



MiChem Dynamics
LEADING CHANGE

MEDICAL LABORATORY METHOD VERIFICATION (SECONDARY VALIDATION) AND UNCERTAINTY OF MEASUREMENT (BASED ON ISO 15189:2022)

This course aims to give an understanding of method verification and uncertainty of measurement based on ISO 15189:2022 in Medical laboratories in the Chemistry, Cytology, Histology, Endocrinology, Haematology, Microbiology, Serology and Molecular Biology fields.

Method verification (secondary validation) is the process used to confirm that the analytical procedure employed form a specific test is suitable for its intended use. Results from method verification can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice.



THE COURSE WILL RUN OVER A PERIOD OF 2 DAYS

LEARNING OUTCOMES:

- Understand the underlying theoretical structure of method validation and verification (secondary validation) as described in ISO 15189:2022.
- Understand the various verification parameters, uncertainty of measurement and its application to evaluate the fitness of use of examination procedures.
- Understand, through practical examples, how data should be applied from the verification study into the verification exercise.

WHO SHOULD ATTEND THIS COURSE:

- Laboratory managers/ supervisors
- Quality managers/ coordinators
- Medical technologist

MINIMUM ENTRY REQUIREMENTS

- Fluency in English writing and reading skills

TUITION

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

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COURSE CONTENT:

DAY 1

- Introduction to method validation and verification
- Designing a method verification procedure
- Designing a method verification plan
- Verification parameter: Accuracy
- Verification parameter: Bias
- Verification parameter: Precision (repeatability and reproducibility)
- Verification parameter: Linearity
- Verification parameter: Working range

DAY 2

- Verification parameter: Limit of Detection (LOD)
- Verification parameter: Limit of Quantification (LOQ)
- Verification parameter: Selectivity / Sensitivity
- Verification parameter: Robustness / Ruggedness
- Uncertainty of measurement
- Compilation of a method verification and Uncertainty of measurement report
- Requirements related to re-verification.
- TEST (ASSESSMENT)

