Ref4U biennial activity report

All JCTLM Members are invited to attend the Members' and Stakeholders’ Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

| Organization Name: Ref4U – Laboratory for Toxicology – Ghent University |
|---------------------------|---------------------------|
| JCTLM Member status: Stakeholder Member | |
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| Period covered: 2020 – 2021 | |

1. Major achievement(s) in support of standardization in laboratory medicine

Ref4U’s activities support the efforts to develop and implement a measurement infrastructure for SI-traceable "measurands" in Laboratory Medicine (EN/ISO 17511).

Ref4U, as a reference laboratory, conducts SI-traceable reference measurement procedures as listed in the database of the "Joint Committee for Traceability in Laboratory Medicine (JCTLM)". It offers services to the in-vitro diagnostic industry, metrological institutes, organizers of external quality assessment and other interested parties. An overview of these services, including the associated reference measurement procedures, is given in the JCTLM database. For these measurement services Ref4U is accredited by BELAC (ISO 17025 and ISO 15195), see also the certificate with accompanying scope.

Ref4U, by representation of Dr. Van Uytfanghe, is active as a partner in the EMN on Traceability in Laboratory Medicine and in the JCTLM task force on reference measurement system implementation.

Ref4U is as reference laboratory very actively involved in the activities of the IFCC Committee for Standardization of Thyroid Function Tests (C-STFT). The mission statement of the C-STFT is to document and improve the standardization status and intrinsic quality of current thyroid hormone immunoassays. One of the tasks was to develop reference measurement systems for the most commonly determined thyroid hormones (TT4, TT3, FT4, FT3 and TSH). Activities are now focused on the implementation of these reference measurement systems: (i) by establishing a network of FT4 reference laboratories, (ii) by ensuring sustainability of TSH harmonization; (iii) by dissemination of the work of the C-STFT so that new research (e.g. in establishing regional reference intervals) will be linked to the standards set by the C-STFT; (iv) supporting IVD-manufacturers in implementing the standardized FT4 and harmonized TSH assays.

Additional research activities are focused on implementation of the principles of standardization beyond the field clinical chemistry, more particular in the field of toxicology, with current focus on the measurement of phosphatidylethanol.

2. Planned activity(ies) in support of standardization in laboratory medicine

The focus of the activities of Ref4U with regard to standardization in laboratory medicine will be on:

1. A continuation of the previous mentioned activities within the C-STFT.
2. Providing reference measurement services to the in-vitro diagnostic industry, and other interested parties.
3. Ref4U also aims to further develop and validate candidate reference measurement procedures for SI-traceable measurands.

4. Ref4U will continue to promote standardization in the field of toxicology.

5. Ref4U will continue its activities within the EMN on Traceability in Laboratory Medicine.

6. Ref4U will continue its activities within the JCTLM task force on reference measurement system implementation.

3. Promoting traceability in laboratory medicine

Traceability has been promoted primarily via publications during the last two years:


4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

- Ref4U is a partner in the FT4 Reference Laboratory Network (RLN), established under the auspices of the C-STFT, other members are: the Centers for Disease Control and Prevention (CDC, Atlanta, USA), the Reference Material Institute for Clinical Chemistry Standards (ReCCS, Japan) and the Radboud University Medical Center of Nijmegen (Nijmegen, the Netherlands).

5. Open questions and suggestions to be addressed by JCTLM