

Performance Monitoring System for *NPM1* Mutation Status Programme

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 LI can provide support and guidance where needed and ensure that the Genetics NQAAP are informed as appropriate. Please note that each programme will be scored independently.

Outline

Two samples are issued for each trial that may or may not feature a *NPM1* exon 11 variant. Please note this region was historically referenced as exon 12 in some early publications in the field. There are three trials per annum. The *NPM1* Mutation Status trial requires a qualitative response from participants; participants are asked if, using their normal laboratory technique, they detect the presence/absence of an exon 11 mutation. The presence/absence of the *NPM1* mutation is determined from the consensus of all participants' results (modal result).

Each participant response is then compared against the consensus 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. If a participant is awarded two 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 with an email and notification on the participant hub on each occurrence of unsatisfactory performance 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, for UK based laboratories, the Genetics NQAAP panel informed.

Participant's results will be reviewed by the lead scientist and any UK 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 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.