Zybio Inc. 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: Zybio Inc.

JCTLM Member status: Stakeholder Member

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Period covered: 2022 - 2023

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

Zybio established the reference system department since 2018 and run the laboratory accordance with the requirements of ISO 17025 and ISO 15195, officially obtained the CNAS accreditation certificate including 7 enzymes and 5 blood cells in 2021.

As the IVD internal reference measurement laboratory, we established effective reference measurement procedures based on the recommendation of JCTLM and more than 160 product traceability have been established for biochemical, luminescent, clinical, and POCT, providing more accurate products and services for end-users.

Up to now,we runs 25 measurand with reference measurement procedures as below:

Analyte category	Analyte	Method
Enzymes	ALT	IFCC reference measurement procedure (37 °C)
	AST	IFCC reference measurement procedure (37 °C)
	ALP	IFCC reference measurement procedure (37 °C)
	CK	IFCC reference measurement procedure (37 °C)
	LDH	IFCC reference measurement procedure (37 °C)
	AMY	IFCC reference measurement procedure (37 °C)
	GGT	IFCC reference measurement procedure (37 °C)
Blood cell	Red blood cell counting	Reference method for enumeration of erythrocytes and leucocytes. Published by：ICSH
	White blood cell counting	Reference method for enumeration of erythrocytes and leucocytes. Published by：ICSH

	Hemoglobin	Recommendations for reference method for haemoglobinometry in human blood.Published by：ICSH
	Hematocrit	Procedure for Determining Packed Cell Volume by the Microhematocrit Method.Published by：ICSH
	Platelet	Platelet Counting by the RBC/Platelet Ratio Method.Published by：ICSH;WS/T 244-2005.Published by:PRC
Proteins	HbA1c	LC-MS/MS
	Total Protein	Spectrophotometry
Non-peptide hormones	TT3	ID-LC-MS/MS
	Total thyroxine	ID-LC-MS/MS
	Testosterone	ID-LC-MS/MS
	Progesterone	ID-LC-MS/MS
	Estriol	ID-LC-MS/MS
	Estradiol-17ß	ID-LC-MS/MS
Metabolites and substrates	Uric acid	ID-LC-MS/MS
	Creatinine	ID-LC-MS/MS
	Total Cholesterol	ID-LC-MS/MS
	Homocysteine	ID-LC-MS/MS
	Glucose	ID-LC-MS/MS

Calibration (reference) measurement services:

Analyte	**Method**	**Clients**	**Time**
5 kinds of Reference Materials.(UA/CREA/UREA/GLU/T/E3)	ID-LC-MS/MS	GDHTCM	2023.05
7 kinds of Reference Materials.(ALT/AST/ALP/AMY/CK/LDH/GGT)	Spectrophotometry	GDHTCM	2023.05
7 kinds of trueness control materials .(ALT/AST/ALP/AMY/CK/LDH/GGT)	Spectrophotometry	Chongqing General Hospital	2023.08
2 kinds of Reference Materials.(UA/CREA)	ID-LC-MS/MS	NIFDC	2023.05
HbA1c	ID-LC-MS/MS	Wondfo	2023.10

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

a) We plan to develop new reference measurement procedures involving measurands such as vitamins, steroid hormones and drugs.

b) We plan to develop hormone, small molecule protein and vitamin standard materials.

c) We will continue to participate in RELA and EQARL and apply methods in the traceability of product value assigns.

d) We plan to apply for inclusion in the JCTLM reference measurement service list to expand our reference measurement service activities.

3. Promoting traceability in laboratory medicine

Committee:

a) National Technical Committee for Metrology of Reference Materials

As a committee member of TCMRM, we participated in the revision of standard documents related to the development of reference materials.

b) National Technical Committee on Medical Clinical Laboratory and in Vitro Diagnostic System of Standardization Administration(SAC/TC136)

The main drafting organization of the medicine standard "Microalbumin Testing Kit(immunoturbidimetry)"

c) Metrology and Testing Alliance for Pharmaceutical and Diagnostic Reagent Industry

As a member of the alliance, we attended the annual meeting in 2022 and 2023, reported our annual work on the medicine metrology.

Conferences:

a) Therapeutics and Diagnostics: Measurements, Standards, Quality and Safety (TD-MSQS 2020) organized jointly by NIM and BIPM in Nanjing, China, in November 2020.

b) Therapeutics and Diagnostics: Measurements, Standards, Quality and Safety (TD-MSQS 2022) organized jointly by NIM and BIPM in Chengdu, China, in May 2023.

Speech: Detection and clinical application of lipoprotein associated phospholipase A2.

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

a) Yearly participates in the EQARL inter-comparison.In 2023, we successfully participated for the reference measurements of Metabolites (Creatinine, UA), Enzymes (ALT, ALP, AST, AMY, CK, GGT, LDH), Thyroid hormone (TT4), Homocysteine.

b) Yearly participates in the RELA inter-comparison. In 2022, we successfully participated for Progesterone, Testosterone,AST, ALT, AST, AMY, GGT, LDH,Creatinine, Estradiol, Glucose, Thyroxin, Total glycerol, Total protein, Triiodothyronine,Estradiol-17β, UA and Urea.

c) Participate in the National Glycohemoglobin Standardization Program(NGSP) and IFCC Network for Standardization of HbA1c each year.

d) Now,we are applying for seven projects to join the JCTLM Reference Measurement Service network in order to serve more international laboratories.

5. Open questions and suggestions to be addressed by JCTLM

In ISO 17511:2020 Scope says:This document is applicable to:b) IVD MDs where the measurement result is reported as a qualitative value established with a ratio of two measurements.

But there was no details about how to use the 6 traceability models to established the value assigned protocol of the manufacturers' calibrators for IVD manufacturers.

So is there any plan to write a consistent standard document for guidance?Or what documents can be refer to?