

Zybio Inc. biennial activity report from JCTLM Member organizations

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

Author(s): Jiangli Wu

Author(s) email(s): RD1298@zy-ivd.com

Period covered: 2024 – 2025

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

Zybio Inc. 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. In 2024, our laboratory have obtained the CNAS certificate for 5 measurands and as of now, a total of 17 measurands have been accredited, including 9 measurands that have been listed in the JCTLM database for reference measurement service.

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-17 β	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/Cooperated Organization	Time
WBC/RBC/PLT/HCT/HGB	/	Shanghai Center for Clinical Laboratories (SCCL)	2023.12
ALT	Spectrophotometry	Guangzhou BDS biological technology Co.,Ltd	2024.07
TBIL	Spectrophotometry	National Institutes for Food and Drug Control	2024.05
Progesterone	ID-LC-MS/MS	National Institutes for Food and Drug Control	2024.05
testosterone	ID-LC-MS/MS	National Institutes for Food and Drug Control	2024.05

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

As a member of SAC/TC136, we participated in the revision and discussion of various standards, led the drafting and revision of the standard "Microalbumin Testing Kit(immunospectrophotometry)", which were released in October 2025.

b) 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.

Conferences:

a) National Conference on Laboratory Medicine Reference System, organized by NCCL in Beijing, China, in November 2024.

b) Academic Conference on Clinical Laboratory Management, organized by NCCL in Chengdu, China, in September 2025.

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

a) Yearly participates in the EQARL and RELA inter-comparison.

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

c) Currently, we have 9 projects joining the JCTLM reference Measurement Service network. More projects will be applied in the future to serve more international laboratories.

5. Open questions and suggestions to be **addressed by JCTLM**

None.