Patient Focused Laboratory Medicine Group

# Terms of Reference

## 1. Purpose

The Patient Focused Laboratory Medicine (PFLM) Group is a group of senior clinical laboratory professionals who are concerned about the status of clinical quality in UK laboratories providing a service to NHS patients.

This group was set-up in 2025 in response to a national HbA1c incident involving the recall of >50,000 patients due to potentially incorrect HbA1c results and subsequent mis-diagnosis.

During the investigation into this event, it became clear that the Clinical Quality Infrastructure for pathology laboratories requires review. [1-3] Specifically, within Clinical Chemistry deficiencies in formal escalation routes, lack of effective framework for laboratories / EQA Providers / Suppliers to work together and wide variation in how laboratories manage quality raised significant concern that the profession is at risk of future major patient safety incidents.

In the absence of professional societies assuming responsibility, it was necessary to have a Patient Focused Laboratory Medicine group which was independent of manufacturers and national societies to address these issues.

The remit of the work undertaken by the PFLM group has the patient at the heart of it. Work will focus on raising awareness amongst all relevant stakeholders and driving change to ensure that the service that Clinical Biochemistry laboratories provide is fit for purpose, for the patient.

In order to share the lessons learned from the HbA1c incident, an open access, free of charge, three hour-webinar was held to discuss the event and give an opportunity for people to contribute to recommendations. Over 1,000 people registered for the event. This showed that there is significant appetite within clinical laboratories for change. [4]

## 2. Accountabilities

Members must operate within the existing governance structures within their local organisations.

## 3. External Relationships

PFLM will liaise with all relevant external stakeholders, but has specific arrangements with the following groups:

- BIVDA
- IBMS
- IVD-CERSI — (Centre for Excellence in Regulatory Science)
- LabMed — Association of Laboratory Medicine
- MHRA
- NHS-E Diagnostic Oversight Group
- RCPath The UK Analytical Performance Specifications Group
- UKAS

## 4. Governance

PFLM Group is accountable through GIRFT as a GIRFT sub-group and can report up to NHS-E.

## 5. Membership and Administration

- Membership is voluntary and there is no financial reimbursement from being a member of this group, both in terms of time and/or related expenses.
- See Appendix 1 for membership.
- No formal minutes of meetings will be taken, though all parties are encouraged to keep their own records. Action lists will be maintained.
- The membership stated in Appendix 1 is the core membership. Additional participation is welcome, from any stakeholder as co-opted members, for Task & Finish Working Groups. All participants will be credited for their contributions to group work.
- Engagement with analytical manufacturers may be required for specific projects.
- In conducting its business, the Group will at all times seek to promote its commitment to equality and diversity by the creation of an environment that is inclusive to all participants including those who have protected characteristics or vulnerabilities.

## 6. Frequency of Meetings

- As and when required.

## 7. Quorum

- The group will aim for a quorum of 50 % of the membership.
- Other non-members may be co-opted or invited to attend.

## 8. Confidentiality

- All members of PFLM are required to maintain confidentiality.
- All members agree not to disclose, copy, clone or modify any confidential information related to the group and agree not to use any such information without obtaining consent.
- Confidential information refers to any data and/or information that is related to individual manufacturers or laboratories, in any form, including, but not limited to, oral, written or electronic.

## 9. Resources

1. 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 2025:45632251367288.
2. PT/EQA/QC: All the pieces in place, yet perpetually puzzled. Available at: https://westgard.com/essays/quality-requirements-and-standards/the-missing-piece-unfit.html. Accesed: 4th January 2026 2025.
3. Barnes DI. Pathology Quality Assurance Review, 2014.
4. Marrington R, Davies G. Getting it Right for the Patient - are we good enough?, in LabMed News – December 2025.

## Appendix 1 — Membership

| | |
|---|---|
| GIRFT Pathology Senior Clinical Advisor | Dr. Martin Myers |
| Clinical Representative | Dr. Danielle Freedman |
| Laboratory Representative | Dr. David Housley |
| Birmingham Quality | Mr. Finlay MacKenzie |
| Birmingham Quality | Dr. Rachel Marrington |
| Weqas | Mrs. Annette Thomas |
| Weqas | Mr. Gareth Davies |
| Patient Representative | Vacant |

**Date Terms of Reference agreed:** Monday 9th February 2026

**Date of Review:** Tuesday 9th February 2027