufacturers with new proprietary testing method developments
- Compare the validation parameters of existing methods

## Our Validation Programs based on:

- AOAC Microbiological Guidelines
- ISO 16140-2:2016
- FDA's Guidelines for Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods
- RB/T 033-2020 Guidance on verification and validation of microbiological testing methods

### ANY QUESTIONS?

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