Performance Scoring for the Redesigned Leukaemia Immunophenotyping Programme

Outline

The Leukaemia Immunophenotyping Programme is designed to assess a laboratory's ability to immunophenotype a leukaemia sample using flow cytometry and immunocytochemistry (where applicable) and to compare this to the consensus overall immunophenotype for the malignant population. Stabilised blood obtained from consenting patients will be issued; this material can be readily analysed using whole blood lysis techniques.

Sample Frequency

One sample is issued at each trial (send out) bimonthly (minimum 4 times and maximum 6 times per annum).

Scoring System Description

The scoring system is based on the comparison of the overall immunophenotype results of the malignant population of a participant to the consensus immunophenotype results derived from all participants' returns. The consensus results (positive or negative) of the 10 commonly tested antigens will be used for scoring. The number of antigens tested for by a participant that appear in the top 10 and the number of these with results within consensus of all participants' results will be used for scoring a participant. Occasionally, when there is no clear consensus for an antigen that appears in the top 10, and where there is no obvious cause, such as clone or fluorochrome effect, it may be omitted from the top 10 and will not be used as part of performance monitoring. In such a scenario, the next most common antigen (usually number 11) with clear consensus will replace the antigen without clear consensus. The consensus levels for each antigen in the top 10 will be assessed over the first two years of scheme operation to establish an expected consensus for each marker. In the interim an antigen's inclusion in the performance monitoring, where there is no clear consensus, will be at the discretion of the programme lead in consultation with the top management and the steering committee.

Please note: UK NEQAS LI uses the top ten most popular antigens for performance monitoring as we feel this gives a reflection on the overall panel design and performance when immunophenotyping a leukaemia sample. This approach and associated performance limits have been designed using an analysis of historical results and approved by an independent scientific advisory committee. This approach is continually monitored as part of routine programme operation.

Scoring System Operation

Participants will receive 2 performance classifications which will be used to derive the Overall Performance Classification used for performance monitoring.

The first is the Panel Design Performance Classification which is based on a participant's panel design and the number of antigens tested by the participant matching the 10 most tested antigens. 50% and above is considered satisfactory.

Number of antigens in top ten	Panel Design Performance Grade	Panel Design Performance Classification
10	A	Satisfactory
9		
8	B	
7		
6	C	
5		
4	D	Critical
3		
2	E	
1		
0	F	

The second is the Antigen Testing Performance Classification which is based on a participant's panel design and the number of antigens tested that are in/out of consensus with the 10 most commonly tested antigens.

Number of antigens in top ten	Antigen Results Within Consensus	Antigen Testing Performance Classification
10	≥7	Satisfactory
9	≥6	
8	≥6	
7	≥5	
6	≤4	Critical
5	≤3	
4	N/A	Critical
3		
2		
1		
0		

Both performance classifications will be used to derive the Overall Performance Classification which will be used for performance monitoring.

Panel Design Performance Classification	Antigen Testing Performance Classification	Overall Performance Classification
Satisfactory	Satisfactory	**Satisfactory**
Critical	Critical	**Critical**
Satisfactory	Critical	**Critical**

Where the number of antigens matching the top 10 is <50%, a participant's Overall Performance Classification will be automatically classed as Critical.

Any laboratory who fails to return a result by the closing date will be regarded as critical for that exercise.

Unsatisfactory performance in this programme is defined as any occurrence of critical performance and this will be initially communicated to participants in their trial report. This will be followed by email and notification on the participant hub on each occurrence of unsatisfactory performance with an offer of support and guidance. The support and guidance offered will be tailored to the 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 (defined as a critical classification on 2 or more occasions within a 12-month period) then this will be initially communicated to participants in their trial report. This will be followed by an email and notification on the participant hub on each occurrence of persistent unsatisfactory performance with an offer of support and guidance. The Haematology National Quality Assurance Advisory Panel informed (for UK participants only).

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 management of the programme retains the right to determine if an individual trial should not be scored.