Information concerning the external quality programs for CLL TP53 and CLL IGHV

Genomics Quality Assessment (GenQA) and UK NEQAS for Leucocyte Immunophenotyping (UK NEQAS LI) are members of the United Kingdom National External Quality Assessment Services (UK NEQAS) consortium and are accredited to ISO 17043: 2012 standards. They are working together with the ERIC (European Research Initiative on CLL – www.ericll.org) *TP53* and IG networks to assure the quality of *TP53* variant analysis and Immunoglobulin gene sequence analysis (IG testing) in patients with Chronic Lymphocytic Leukaemia (CLL).

The ERIC consortium educates laboratories and clinical units on how to reliably analyse and use prognostic markers to improve the treatment of patients with CLL. Since 2014, the *TP53* and IG Networks have organized external quality control programs, called *TP53* and IGHV certification, by providing testing samples to participating laboratories and evaluating the results of their analyses. In 2019, GenQA expanded their Chronic lymphocytic leukaemia external quality assessments (EQAs), in collaboration with UK NEQAS LI and ERIC, to include molecular testing for *TP53* and IGHV gene somatic hypermutation status.

How do ERIC and GenQA/UK NEQAS LI cooperate in *TP53* and IG testing for patients with CLL?
ERIC works initially with laboratories to achieve accuracy of testing through the ERIC certification process that ensures the initial quality control of *TP53* or IG gene analyses. **GenQA and UK NEQAS LI** assure the maintenance of testing accuracy and competency of previously ERIC-certified laboratories through participation in their UKAS accredited EQAs and are aimed at laboratories that have already received ERIC certification for *TP53* and/or IGH testing (http://www.ericll.org/diagnostics).

What is EQA
External quality assessment (EQA) is an overarching/umbrella term, which describes the services offered via both ERIC certification, and the proficiency testing offered by GenQA and UK NEQAS LI. EQA allows a laboratory to compare their own test performance, to that of an external source, such as the performance of a reference laboratory, or a peer group of laboratories.

How does the EQA work?
Within both ERIC certification networks and GenQA/UK NEQAS LI EQA programs, the participants receive a set of test samples to be analysed and reported according to their standard procedures, within a given time period. The accuracy of the results produced is then evaluated, and laboratories receive the outcome of the assessment of their results together with a statement of the quality of the laboratory report.

Why is participating in EQAs important?
Participating in EQAs helps your laboratory to meet the national/international guidelines and standards, necessary for laboratory accreditation, and demonstrates that your laboratory is committed to providing the highest quality of analysis for all patients.
EQA is one of the critical elements of a laboratory quality management system. Laboratories in most European countries are expected to be accredited to the ISO 15189: 2012 standard and are therefore required to participate in EQA programs where available.

Is there any difference between the ERIC certification process and GenQA EQAs?
Both the ERIC certification and the GenQA/UK NEQAS LI EQAs follow a similar assessment process, adhering to ERIC recommendations for analysis and interpretation of *TP53* and IG somatic

hypermutation status testing. The ERIC certification process is for the initial certification, GenQA/UK NEQAS LI EQAs are for maintenance of the competency in the subsequent years.

How do I decide whether to participate in the ERIC certification or in the GenQA EQAs for *TP53* and IGHV testing in CLL?
The laboratory should initially pass the ERIC certification. Once you successfully completed the ERIC certification, the next year you may enrol in GenQA/UK NEQAS LI EQA for proficiency testing and maintenance.

What certificates should I expect to receive following participation in the ERIC certification?
ERIC Certification provides each successful laboratory with a certificate, and a letter summarising their performance. Any unsuccessful laboratories will be provided with necessary guidance to re-apply at the next round of ERIC certification.

What certificates should I expect to receive following participation in the GenQA/UK NEQAS LI proficiency testing EQAs?
GenQA UK NEQAS LI provide the outcome of EQA participation to laboratories in the format of an Individual Laboratory Report (ILR). This ILR outlines the laboratory's individual scores and includes any specific individual comments/recommendations for the participating laboratory.

Participants of GenQA/UK NEQAS LI proficiency testing EQAs also have access to a "live" online certificate (available to download), which indicates the laboratory's performance in all relevant GenQA EQAs.

In addition, GenQA also provides a general Summary Report for each EQA, which details a summary of performance of all laboratories, thereby allowing participants to compare their assay performance across time, methods, and networks.

I participated in GenQA CLL IGHV/ TP53 EQA in 2021 but did not receive a certificate.
GenQA UK NEQAS LI *TP53* and IGHV EQAs were previously in pilot phase, therefore the ILRs between 2019-2021 indicated the laboratory's score within the EQA, but gave no final performance outcome designation, i.e., "satisfactory performance" or "poor performance". Beginning in 2022, both GenQA UK NEQAS LI CLL *TP53* and CLL IGHV EQAs are fully accredited against ISO 17043 standards, therefore participant ILR will now include a performance outcome (satisfactory or poor), as well as an EQA score.

How many testing samples are provided, and how often should the laboratory participate?
In the ERIC Certification, five samples are issued for testing per round, and the certificate is valid for a maximum of three years (or until the key lab personnel changes). GenQA provides three test samples and laboratories must participate annually.

May I use any laboratory method?
You can use either next generation sequencing or Sanger sequencing when participating in both ERIC certification, and GenQA UK NEQAS LI EQAs.
DNA samples are provided by both ERIC and GenQA UK NEQAS LI for *TP53* analysis.
For IGHV testing ERIC provides DNA or cDNA while the samples provided by GenQA UK NEQAS LI includes DNA or cDNA or lyophilised cells, from which participants can extract DNA or prepare cDNA for analysis.

How much does it cost to participate?

Participation in the ERIC certification is free.
The GenQA UK NEQAS LI participation fee for 2023, is £385 per EQA. Note that there is no annual registration fee.

May I ask for financial support to cover the costs?
Laboratories from evolving economies can benefit from a discounted price for GenQA UK NEQAS LI EQA participation. In addition to GenQAs evolving economies policy (https://genqa.org), participants in GenQA UK NEQAS LI EQAs can also apply for additional financial support provided by ERIC (http://www.ericll.org) as part of this collaborative approach.

How to register for ERIC certification?
Non-ERIC certified laboratories **(First round of certification)** should register at: http://www.ericll.org/diagnostics/
For further information please email: office@ericll.org

How to register for GenQA/UK NEQAS LI programs?
ERIC-certified laboratories **(Subsequent rounds of certification)** should enrol at: https://genqa.org,
For further information, contact info@genqa.org or office@ericll.org