



Instituto Nacional de
Enfermedades Infecciosas

INEI

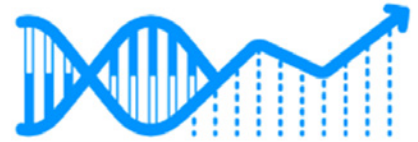
A.N.L.I.S. "Dr. Carlos G. Malbrán" - Argentina



1916 - 2016

- INSTITUTO -
MALBRÁN

200 AÑOS DE INDEPENDENCIA
100 AÑOS DE INVESTIGACIÓN EN SALUD



VALIDACION Y VERIFICACION DE METODOS
DE DIAGNOSTICO MOLECULAR



10TH EDITION

“Molecular Diagnostic Methods, Validation and Verification Process”

September 25 to 29
from 9 a.m. to 3 p.m.



**ANLIS
MALBRÁN**

ADMINISTRACIÓN NACIONAL DE LABORATORIOS
E INSTITUTOS DE SALUD "DR. CARLOS G. MALBRÁN"

Development, Standardization, Analytical Validation and Clinical Performance Evaluation

This course is designed to provide theoretical-practical training to all those who want to develop or modify IVD diagnostic reagents or develop LDT (Laboratory Developed Test), and who need to implement tools to estimate performance characteristics (validation) or evaluate over time the performance of their methods (verification), and thus issue diagnostic results, follow up patients, monitor the results of treatments, produce epidemiological reports, or simply publish these performances in different scientific fields, in a robust and unbiased manner.

Topics

- State-of-the-Art Evaluation of Diagnostic Methods
 - Implementation of the “Model of Life Phases of Methods,” CLSI EP19-ED3:2022 3rd Edition.
 - Standardization and optimization of Real Time PCR absolute quantification
 - Standardization and optimization of Real Time PCR relative quantification
 - LAMP standardization and optimization
 - Validation/Verification Plan of molecular IVD and “in-house” IVDs
 - Validation/verification criteria for researchers and developers (R&D)
- Risk Management
- Selection and estimation of parameters for the validation/verification of molecular methods of quantitative/qualitative response (Real-Time PCR-LAMP)
 - Assay estimation of repeatability / precision // linearity / working range // Limit of detection (LoD) / Limit of quantification (LoQ) // Bias // Uncertainty
 - Diagnostic Validation: selection of the reference subpopulation // Cut-off calculation // ROC curves // estimation of diagnostic sensitivity and specificity // positive-negative predictive values // positive-negative likelihood ratio // comparison of methods // Good Statistical Practices applied to Methods Evaluation
 - Performance monitoring of IVD and LDT methods or “in house”
 - Interlaboratory Harmonization Tests // External Quality Assessment
 - Interpretation and Reporting of results. Decision making.
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Training place

THEORETICAL-PRACTICAL CLASSES

- Conference Room at ANLIS “Dr. Carlos G. Malbrán,” Av. Vélez Sarsfield 563, Buenos Aires, Argentina

THEORETICAL CLASSES

- Live transmission on Zoom
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Director

- **Dr. Marcelo Rodríguez,**
Specialist in Scientific Research Methodology,
National Institute of Infectious Diseases,
ANLIS “Dr Carlos G. Malbrán”
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Staff Coordination and Teaching

- **Lic. Lucia Irazu,** Graduate in Statistics, Specialist in Scientific Research Methodology, National Institute of Infectious Diseases, ANLIS “Dr Carlos G. Malbrán”
 - **Dra. Karina Rodríguez,** Biochem. Pharm. National Institute of Infectious Diseases, ANLIS “Dr Carlos G. Malbrán”
 - **Lic. Rocío García,** National Institute of Infectious Diseases, ANLIS “Dr Carlos G. Malbrán” ”
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Registration

- **Registration link EXCLUSIVE for ANLIS Agents**
<https://forms.gle/yfUuUQcynesLjBad8>
 - **Registration link**
<https://forms.gle/sXfWwKRDkCtk77e49>
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