

Certified Reference Materials, Reference Materials or Inter-laboratory Quality Control Materials are an integral part of a laboratory's quality assurance programme to provide confidence that the measurement process is working as expected. They may be used for method validation, calibration, quality control including ongoing monitoring of equipment, training, and method comparisons.

Reference & Quality Control Material Types:

- **Certified Reference Materials (CRM)**

A CRM must be traceable to an accurate realisation of the unit in which the property is expressed. This is termed Metrological Traceability. A certificate stating the property values and their associated uncertainties MUST accompany a CRM.

CRM's are normally used for calibration, method validation, methodology verification, and less frequent instrument checks needed for quality control. The accuracy, precision, and metrological traceability of the reference values means they can be used for specific method validation and optimisation. The confidence in the reference values is very high, as the uncertainty includes every known component of variability including the standard error of the assigned value, homogeneity and stability

- **Reference Materials (RM)**

These too, are used for similar purposes to CRM's, but lack metrological traceability to a single method. Accurate uncertainty budgets for homogeneity and / or stability may not be known, however both have been established as appropriate for the intended use. Due to the lower cost of reference materials compared to CRMs, they can also be used for training, and more frequent instrument checks. But the lack of metrological traceability means RM's are not generally suitable for calibration, or critical method validation. They can be very useful for ongoing monitoring of test and equipment performance and training purposes.

- **Inter-laboratory Quality Control Materials (QCM)**

These materials are often provided where RM's are not available and usually provide the user an assigned value and range for the analyte offered. They are not used for purposes that require a high degree of precision or confidence in the assigned value as there is not usually an uncertainty associated with the assigned value. QC materials are not recommended for method validation, but are usually a lower cost alternative for frequent and routine instrument and process flow checks.

The selection of the appropriate material lies with the user. The cost, the quantity, and the confidence in the assigned values of the material should all be taken into consideration, as well as its purpose. Global Proficiency recommend that all users of GP RM and QC materials are familiar with and use materials in compliance with, ISO Guide 33 – *Reference Materials – Good practice in using reference materials*.

Global Proficiency's Reference Materials

Global Proficiency's procedures for the selection, handling, and description of Reference Materials (CRM and RM) have been developed in accordance with ISO 17034:2016 "General Requirements for the Competence of Reference Material Producers".

- **Certified Reference Materials (CRM)**

Global Proficiency's characterisation strategy for Certified Reference Materials is based on the selection of operationally-defined quantitative measurands using a network of competent laboratories to ensure appropriate traceability and sufficient reliability. The characterisation process considers the contribution to the uncertainty of the assigned value from multiple sources including product homogeneity (considering inherent product variability as well as mixing); product stability during both storage and transport and method reproducibility. Technical information relating to test methods and equipment, and laboratory performance are carefully considered as part of the characterisation process.

Global Proficiency is in the final stages of planning the release of a Whole Milk Powder Certified Reference Material offering certified values for %Protein (Kjeldahl x 6.38) and %Gravimetric Fat. Watch our website for further information;

www.global-proficiency.com/reference-and-qc-materials/

- **Reference Materials (RM)**

Following presentation in Proficiency Testing rounds, material batches are assessed for suitability as matrix Reference Materials. Assessment of the suitability of a RM takes account of the quality of test results (including blind duplicates where available), the distribution of test data for each test (or method), the strength of consensus between participating laboratories, and the apparent homogeneity and stability of the material. The assigned value (mean; outliers removed) includes the uncertainty of the mean (an expanded standard error at 95% confidence) based on n results, and the test methods used to establish the assigned value.

Example

Test Name	n Labs	n Values	Mean	Uncertainty of Mean ¹	k	Methods
Fat by Difference (%)	6	11	81.70	+/- 0.064	2.23	IDF 191-3, ISO 8851-3, NZTM3.6.9
Moisture Oven/Hot Plate (%)	7	14	15.52	+/- 0.044	2.16	ISO 8851-1/IDF 191-1, NZTM3.12.4
Salt (%)	5	9	1.80	+/- 0.006	2.31	ISO 15648/IDF 179, NZTM3.9.20, NZTM3.9.5
SNF (%)	7	14	2.73	+/- 0.059	2.16	IDF 191-2, ISO 8851-2, NZTM3.12.19

¹ Uncertainty of Mean is an expanded standard error of the mean (SEM) with a level of confidence of 95%. The coverage factor (k) is the critical value of Student's t distribution with $n - 1$ degrees of freedom. This uncertainty may only represent the measurement reproducibility of the data used. It does not include all known associated uncertainties and does not suggest that all methods used are statistically equivalent.

Global Proficiency offers a wide range of reference materials in the following categories:

- **Organic – Foodstuffs:** Dairy Products, Infant formula and UHT Milk
- **Environmental – Soils and Sludges:** Soils & Acid Sulphate Soils
- **Environmental – Plant Material:** Plants

Only analytes that pass strict characterisation criteria are displayed on the RM Data Sheet. Please refer to our website for our lists of current reference materials: www.global-proficiency.com/reference-and-qc-materials/

- **Inter-laboratory Quality Control Materials (QCM)**

These materials are also produced using data from Proficiency Testing rounds, however are derived using data from a single presentation. The assigned value is the consensus median (outliers removed) of n results, with an associated assigned range which can be a robust estimate of 2 standard deviations of n values, or the minimum and maximum values in the case of discrete or non-continuous data.

Example

Test Name	n Values	Assigned Value	Assigned Range
Ash (%)	20	5.71	5.62 -5.80
Fat RG (%)	24	27.81	27.61 -28.00
Free Fat - in powder (%)	17	2.18	2.06 -2.30

Please refer to our website for our lists of inter-laboratory quality control materials: www.global-proficiency.com/reference-and-qc-materials/

CONTACT US TO DISCUSS YOUR REQUIREMENTS

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or visit our website at

www.global-proficiency.com