

ARC Laboratory Quality Policy

Policy Statement

ARC Laboratory Services is dedicated to delivering high-quality biomarker testing services in support of precision medicine clinical trials and In Vitro Diagnostic (IVD) medical device performance validation. We are committed to understanding and meeting the needs of our clients and partners through a consistent focus on quality, technical excellence, regulatory compliance, and customer satisfaction.

We uphold the highest standards of technical competence, impartiality, and regulatory adherence, ensuring that all laboratory activities comply with ISO 15189, CAP/CLIA requirements, Good Clinical Practice (GCP), and Good Laboratory Practice (GLP). Our assay development and validation processes align with ISO 13485, ISO 14971, ISO 20916, FDA Quality Management System Regulation (QMSR) and Human Tissue Authority (HTA) standards.

Our Laboratory Services comply with international regulations, including the EU In Vitro Diagnostic Regulation (IVDR) and the FDA's Investigational Device Exemption (IDE) regulations, to ensure the highest levels of quality, performance, and safety.

Commitment to Quality

- **Regulatory Compliance:** We strictly adhere to all applicable international, national and regional standards, ensuring the validity, traceability, accuracy, and reliability of test results.
- **Continuous Improvement:** Our QMS is continuously monitored and enhanced through internal audits, management reviews, corrective actions, and proactive risk management.
- **Customer Focus:** We are committed to exceeding customer expectations by delivering transparent, reliable, and timely test results.
- **Personnel Competency:** We ensure that all laboratory personnel are trained, competent, and continuously updated on best practices and regulatory requirements.
- **Data Integrity & Confidentiality:** We safeguard all data and information gathered or generated, maintaining strict confidentiality and compliance with data protection laws.
- **Equipment & Method Validation:** We utilise state-of-the-art equipment from approved suppliers and validated test methods to ensure precision and consistency in all test methods.
- **Risk Management:** We proactively identify, assess, and mitigate risks that could impact the validity of laboratory results.

ARC Laboratory Quality Policy

- **Environmental & Facility Controls:** We maintain controlled laboratory conditions to ensure accurate and reliable test outcomes.
- **Quality objectives:** We regularly review and refine our laboratory quality objectives to align with regulatory, customer, and organisational requirements.

The Laboratory Management Team is responsible for ensuring that this Quality Policy is clearly understood by all employees and consistently upheld. This policy will be readily accessible to all staff and reviewed periodically to maintain its relevance and effectiveness.