Draft template for 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: Autobio Diagnostics Co., Ltd

JCTLM Member status: Stakeholder Member

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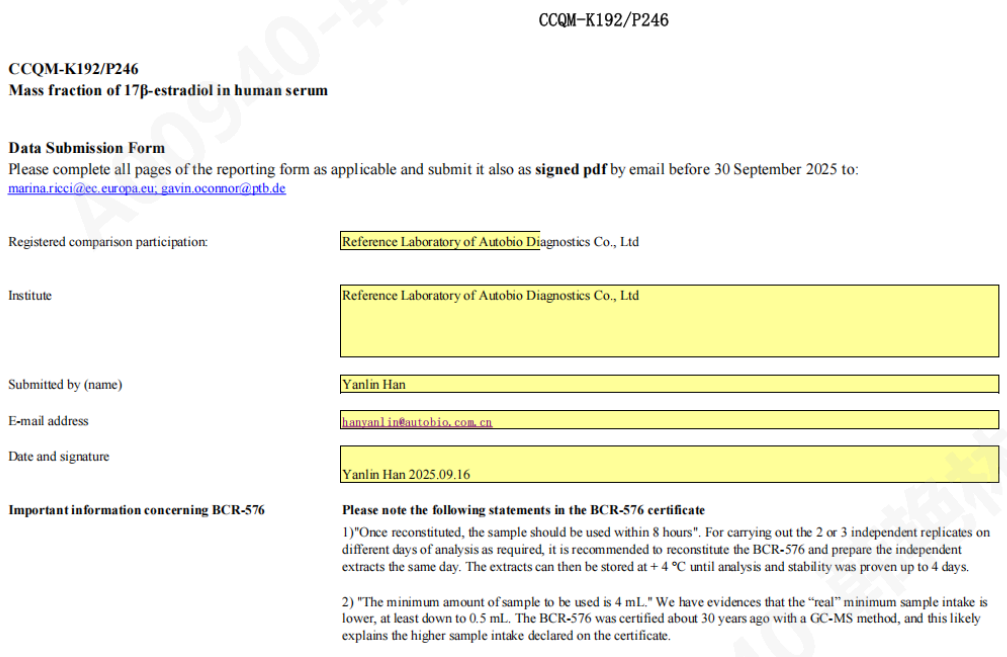
Period covered: 2024 – 2025

1. **Major achievement(s) in support of standardization in laboratory medicine**
   (Please describe what activities your organization has undertaken related to the implementation of reference measurement systems in laboratory medicine during the last two years, including but not limited to information on: the production of certified reference materials; the development of reference measurement methods; or the establishment of calibration (reference) measurement services. Outline the measurement area(s)/measurands covered, and provide a listing of the relevant technical/scientific publications.)

1)Assignment of CRM

We have paticipated in assignment of CRM (CCQM -- 17 β -estradiol in human serum)in 2025.



CCQM-K192/P246

CCQM-K192/P246
Mass fraction of 17β-estradiol in human serum

Data Submission Form
Please complete all pages of the reporting form as applicable and submit it also as **signed pdf** by email before 30 September 2025 to:
marina.ricci@ec.europa.eu; gavin.oconnor@ptb.de

Registered comparison participation:	Reference Laboratory of Autobio Diagnostics Co., Ltd
Institute	Reference Laboratory of Autobio Diagnostics Co., Ltd
Submitted by (name)	Yanlin Han
E-mail address	hanyanlin@autobio.com.cn
Date and signature	Yanlin Han 2025.09.16

Important information concerning BCR-576

Please note the following statements in the BCR-576 certificate

1)"Once reconstituted, the sample should be used within 8 hours". For carrying out the 2 or 3 independent replicates on different days of analysis as required, it is recommended to reconstitute the BCR-576 and prepare the independent extracts the same day. The extracts can then be stored at + 4 °C until analysis and stability was proven up to 4 days.

2) "The minimum amount of sample to be used is 4 mL." We have evidences that the "real" minimum sample intake is lower, at least down to 0.5 mL. The BCR-576 was certified about 30 years ago with a GC-MS method, and this likely explains the higher sample intake declared on the certificate.

2) the development of reference measurement methods

We have developed two candidate reference measurement procedures of glycocholic acid and Insulin in human serum, and these two articles have already been published in 2024 and 2025.

A candidate reference measurement procedure for quantifcation of glycocholic acid in human serum based on isotope dilution liquid chromatography-tandem mass spectrometry;Analytical and Bioanalytical Chemistry , https://doi.org/10.1007/s00216-024-05449-9 (July 2024)

A candidate reference measurement procedure for quantification of human insulin in serum based on immunoaffinity extraction and isotope dilution-liquid chromatography-tandem mass spectrometry;Analytical and Bioanalytical Chemistry ,https://doi.org/10.1007/s00216-025-05900-5; (May 2025)

3) Reference measurement services in list JCTLM database

Analyte	Material or matrix	Service provider	Quantity	Service measurement range	Range of expanded uncertainty
total testosterone	Blood plasma, Blood serum	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of-substance concentration	0.511 nmol/L to 49.7 nmol/L The range of concentration does not involve the dilution of the sample	2.3 % to 3.9 % Level of confidence 95%
cortisol	Blood plasma, Blood serum	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of-substance concentration	13.24 nmol/L to 1238 nmol/L The range of concentration does not involve the dilution of the sample	0.89 % to 2.3 % Level of confidence 95%
total thyroxine	Blood plasma, Blood serum	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of-substance concentration	22.12 nmol/L to 425.5 nmol/L The range of concentration does not involve the dilution of the sample	1 % to 2.4 % Level of confidence 95%
17β-estradiol	Blood plasma, Blood serum	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of-substance concentration	0.0618 nmol/L to 19.43 nmol/L The range of concentration does not involve the dilution of the sample	2.4 % to 4.5 % Level of confidence 95%
progesterone	human serum/plasma; lyophilized, fresh or frozen	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of-substance concentration	0.625 nmol/L to 183 nmol/L The range of concentration does not involve the dilution of the sample	0.97 % to 3.5 % Level of confidence 95%
total 3,3',5-triiodothyronine	human serum/plasma; lyophilized, fresh or frozen	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of substance concentration	0.1714 nmol/L to 14.15 nmol/L The range of concentration does not involve the dilution of the sample	2 % to 4.6 % Level of confidence 95%
17α-hydroxyprogesterone	human serum/plasma; lyophilized, fresh or frozen	Reference Laboratory of Autobio Diagnostics Co., Ltd (AutoRL Zhengzhou) - China http://www.autobio.com.cn/	Amount-of substance concentration	0.964 nmol/L to 297 nmol/L The range of concentration does not involve the dilution of the sample	2.7 % to 4.4 % Level of confidence 95%

2. **Planned activity(ies) in support of standardization in laboratory medicine**
(Please outline R&D project(s) and/or programme(s) planned by your organization in the next two years including information on: new measurement area(s)/meaurands of interest for your organization; new CRMs and renewals of materials; development of methods (new measurands and improved measurement technique/principle); and extensions of your calibration measurement service(s) portfolio.)

development of methods (new measurands and improved measurement technique/principle)	extensions of your calibration measurement service
Peptide/vitamin	Vitamin/non-peptide
Calcitonin,endothelin, Cystatin C ,C-P, Insulin Vitamin A and K,25-OH-VD2	25-OH-VD3 E3

3. **Promoting traceability in laboratory medicine**
(Please describe activities your organization has undertaken during the last two years for promoting traceability in laboratory medicine including but not limited to a listing of your publication(s), presentation(s) and other communication(s) on traceability at international and national conferences or congresses, or other forums for clinical laboratory medicine)

We have participated in Reference System Annual Conference(CHINA,organized by NCCL, National Center for Clinical Laboratories),and shared our experiences with the protein-based candidate reference methods.

4. **Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems**
(Please describe your participation in laboratory networks, forums or professional/technical committees linked to reference measurements system development/implementation, and contributions to JCTLM Working Group activities.)

We have participated in the RELA comparison of the above projects and the reference measurement competency verification of NCCL(CHINA), and achieved qualified results, proving our ability to operate and maintain reference measurement services.

We have joined The National Clinical Medical Metrology Technology Committee (organized by National Institute of Metrology,China),have participated in the formulation and review of the technical specifications for reference measurement methods.

We have join some standardization working groups of IFCC, such as Growth Hormone (WG-hGH),Standardization of Troponin I (WG-TNI),Biomarkers of Neurodegenerative Diseases (WG-BND).

We held a meeting with the insulin standardization working group to discuss the development of methods for C-peptide and insulin.

5. **Open questions and suggestions to be addressed by JCTLM**
(Suggestions on issues related to standardization and metrological traceability that should be considered by the JCTLM)

1) add more projects to RELA EQA activities in the coming years, such as C-peptide, insulin , Aβ-1-42/1-40.

Note: The information of this report will be accessible publicly on the relevant JCTLM Members webpage, unless the author of the report states otherwise. In the case the organization does not authorizes the publication of the report in part or full, the author will add a statement to clarify which part(s) of the report will /will not be rendered public.