

Microbiological Certified Reference Material

By Kelly Ehnes



There has been a lot of talk in the industry about Certified Reference Material (CRM). Unfortunately, many of these conversations include unanswered questions. Microbiologics is here to offer support and hopefully answer some of those questions.

Who should be using Certified Reference Material?

ISO 17025 accredited laboratories should use CRM. ISO 17025, General requirements for the competence of testing and calibration laboratories, states “Reference materials shall, where possible, be traceable to SI units of measurement, or to Certified Reference Materials”. There is increasing interest in the food industry to become ISO 17025 accredited. Several factors have contributed to this push towards laboratory accreditation. The new Food Safety Modernization Act (FSMA) has placed increased emphasis on preventative controls and requires certain food testing to be carried out by an accredited laboratory. In addition, the USDA FSIS released a guidance document, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory, which suggests testing laboratories become ISO 17025 accredited in order to provide, “increased confidence in the accuracy and quality of the test results produced by a laboratory”.

What is Certified Reference Material?

CRM products comply with ISO Guide 34 requirements and are traceable. They are accompanied by a certificate and have a property value with an uncertainty level assigned. The value may be a

qualitative property such as identity or characteristics, or it may be quantitative property such as colony forming units. Certified Reference Materials undergo rigorous testing to verify each sample is homogeneous and stable.

Where can I purchase Certified Reference Materials?

Certified Reference Materials should be purchased from an ISO Guide 34 accredited manufacturer. This accreditation verifies the manufacturer is qualified to produce CRM products. Microbiologics is ISO Guide 34 accredited and offers CRM products in both qualitative and quantitative formats.

When should Certified Reference Materials be used?

Certified reference materials can be used for method validations such as new test methods or cleaning methods. They can be used to validate or calibrate laboratory equipment, such as identification systems. They can also be used to train or evaluate the performance of laboratory personnel through proficiency testing.

Why should a laboratory use Certified Reference Materials?

Certified Reference Materials should be used in order to meet ISO 17025 recommendations. Following ISO 17025 recommendations demonstrates compliance and decreases issues during audits. Microorganism CRMs are highly characterized strains which are recognized as the highest quality materials throughout a number of industries. Certified Reference Materials provide traceability and reliability.

How are Certified Reference materials manufactured?

Certified Reference Materials are manufactured by ISO Guide 34 accredited production and testing facilities. CRMs are highly characterized through an expanded measurement of uncertainty which gauges the variability within a sample. They are tested for homogeneity to verify consistency within a lot. They are also tested for stability over time and during transport.

Microbiologics® Certified Reference Material

Microbiologics has the largest collection of microbiological Certified Reference Material. We offer both qualitative and quantitative CRM products that are easy-to-use, convenient and affordable. Visit www.microbiologics.com to learn more about how Microbiologics CRM can help you maintain compliance with ISO 17025 requirements!

Biography



Kelly Ehnes holds a Bachelor of Science Degree in Microbiology. Her experience at Microbiologics includes working as a microbiologists and directing one of the quality control laboratories. Currently, she assists sales and marketing with her technical expertise. Kelly has industrial experience with biological and chemical testing of wastewater samples, as well as experience in food quality with bacterial and chemical testing of ingredients and food samples. Through her education and career, Kelly has developed a strong background in microbial testing and identification. She has experience with validations of laboratory equipment and processes, and is also a certified internal auditor for ISO 9001:2008.