

UK NEOQAS

Leucocyte Immunophenotyping

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UK NEQAS Leukaemia Immunophenotyping Programme - Performance Scoring System

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 upon the comparison of the overall immunophenotype of the malignant population for the core antigens (currently CD2, CD3, CD5, CD13, CD19 and CD20) to the consensus immunophenotype derived from all participant returns. In addition technical information on the performance of individual antigens is also provided in the form of a robust mean and robust standard deviation from the returned results.

Scoring System Operation

Participants are scored based on their overall immunophenotype for the core antigens (currently CD2, CD3, CD5, CD13, CD19 and CD20) on the malignant population in terms of positive/negative expression of these antigens within the malignant population. This is then expressed as a semi-

qualitative grade based on comparison to the consensus result of the core antigens with different grades being awarded for each core antigen within consensus as shown below.

All 6 core antigens in consensus – A

1 antigen out of consensus – B

2 antigens out of consensus - C

3 antigens out of consensus - D

4 antigens out of consensus - E

5 antigens out of consensus – F

All 6 antigens out of consensus – G

A non return will be considered to be all 6 antigens out of consensus and will therefore be awarded a grade G.

Unsatisfactory performance in this programme is defined as any occurrence of critical performance (grades D, E, F and G) and this will be initially communicated to participants on their trial report. This will be followed up with a letter highlighting that performance on the last sample 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 Haematology National Quality Assurance Advisory Panel informed (for UK participants only).

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

Please note performance monitoring for this programme is semi-qualitative and is based on the overall performance grade obtained from the consensus immunophenotype on the core antigens on the malignant population. The robust statistics are related to technical performance on individual antigens and are not used for performance monitoring.

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