UK NEQAS

Leucocyte Immunophenotyping

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UK NEQAS LI *BCR-ABL1* (major) Quantitation – Molecular Programme

Performance Scoring System

Aim

The scoring system is a rolling scheme that will identify unsatisfactory performance or persistent unsatisfactory performance of any participant. This is in order that UK NEQAS for Leucocyte Immunophenotyping (LI) can provide support and guidance where needed and ensure that the Genetics National Quality Assurance Advisory Panel (NQAAP) are informed as appropriate. Please note that each programme is scored independently.

Outline

2 samples are issued in each trial with varying levels of %*BCR-ABL1*/control gene. There are a maximum of 3 trials per annum.

The *BCR-ABL1* translocation is identified using molecular techniques and requires a quantitative response. Therefore, participants are asked, using their normal laboratory technique, to produce a %*BCR-ABL1*/control gene result for each sample. It has not been possible to devise a scoring system to assess participants performance based on the %*BCR-ABL1*/control gene data reported; this is due to participants using four different control genes, each of which produce very different median values. Since a single scoring system which can be applied to all participants is required, the scoring system being implemented is a quantitative approach based upon the log reduction of the %*BCR-ABL1*/control gene result calculated from the data returned by the participants for the 2 samples.

From the participant's submitted results for each sample a log reduction is calculated using the following formula:

$$log10(\frac{BCRABL1/ControlGene\ (\%)\ Sample1}{BCRABL1/ControlGene\ (\%)\ Sample\ 2})$$

The log reduction value is then used in conjunction with the robust mean and robust standard deviation to calculate a z score using the following formula:

$$z = (x - X)/\hat{\sigma}$$

where x is the result returned by the testing laboratory, X is the assigned value (robust mean) and $\hat{\sigma}$ is the standard deviation for proficiency assessment (robust SD).

The robust mean and robust SD are derived from participant data using Algorithm A (ISO 5725-5) that ensures that all data is included in the generation of the robust mean and robust SD but also minimizes the effect of outliers upon the final values. The robust mean and SD are calculated to 1 decimal place (d.p.).

Interpretation of z-scores in the context of this programme is as follows:

- A result between 2.5 and -2.5 will be classed as satisfactory

- A result between 3.5 and 2.5 or -2.5 and -3.5 is seen as an 'action' result. This highlights a potential issue to the laboratory. Two 'action' results in a period of two trial issues would result in classification as a 'critical'
- A result above 3.5 or below -3.5 is considered to be a 'critical' result requiring immediate investigation by the laboratory.

For this programme, participants can choose to be scored on their unconverted %*BCR-ABL1*/control gene, their % International Scale (%IS) results or both results depending on their laboratory preference. If a participant chooses to be scored on both the % International Scale (%IS) and unconverted %*BCR-ABL1*/control gene submitted results, a maximum of one 'Action' or 'Critical' result is used per trial distribution to inform running performance.

Due to the nature of how z-scores are generated a positive z-score highlights a positive bias in a laboratory's results whereas a negative z-score shows a negative bias. As such, this adds value to the performance monitoring information provided to laboratories because the z-score immediately highlights to the participating centre if their result is above or below the expected consensus value.

Any laboratory who fails to return a result by the closing date will be classified as 'Critical' for the 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.

Unsatisfactory performance in this programme is defined as any occurrence of 'Critical' performance and this will be initially communicated to participants on their trial report. This will be followed up with a letter on each occurrence of unsatisfactory performance highlighting that performance on the last sample(s) was out of consensus and offering support and guidance to assist in returning to satisfactory performance. This may take the form of repeat/additional samples, communications by email, telephone conversations or face to face communications.

If a participant's status is elevated to persistent unsatisfactory performance (defined as a 'Critical' classification on 2 or more occasions within a 12 month period) then a further letter will be issued and the Genetics NQAAP informed (for UK participants only).

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 scoring systems it is important to note that the limits will be constantly reviewed to determine whether they are providing the information required. The Director of the programme retains the right to determine if an individual trial should not be scored.