Recent progress in the production of health-related certified reference materials by the Joint Research Centre

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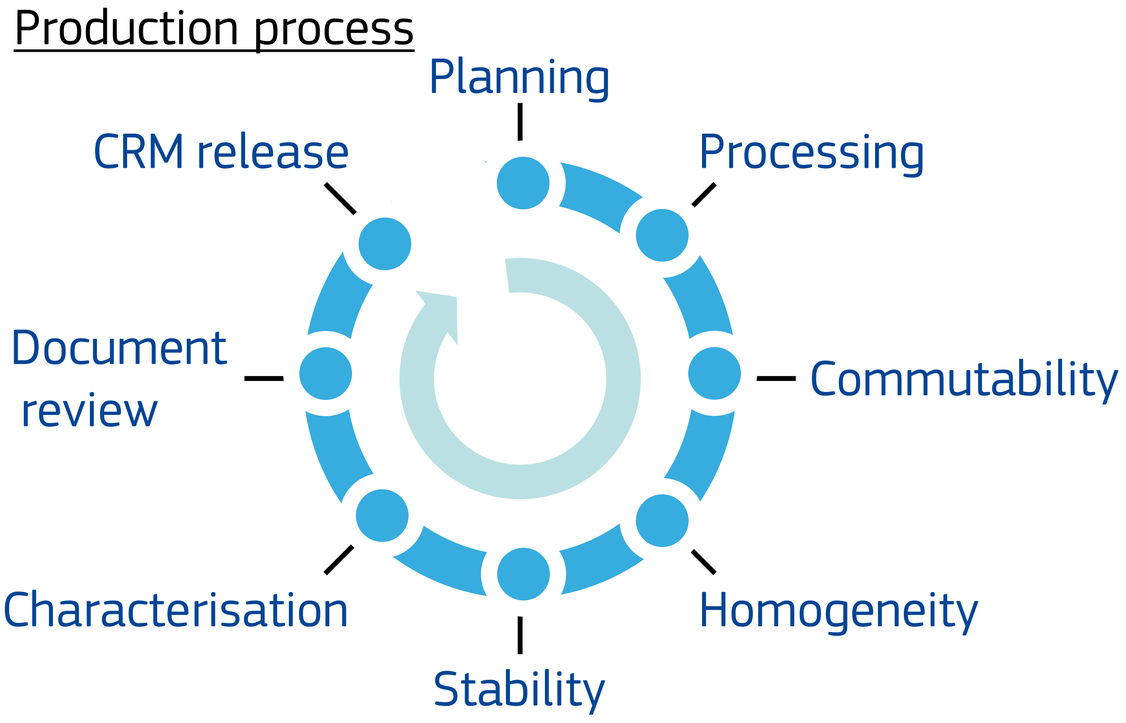
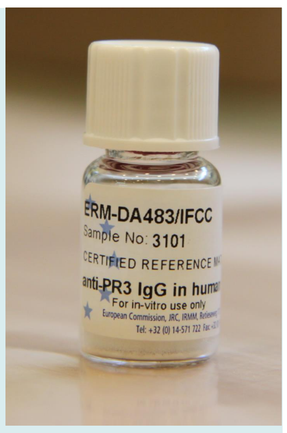
Background: Certified Reference Materials (CRMs) are essential for the development of reference systems for the standardisation of In-Vitro Diagnostics (IVD). The use of CRMs is also required by the IVD Regulation (EU) 2017/746. The European Commission's Joint Research Centre (JRC) develops several CRMs for IVD testing in close collaboration with IFCC working groups. The production of CRMs for protein IVD is a challenging process which requires investigations on several parameters.



ERM®-DA480/IFCC, ERM®-DA481/IFCC, ERM®-DA482/IFCC

- Liquid frozen human cerebrospinal fluid
- Certified for the concentration of Amyloid–β1-42 ($A\beta_{1-42}$) at three levels
- $A\beta_{1-42}$ is a biomarker used for the early detection of Alzheimer's disease
- The CRMs were released in December 2017

ERM®-DA483/IFCC



- Lyophilised human serum
- Certified for the concentration of immunoglobulin G proteinase 3 anti-neutrophil cytoplasmic antibodies (IgG PR3 ANCAs)
- Measurement of IgG PR3 ANCAs is the diagnostic cornerstone of ANCA-associated vasculitides testing (autoimmune testing)
- The CRM was released in February 2017

ERM®-AD456/IFCC

- Lyophilised human pancreatic amylase in artificial matrix
- Certified for the catalytic activity of amylase according to the reference measurement procedure of the IFCC
- Amylase measurements are frequently used for the evaluation of disorders of the pancreas and the gastrointestinal tract
- The CRM was released in October 2019

In the upcoming years, the JRC will continue the development of new CRMs for biomarkers in various clinical fields including Alzheimer's disease, autoimmune disorders, β-thalassemia and cardiovascular diseases.

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Certified Reference Materials catalogue of the JRC: https://crm.jrc.ec.europa.eu/

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