

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: Birmingham Quality (UK National External Quality Assessment Service)

JCTLM Member status: Stakeholder Member

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Period covered: 2024 – 2025

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

Birmingham Quality offers ISO/IEC 17043:2023 accredited External Quality Assessment (EQA) schemes to medical laboratories internationally. These data allow laboratories to assess comparability of results between methodologies. Periodic reference method assignment for selected analytes (e.g. glycated haemoglobin, creatinine, vitamin D, testosterone, cortisol, etc.) provides an assessment of agreement with metrologically superior methods. Post-market surveillance activities include liaising with laboratories, manufacturers and regulatory bodies like the Medicines and Healthcare products Regulatory Agency (MHRA) when variation between methods is impacting clinical utility of the measurand. This communication includes MHRA Yellow Cards, performance letters to laboratory Clinical Directors, stakeholder meetings, commentaries on EQA reports, webinars, publications, poster presentations, etc. Up until 31st December 2025, Birmingham Quality also escalated poor performance via a Royal College of Pathologists supported National Quality Assurance Advisory Panel (NQAAP) and Quality Assurance Pathology Committee (QAPC). From 1st January 2026, the NQAAP and QAPC have been suspended. More information can be found at <https://birminghamquality.org.uk/qapc-nqaaps/>.

Dr Rachel Marrington and Finlay MacKenzie were awarded the LabMedUK 2025 Impact Award for patient-centric EQA for acute kidney injury; They contributed to national recommendations to standardize acute kidney injury detection and alerting (doi: 10.1177/00045632231180403; Getting It Right First Time (GIRFT) National recommendations to standardise acute kidney injury detection and alerting; UK Kidney Association (UKKA) Acute Kidney Injury National Summit Report and Recommendations).

Our article on The missing piece: Who is responsible for ensuring clinical chemistry assays used in the UK are fit for purpose? Ann Clin Biochem. 2025 Jul 29;45632251367288. doi: 10.1177/00045632251367288. has been reviewed and included as a WestgardQC essay (<https://westgard.com/essays/quality-requirements-and-standards/the-missing-piece-unfit.html>) which also helps to raise awareness of lack of standardization in clinical biochemistry assays.

We are working with the Society for Endocrinology looking at Testosterone. Multiple single unit donations with reference method assignment, were analysed by all participants in our UK NEQAS for Steroid Hormones Scheme, at the same time. The data is in the process of being reviewed with an aim of developing assay specific total testosterone thresholds for the diagnosis of male hypogonadism. This work has the potential to change international practice.

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

Continue to offer ISO/IEC 17043:2023 accredited EQA schemes which are responsive to emerging issues/clinical priorities. Continued participation in the EQALM COMET project and EurA1c Trial (from IFCC Committee on Education in the Use of Biomarkers in Diabetes, C-EUBD). Additional projects include:

- EQALM's Role in Harmonization of Measurement Units in Laboratory Reporting
- A joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation (HALMA, Working Group for Measurands)
- Noklus Patient Median (NOPAM)
- Experiments with reference method assessment:
 - Renin and Aldosterone Standardisation and Harmonisation UK (RASH-UK) working group
 - Calcium recovery experiments.
- Atlas of Variation for Vitamin B12.

3. Promoting traceability in laboratory medicine

Birmingham Quality significantly contribute to national and international meetings, workshops and working groups, including posters and oral presentations. Some relevant publications include:

- Letter accepted for publication in Clin Chem Lab Med (Nov. 2025). Marrington R, Davies SL, MacKenzie F. Shift Happens: The Utility of External Quality Assessment Data in evaluating Folate Lot Changes.
- Elhassan YS, Hawley JM, Cussen L, et al. Society for Endocrinology Clinical Practice Guideline for the Evaluation of Androgen Excess in Women. Clin Endocrinol (Oxf). 2025 Oct;103(4):540-566. doi: 10.1111/cen.15265.
- Marrington R, Sinclair G, MacKenzie F. The missing piece: Who is responsible for ensuring clinical chemistry assays used in the UK are fit for purpose? Ann Clin Biochem. 2025 Jul 29;45632251367288. doi: 10.1177/00045632251367288.
- Marrington R, MacKenzie F. Understanding the limitations of your assay using EQA data with serum creatinine as an example. Clin Chem Lab Med. 2024 Apr 4;62(9):1824-1834. doi: 10.1515/cclm-2024-0027.
- Stephenson AA, Robinson CG, Marrington R, et al. Investigation into the linearity of the Roche c 702 carbamazepine assay. Ann Clin Biochem. 2025 Mar;62(2):135-139. doi: 10.1177/00045632241292510.
- MacKenzie F. Are the benefits of External Quality Assessment (EQA) recognized beyond the echo chamber? Clin Chem Lab Med. 2025 Jan 13;63(5):841-843. doi: 10.1515/cclm-2025-0020. PMID: 39791499.
- Buchta C, Marrington R, De la Salle B, Albarède S, Badrick T, Bietenbeck A, Bullock D, Cadamuro J, Delatour V, Dusinovic E, Geilenkeuser WJ, Gidske G, Griesmacher A, Haliassos A, Holzhauser D, Huggett JF, Karathanos S, Pezzati P, Sandberg S, Sarkar A, Solsvik AE, Spannagl M, Thelen M, Restelli V, Perrone LA. Behind the scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA): Part I – EQA in general and EQA programs in particular. Clin Chem Lab Med. 2025 Jan 6;63(5):844-858. doi: 10.1515/cclm-2024-1289. PMID: 39753377.
- Buchta C, Marrington R, De la Salle B, et al. Behind the scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA): Part II – EQA cycles. Clin Chem Lab Med. 2025 Jan 6;63(5):859-867. doi: 10.1515/cclm-2024-1290.
- Buchta C, Marrington R, De la Salle B, et al. Behind the scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA): Part III – EQA samples. Clin Chem Lab Med. 2025 Jan 6;63(5):868-878. doi: 10.1515/cclm-2024-1291.
- Buchta C, De la Salle B, Marrington R, et al. Behind the scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA): Part IV – Benefits for participant laboratories. Clin Chem Lab Med. 2025 Jan 6;63(5):879-897. doi: 10.1515/cclm-2024-1292.
- Buchta C, De la Salle B, Marrington R, et al. Behind the scenes of EQA – characteristics, capabilities, benefits and assets of external quality assessment (EQA): Part V – Benefits for stakeholders other than participants. Clin Chem Lab Med. 2025 Jan 6;63(5):898-915. doi: 10.1515/cclm-2024-1293.
- Evans C, MacKenzie F, Marrington R. Variation in liver function testing and the effect of pyridoxal-5-phosphate on ALT, AST and FIB-4 results. Ann Clin Biochem. 2024 Nov;61(6):459-468. doi: 10.1177/00045632241269741. Epub 2024 Aug 5. PMID: 39054266.

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

Notable participation in professional/technical committees includes:

- IFCC Working Group for Commutability in Metrological Traceability – Finlay MacKenzie
- CLSI C66 (Vitamin D Testing in the Medical Laboratory) – Dr Rachel Marrington
- Member JCTLM Review Team for Non-Peptide Hormones – Sarah Davies
- Corresponding Member IFCC Committee for Traceability in Laboratory Medicine – Sarah Davies
- Lipoprotein(a) taskforce – Finlay MacKenzie and Sarah Davies

5. Open questions and suggestions to be addressed by JCTLM