

Organization Name: D.I. Mendeleev Institute for metrology (VNIIM)

JCTLM Member status: National and Regional 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.)

List of certified reference materials produced by VNIIM in 2024-2025 for laboratory medicine:

- CRM of blood form elements composition - hematologic control “GC-VNIIM set” (GSO 10669-2015);
- CRM of artificial urine composition (GSO 10023-2011);
- CRM of cholesterol molar concentration (GSO 9913-2011);
- CRM of hemiglobincyanide solution composition (GSO 10238-2013);
- CRM of testosterone molar concentration in blood serum “TESTOSTERON-VNIIM set” (GSO 10390-2013);
- CRM of blood biochemical analytes composition “BH-VNIIM set” (GSO 11312-2019);
- CRM of low molecular weight nitrogenous substances in blood (GSO 11192-2018);
- CRM of inorganic substances molar concentration in blood (GSO 11291-2019);
- CRM of soy DNA composition “GM-SOY-VNIIM set” (GSO 9866-2011);
- CRM of uric acid composition (GSO 11917-2022);
- CRM of urea composition (GSO 11918-2022);
- CRM of the composition of the biological matrix - blood serum (urea), “C-MCH-VNIIM” (GSO 12010-2022);
- CRM of the composition of the biological matrix - blood serum (uric acid), “C-MK-VNIIM” (GSO 12009-2022).

Certified reference materials produced by VNIIM are designated for:

- verification and calibration of biochemical, hematological or immunoassay analyzers, as well as control of their metrological characteristics during trials;
- metrological attestation of measurement procedures or methods;
- control of accuracy of measurement results obtained by the methods (procedures) in the process of their application;
- development of reference measurement procedures.
- EQA conduction

State primary standard of DNA sequence copy number unit was approved in 2024. This standard ensures metrological traceability of values assigned to calibrators in test-systems for DNA analysis in laboratory medicine – according to ISO 17511. Certification of developed reference material of human DNA c.1633G>A (p.E545K)/PIK3CA wt gene copy number ratio is in progress now and will be finished in 2025.

VNIIM participate in GOST TK 380 “Clinical laboratory examinations and in vitro diagnostic test systems” (the mirror TK for the ISO TK 212) and taking part in preparation of the new standard project “Laboratory clinical investigations. Guidelines for in-laboratory quality control of quantitative methods”.

Internal study was initiated in 2025 in VNIIM focused on investigation of current level of standardization of thyroid hormones measurements (T3, T4, TSH) on different immunoassays in the country. The study aimed to development of new reference materials traceable to the state standard.

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)/meurands 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.)

In cooperation with Roszdravnadzor (Governmental regulator in healthcare) control materials will be prepared with assigned values of viral genome copy number concentration for 7 bloodborn viruses.

In cooperation with Russian tissue culture collection, reference materials will be developed certified by DNA sequence oncomarkers content. Liquid biopsy mimicking RMs will be developed.

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)

List of VNIIM publications related to the topic:

Nadezhda A. Kovyavina et al. Measurements in laboratory medicine and external quality assessment. 2025. Measurement Techniques. 74(5), p. 88-97. DOI: 10.32446/0368-1025it.2025-5-88-97

Lianhua Dong et al. CCQM-K181 SARS-CoV-2 RNA copy number quantification. 2025 Metrologia 62 08016. DOI 10.1088/0026-1394/62/1A/08016

Lianhua Dong et al. CCQM-K176 breast cancer biomarker HER2 copy number variation (CNV) measurement. 2024 Metrologia 61 08017 DOI 10.1088/0026-1394/61/1A/08017

Maxim S. Vonsky et al. Molecular Diagnostics of Oncological Disease: Prospects for the Development of a Reference Material for the HER2 Gene Content. 2024. In book: Reference Materials in Measurement and Technology. DOI: 10.1007/978-3-031-49200-6_7

List of presentations:

- 2024-01-26 Shaping requirements for functional/analytical characteristics of the reference material. The Milan Model. Meeting of the committee for standardization of the Federation for Laboratory medicine.
- 2024-04-02 Analytical quality of laboratory studies: actualization of established and development of new requirements. XXIX All-Russian scientific and practical conference "Interpretation of laboratory studies results"
- 2024-04-15 Actual Problems of MD IVD production: ensuring metrological traceability in laboratory medicine. Analytical Center under the Government of the Russian Federation meeting.
- 2024-05-18 Features of Nucleic Acid Analysis Metrological Support in Laboratory Medicine. VIII Russian-Chinese EXPO "Metrology for Medicine and Healthcare"
- 2024-09-02 DNA reference materials for the laboratory medicine. VI International Scientific conference "Reference materials in measurements and technologies".
- 2024-09-17 International experience of interdepartmental cooperation to ensure metrological traceability in laboratory medicine. All-Russian scientific and technical conference "Problems of metrological support in healthcare and production of medical equipment"
- 2024-09-17 On the creation of a new state primary standard for the unit of the DNA sequence number of copies. All-Russian scientific and technical conference "Problems of metrological support in healthcare and production of medical equipment"
- 2024-09-17 Confirming metrological traceability during trials of medical devices for compliance purposes. All-Russian scientific and technical conference "Problems of metrological support in healthcare and production of medical equipment".
- 2024-12-06 Implementation of Government Decision No. 3183-r dated 11/14/2023 "On Approval of the List of Biological Standardization Laboratories": The State primary standard for the unit of DNA

- sequence number of copies. XVII All-Russian Scientific and Practical Conference with International Participation "Medicine and Quality – 2024.
- 2024-12-17 Metrological traceability of values, assigned to calibrators and control materials. Scolcovo conference “MD IVD registration” (Presentation 1 of 3).
 - 2025-03-28 Problematic issues of ensuring the uniformity of bioanalytical measurements in the Russian Federation and their international comparability, metrological support for the sequencers and PCR analyzers. Meeting of the Working group on Standardization, Metrology, quality and Conformity Assessment at the Advisory Council of the Ministry of Industry and Trade of the Russian Federation.
 - 2025-01-25 Metrological traceability of values attributed to calibrators and control materials: estimation of measurement uncertainty. Scolcovo conference “MD IVD registration” (Presentation 2 of 3).
 - 2025-04-29 Problems of metrological support of MD IVD production in Russian Federation. Analytical council of Government of Russian Federation.
 - 2025-05-19 Improvement of the reference instrumentation and development of CRM in the field of bioanalysis. V All-Russian conference of the State CRM service (GSSO) participants.
 - 2025-07-24 Features of metrological traceability realization in laboratory medicine. Scolcovo conference “MD IVD registration” (Presentation 3 of 3).
 - 2025-09-02 State primary standart of the DNA sequence copy number unit. VII international conference “Metrology of physico-chemical measurements”
 - 2025-09-16 Metrological support of nucleic acid analysis methods in laboratory medicine. The XIV All-Russian Scientific and Technical Conference "Problems of metrological support in healthcare and production of medical equipment".
 - 2025-09-17 Determination and control of metrological characteristics of medical devices. The XIV All-Russian Scientific and Technical Conference "Problems of metrological support in healthcare and production of medical equipment".
 - 2025-10-02 Ensuring metrological traceability of the results of molecular genetic diagnostics: The state primary standard for the number of copies of a DNA sequence. V Russian Diagnostic Summit. Russian Congress of Laboratory Medicine.
 - 2025-10-10 Ensuring metrological traceability of the results of molecular genetic tests. All-Russian Scientific and Practical Conference with international participation "Time of the first: medical genetics - the future in the present"
 - 2025-11-12 Metrological support of molecular genetic diagnostics. XII International Scientific and Practical Conference. 2025 Molecular Diagnostics.
 - 2025-11-14 Metrological Traceability in Ensuring the Quality of Molecular Genetic Testing. Cooperation between the Russian Federation and the People's Republic of China. Russian-Chinese International Forum on Innovative Cooperation in the field of Molecular Medicine.

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.)

VNIIM experts participate in Nucleic acids analysis working group and Cellular analysis working group of Consultative committee for metrology in chemistry and biology BIPM, taking part in pilot studies and key comparisons to establish measurement standards as the highest level for traceability hierarchy.

VNIIM experts participate in ISO TK 212 and mirror GOST TK 212 “Clinical laboratory examinations and in vitro diagnostic test systems”.

VNIIM experts participate in the Laboratory Medicine Federation – Russian national society for laboratory medicine professionals.

VNIIM participate in JCTLM-TEPWG activities, took part in “Overview of traceability in Laboratory Medicine” preparation.

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)

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