Performance Monitoring System *KIT* p.Asp816Val (D816V) Mutation Status for Mast Cell Disease 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 National Quality Assurance Advisory Panel (NQAAP) are informed as appropriate. Please note that each programme will be scored independently.

Outline

Two samples are issued at each trial that may or may not harbour a *KIT* p.Asp816Val (D816V) variant (mutation). There are three trials per annum.

The *KIT* p.Asp816Val (D816V) Mutation status trial requires a qualitative response from participants; therefore, participants are asked if, using their normal laboratory technique, they have detected the presence/absence of the *KIT* p.Asp816Val (D816V) variant. The presence/absence of the *KIT* p.Asp816Val (D816V) variant is determined by consensus (modal result) from participant data. 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.

A small number of participants perform mast cell enrichment (for example using micro dissection, flow cytometric sorting or magnetic beads cell separation) on clinical samples. These methods are not compatible with UK NEQAS LI's lyophilised material and as such these participants are at risk of compromised sensitivity, having deviated from their standard clinical procedure. UK NEQAS LI will identify such participants who are at risk of missing low-level samples and exclude them from scoring where appropriate.

If a participant is awarded two Critical statuses out of three trials issued, then their overall status will escalate to persistent unsatisfactory performance and for UK based laboratories the Genetics NQAAP informed.

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 an email and notification on the Participant Hub on each occurrence of unsatisfactory performance, highlighting that their performance was unsatisfactory on the last trial and offering support/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.

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 chairperson, 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.