

Project 10

Quantification of an SI-traceable reference material in cells post-transfection

Objectives

The aim of this work is to generate quantitative, comparability datasets for an SI-traceable reference material in cells pre-transfected with the material. The material is a major component of self-assembling virus-like particles (VLPs).

Background

There is a persistent need for the reproducible and quantifiable delivery of macromolecular cargo into the cell. Of particular importance this is for the areas of gene and immune therapies as well as vaccine development where harmonisation for characterisation and testing is required, but lacking.

The study seeks to generate datasets for an SI-traceable reference material developed to benchmark intracellular delivery. The purity profiles of the material has been validated to the highest metrological order.

Standardization needs

Pre-standardisation needs focus on:

- assigned values consistent between laboratories and validated using mass spectrometry
- methods for quantitative analysis of the values by reproducible measurements

- ability to quantify the material to a common material specification

Relevant guidelines & standards

ISO 15195:2018 (Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures)

ISO17034 (reference materials production)
CHMP/GTWP/671639/2008
ISO Guide 35 Reference materials
ISO 13022:2012
CCQM BIPM
ISO 13485:2016

Relevant Committees

[ISO/TC 276](#) - Biotechnology
[ISO/TC 229](#) - Nanotechnology
[ISO/REMCO](#) - Reference Materials

Work Programme

- Post-transfected cell lysates and the reference material are prepared and distributed
- Materials are quantified by participating laboratories using mass-spectrometry
- Data is analysed with full uncertainty evaluations

CALL FOR PARTICIPATION

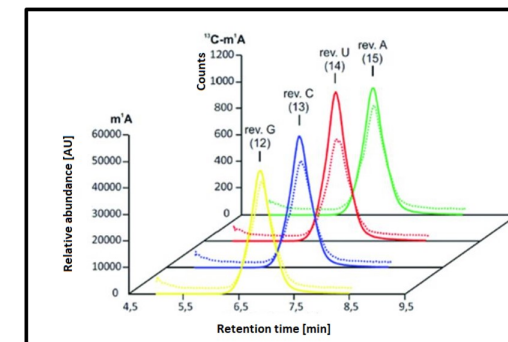
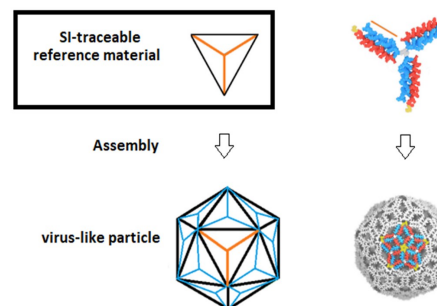


Figure: (left) Schematic and model of the material and (right) the quantification approach of the study using liquid chromatography mass-spectrometry.

Second stage analysis

- Procedures developed will be repeated by a smaller group of participants to assess reproducibility, with the application of orthogonal measurements to cross-correlate quantitative data obtained.

Knowledge Transfer

International round-robin tests, good practice guidelines, peer-review publications and presentations in conferences and standardisation venues.

Status

Study in progress since Sept 2022

Funding

Participants fund their own involvement in the study.

[Register your interest](#)



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