Performance Monitoring System for the IG/TCR Clonality Status Programme

Aim

The performance monitoring system is a rolling scheme that will identify unsatisfactory performance or persistent unsatisfactory performance of any participant. This is in order that UK NEQAS LI can provide support and guidance where needed and ensure that the Genetics NQAAP are informed as appropriate (UK laboratories only). Please note that each programme will be scored independently.

Outline

Two samples are issued at each trial: one for Ig clonality analysis and one for TCR clonality analysis, if available, a clinical scenario is provided with each sample. There are 3 trials per annum.

Following IG/TCR clonality testing using their normal laboratory technique, participants are asked to provide a molecular conclusion in line with the EuroClonality Uniform System for Molecular Conclusion[1] for each sample. Options available to participants are:

Overall technical description for all Ig or TCR targets	Molecular interpretation/conclusion	Optional: more detailed molecular interpretation
No (specific) product*	No rearrangement in IG/TCR targets detected	No further interpretation possible
Clonal	Clonality detected	Clonality detected (biallelic products)
		Clonality detected (biclonality)
		Clonality detected (minor clonal product)
		Clonality detected (isolated rearrangement)
		Clonality detected (with caution, plus advice for follow-up analysis/new sample)
		Clonality detected in addition to background of B/T cells
		No further interpretation possible
Pseudoclonal (one or more non-reproducible products)	No clonality detected, suggestive of low template amount	No further interpretation possible
Multiple reproducible products (n≥3)	Oligoclonality/multiple clones detected	Dominant clone in oligo/polyclonal background
		No further interpretation possible
Polyclonal (not clonal)	Polyclonality detected (no clonality detected)	Polyclonality detected plus minor clone of unknown significance
		No further interpretation possible
Not evaluable	Not evaluable	No further interpretation possible

*Please note, No (specific) product, poor DNA quality is not provided as an option as with the aid of pre issue testing UK NEQAS LI will ensure all samples have amplifiable rearrangements rendering this option obsolete.

The correct response will initially be derived from the modal response for the 'overall technical description for all targets' from the data submitted. However, in the event that there is a lack of consensus the 'molecular interpretation/conclusion' and 'optional: more detailed molecular interpretation' can be used to inform the correct result. There may be occasions where more than one response is deemed appropriate by UK NEQAS LI's Specialist Advisory Group.

Each participant's response is then compared against the correct results. If the participant is out of consensus for one or both sample(s) a Critical (unsatisfactory) status is awarded for that trial. Non returns will result in an immediate Critical status for that trial.

Please note, results should not be submitted if samples fail internal quality control measures. Repeat samples are available for all trials, if required. If following repeat sample(s) processing, results obtained still do not pass local internal QC please contact UK NEQAS LI. If results are submitted based on the suboptimal results they will be subjected to the same performance monitoring mechanisms as all other participants.

If a participant is awarded two or more Critical statuses out of three trials issued, then their overall status will escalate to persistent unsatisfactory performance.

Unsatisfactory performance will be initially communicated to participants on their trial report. This will be followed up with an email and notification on the participant hub highlighting to participants that their performance was unsatisfactory on the last trial, and offering support and guidance. The support and guidance offered will be tailored to the particular needs of the participant but may include the provision of repeat/additional samples plus telephone, email or face-to-face communications. If a participant's status is elevated to persistent unsatisfactory performance then a further email and hub notification will be issued highlighting this and the Genetics NQAAP panel informed in the case of any UK laboratories.

Participant's results will be reviewed by the lead scientist and the participant may, at the discretion of the Director and Specialist Advisory Group chair person, be referred Genetics NQAAP even if they have not met the criteria for persistent unsatisfactory performance in any individual EQA.

As with all performance monitoring systems it is important to note that these will be constantly reviewed to determine if they are providing the information required. The Director of the scheme retains the discretion to determine if any individual trial should not be scored or scoring amended.

References

1. Langerak, A. W. *et al.* EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations. *Leukemia* **26,** 2159–71 (2012).