Performance Monitoring System for Paroxysmal Nocturnal Haemoglobinuria

Outline

The PNH programme assesses the ability of individual participants to identify the presence (or absence) of a PNH clone. There are a high number of flow cytometric approaches that can be used for determining PNH clone size and all are linked to the absence of the PIG-A gene and thus reduced or lack of expression of antigens that rely on this gene for their production. However, because there are a variety of approaches (and new methods constantly being devised) it has been determined that the fundamental question within this programme is to actually determine the presence/absence regardless of technique used of a PNH clone. Therefore, participants are assessed if using their normal laboratory technique they have detected the presence/absence of a PNH clone using a simple Quantitative approach (Yes/No).

Sample Frequency

Two samples are issued at each trial (send out) that may or may not have a PNH clone (red cell, monocyte, granulocyte). Send outs are a minimum of 5 and maximum of 6 send outs per annum.

Scoring System Classification

The scoring system is a quantitative approach based upon the detection of a PNH clone. It is a rolling scheme that will identify unsatisfactory performance and persistent unsatisfactory performance of any participant.

Satisfactory performance = No problems;
Critical = Unsatisfactory Performance (support and guidance may be required to improve performance prior to the next trial issue);
Critical PUP = Persistent Unsatisfactory Performance immediate action required, support and guidance will continue to be offered but for UK labs Haematology NQAAP will be also informed.

Scoring System Operation

Two samples are issued each trial. The presence of a clone is determined from the data submitted by consensus. Each participant response for each sample is then compared to the consensus response. If the participant is out of consensus a critical notification is given. Three critical notifications within a 12 sample window will elevate the participant to persistent unsatisfactory performance and for UK centres the Haematology NQAAP informed.

Nil returns or no response to the question of whether or not a PNH clone is present are immediately given a critical status.

Unsatisfactory performance (critical notification) will be initially communicated to participants on their trial report. This will be followed up with a letter highlighting that their performance was unsatisfactory on the last trial and offering support and guidance that will be tailored to the particular requirements of the participant. This may take the form of repeat/additional samples and communications by email, telephone conversations or face to face communications. If a participant's status is elevated to persistent unsatisfactory performance (critical PUP) then a further letter will be issued and for UK labs, the Haematology NQAAP informed.

As with all scoring systems it is important that to note that these will be constantly reviewed to determine whether they are providing the information required. UK NEQAS LI top management retain the right to determine if an individual trial should not be scored.