Your trusted partner for
meeting ISO 15189:2012

Medical laboratory requirements for quality and competence

Be prepared for compliance to ISO 15189
with Thermo Fisher Scientific

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Achieving global standard

ISO 15189 is emerging as a global standard for quality in medical laboratories, with compliance now becoming a requirement. It involves the management of resources that are used to support the core processes of the medical laboratory, and specifies the requirements for quality and competence, including a defined quality system.

Combining over 150 years of technical and scientific expertise in serving the microbiology community, Remel™, Oxoid™, VersaTREK™ and Sensititre™ products are part of the industry-leading Thermo Scientific™ product portfolio, renowned for quality, accuracy, reliability and innovation. With powerful manual and automated technologies, and a comprehensive line of media and diagnostic products our products help diagnose infections quickly and accurately to speed valuable information to clinicians, facilitating faster treatment decisions, and overall better patient care.

Thermo Fisher Scientific has assembled a number of resources and easy-to-access documentation, combined with experienced technical and regulatory support, to help you take control of your quality program and meet ISO 15189.

Product performance and evaluation

The following resources are available for Thermo Scientific products to demonstrate product performance specification and to support evaluation and verification requirements in ISO 15189. These will include product specific, generic and batch specific documents.

Product specification

- Details of the product formulation, preparation method and format where applicable.
- Details of QC testing including international test strains and performance specifications.

Instructions for use (IFU)

- Detail of the intended use, principles of the test procedure, performance data, QC testing and product limitations.

Safety data sheets

- Information to support the safe use of the product and risk assessments.

Methods

- Detailed performance methods for product review, verification and validation.

Stability testing

- Stability testing according to ISO 23640:2013. Evaluation of stability of in vitro diagnostic reagents includes product testing for shelf life and transportation, for use as part of the product verification and acceptance testing.

Certificates of analysis (C of A's)

- Certificates of Analysis (C of A's) contain specific performance data for each batch, which can be used during verification and ongoing acceptance testing.
- All information is available to keep as part of your laboratory management records (including product number, description, batch number and expiry date).

Supplier selection and evaluation

The following resources are available for Thermo Scientific products to aid supplier selection and evaluation as required by ISO 15189.

Quality standards

- Thermo Fisher Scientific Microbiology conforms to ISO 9001 and ISO 13485 Quality Standards.
- Prepared media manufacturing facility laboratory in the U.K. is accredited to ISO 17205.
- Change Control is provided for significant changes in product specification, methods, format and intended use.
- Our quality professionals can provide assistance as required via our experienced Technical Support Teams.

Supplier assessment and performance

- Support of supplier assessments with quality questionnaires and customer audits can be conducted upon request.

Mutually beneficial supplier relationships

- Manage service and technical complaints to ensure resolution in a timely manner using a fully auditable system.
- Detailed technical investigation reports are available as required.
- Implementation of risk control measures, corrective action processes and a robust vigilance approach provides assurance that quality notifications are an integral part of our quality system.

For more information on how we can help you meet the requirements of ISO 15189, please visit **thermoscientific.com/microbiology** or contact your local Technical Service Team at **microbiology.techsupport.uk@thermofisher.com**. Alternatively you can call us on **+44(0) 1256 694238**.

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