

Title Evaluation of a worldwide EQA scheme for complex clonality analysis of clinical lymphoproliferative cases demonstrates a learning effect.

Journal Virchows Archiv

Authors Cleo Keppens, Elke Boone, Paula Gameiro, Véronique Tack, Elisabeth Moreau, Elizabeth Hodges, Paul Evans, Monika Brüggemann, Ian Carter, Dido Lenze, Maria Eugenia Sarasquete, Markus Möbs, Hongxiang Liu, Elisabeth MC Dequeker, Patricia JTA Groenen

Correspondence Dr. Patricia JTA Groenen
Radboud University Medical Center
Department of Pathology
Geert Grooteplein Zuid 10
6525 GA Nijmegen, the Netherlands
Email: Patricia.Groenen@radboudumc.nl

Supplemental Table 1. (Inter)national providers of clonality testing EQA programs.

| EQA provider | Region | Accredited provider? | # rounds per annum | Targets | Sample type | # samples distributed | criterion for successful performance | action in case of unsatisfactory performance | criteria for persistent poor performance | Action in case of unsatisfactory performance |
|---|--------|------------------------------------|--------------------|---|--|---------------------------|--|--|--|--|
| BQA Research Unit KU Leuven in collaboration with EuroClonality Consortium ^[29,31] | Europe | yes, ISO17043:2010 ^[30] | 1 | IGH VH-JH, IGH DH-JH, IGK VK-JK, IGK V/intron-KDe, TRB VB-JB, TRB DB-JB, TRG VG-JG, | Paper based cases and extracted DNA from patient samples | 10: 5 for IG and 5 for TR | maximum 1 error on total of 5 samples (for IG and TR separately) | Face-to-face discussion of EQA results during post-EQA workshop for EuroClonality Consortium affiliated labs | Max. 1 error on total of 10 samples over 2 rounds (for IG and TR separately) | No |

Supplemental Table 1 (Continued). (Inter)national providers of clonality testing EQA programs.

| EQA provider | Region | Accredited provider? | # rounds per annum | Targets | Sample type | # samples distributed | criterion for successful performance | action in case of unsatisfactory performance | criteria for persistent poor performance | Action in case of unsatisfactory performance |
|---|--|------------------------------------|--------------------|---|--|--|--|--|--|---|
| UK NEQAS ^[20] | UK (European participants may also register) | yes, ISO17043:2010 ^[30] | 3 | IGH VH-JH, IGH DH-JH, IGK VK-JK, IGK Kde, IGL, TCRB V β -J β , TCRB D β -J β , TCRG V γ -J γ , TCRD | Lyophilized cell-lines or patient derived material, 1 paper case | 6: 1 sample for IG and 1 sample for TR each round, 1 paper case <i>per annum</i> | Incorrect outcome for 1 or 2 samples or no results submission | Communication to participants in report and performance letter, support and guidance (provision of repeat samples, telephone, email or face-to-face communications.) | 2/3 unsuccessful trials | Communicated to Genetics NQAAP panel for UK laboratories only. |
| WIV/ISP (Sciensano) (via UKNEQAS) ^[20] | Belgium | yes, ISO17043:2010 ^[30] | See UK NEQAS | | | | | | | No |
| CAP ^[21] | USA | yes, CAP, CLIA | 2 | IGH, IGH/BCL2 major and minor, IGH/CCND1, IGK TRB, TRG | Extracted DNA sample | 12: 3 samples per round, each sample in duplicate | at least 80% for a subspecialty or clerical errors or data omissions | laboratory to complete a Proficiency Testing Compliance Notice (PTCN) form, documenting corrective actions | 3 consecutive unsuccessful trials or 3/4 or 2/2 trials | Cease patient/client testing for a period of 6 months. Perform 2 successful trials before reinstatements and submit documentation (investigation, corrective action, patient impact and retraining) |

Supplemental Table 1 (Continued). (Inter)national providers of clonality testing EQA programs.

| EQA provider | Region | Accredited provider? | # rounds per annum | Targets | Sample type | # samples distributed | criterion for successful performance | action in case of unsatisfactory performance | criteria for persistent poor performance | Action in case of unsatisfactory performance |
|-------------------------|-------------|-------------------------------|--------------------|--|----------------------|---------------------------|--|--|--|--|
| QuiP ^[23] | Germany | No (ongoing) | 1 | Immunoglobulin G heavy chains and T cell receptor gamma and T cell receptor beta | Extracted DNA sample | 10: 5 for IG and 5 for TR | All cases must be identified correctly (100%) and if a participant has a technical issue with one sample they can order a new tube of that sample. | Legally QuiP cannot sanction poor performance. There are no official bodies to inform about persistent poor performers. Poor performers do not get a certificate but we always offer additional one-to one feedback and the possibility to talk about measures to improve performance. | | |
| RCPAQAP ^[24] | Australasia | yes, ISO17043 ^[30] | 1 | IgH, TCR, unspecified | Extracted DNA sample | 5 (2019) 3 (2020) | <p>assess each sample using the following criteria:</p> <p>Concordant – Meets the expected response</p> <p>Discordant – Deemed unacceptable or does not meet the expected response</p> <p>Not Assessed - The submission is unable to be assessed due to sample issues and/or assay sensitivity</p> | | No actions, but poor performers are reported to National Association of Testing Authorities, Australia (NATA), after which laboratories need to demonstrate improvement plans during accreditation audit | |

Abbreviations: EQA, external quality assessment; CAP, College of American Pathologists; CLIA, Clinical Laboratory Improvement Amendments; IG, immunoglobulin gene; QuiP, Qualitätssicherungs-Initiative Pathologie; RCPAQAP, The Royal College of Pathologists of Australasia Quality Assurance Programs; TR, T-cell receptor gene; UK NEQAS, United Kingdom External Quality Assessment Services; WIV/ISP, Wetenschappelijk Instituut Volksgezondheid/Institut scientifique de la Santé publique.