UK NEQAS ICC & ISH

PERFORMANCE CRITERIA

Poor Performance Monitoring of (UK Clinical Laboratories Only)

All UK EQA schemes are required by their accrediting body (UKAS ISO 17043/15189), to have in place a formal system whereby the performance of all of its UK based clinical laboratories are monitored. The service is required to notify the National Quality Assurance Advisory Panel (NQAAP) of any cases of persistent substandard performance in participating UK clinical laboratories.

From September 2010, NQAAP made it mandatory for EQA schemes to use a 'traffic light' system for the grading of all its UK participants:

	Green Rating: No issues with poor performance
	Amber rating: Issues with poor performance, managed locally by the scheme
	Red rating: Poor performance issues unresolved; persistent poor performer – referred to NQAAP

Although in-house sections are not part of the front-line poor performance monitoring procedure, the importance of good in-house staining is to be emphasised and laboratories may be contacted if their in-house controls are suboptimal, or their choice of in-house control material is not appropriate. It will not be acceptable to perform well on UK NEQAS ICC & ISH material alone. Laboratories with persistent suboptimal staining of their in-house material will be contacted, and their EQA results discussed with a view to further action being taken if the situation continues.

- The UK NEQAS ICC & ISH Poor Performance monitoring covers the **5** most recent runs following the upload of reports after each assessment.
- For the generic modules, each module is treated as a separate entity; low scores from one module are not combined with low scores from another module to produce a poor performance. Therefore, a laboratory that is underperforming in one module may continue to submit returns for any of the other generic modules in which they are not underperforming.

Offer of Assistance letters

When a laboratory has under-achieved in one (biomarker) or two (generic) assessments, the scheme will notify the laboratory to alert them of this situation. This will be an '**Offer of Assistance' letter**. Although participants are not obliged to contact UK NEQAS ICC & ISH at this point, they may still wish to do so for advice and feedback to improve on future assessment results. Please note that for the generic modules it is possible to have one failed score, then two failed scores at a subsequent run and therefore receive an Amber letter (3 failed scores over 5 runs).

Non-submission of slides:

This will result in a score of zero (0), and will be included in poor performance monitoring, unless the laboratory has informed UK NEQAS ICC & ISH of a valid reason for the non-submission.

NQAAP has stated that submission rates should be **100%** for all UK Clinical laboratories. If a laboratory has not submitted for a run, then the EQA provider (UK NEQAS ICC & ISH) should be given/sent a valid explanation or reason why; e.g. antibody not stocked, not clinically testing or testing being outsourced.
Retrospective explanations following the production of results, and subsequent poor performance reports, may not be acceptable.

Important: The monitoring procedure shown above is liable to change depending on approval from NQAAP. UK participants will be notified of any changes in a separate communication.

Generic modules (all modules except Breast Hormonal, Breast HER2 IHC and ISH, Gastric HER2 IHC, and NSCLC ALK IHC)

This includes General Pathology, Cytology, Neuropathology, Lymphoma, and Alimentary tract (GIST) and MMR/Lynch Syndrome.

Status	When Triggered	Monitoring Procedure
GREEN	**2 underperformances** (scores <10/20) over 5 runs on NEQAS ICC Gold or second chosen antibody slides	No issues with poor performance. Participant will be offered assistance to improve.
AMBER	**3 underperformances** (scores <10/20) over 5 runs on NEQAS ICC Gold or second chosen antibody slides	Participant and Head of Department will be notified of continued underperformance and will be sent a '**Warning letter'** indicating that they are close to being deemed a poor performer and to contact the scheme Director. The scheme Director will then provide advice and assistance on how the laboratory concerned might improve their results
RED	**4 underperformances** (scores <10/20) over 5 runs on NEQAS ICC Gold or second chosen antibody slides	Participant and Head of Department will be notified that they have been deemed a **'poor performer'** and to contact the scheme Director to discuss the situation. The scheme is also obliged to refer the laboratory to NQAAP
Although in-house sections are not part of the poor performance monitoring system of this module, in-house material may also be used to gauge overall performance status. Laboratories should make every effort to submit appropriate control material for the antigen requested.		

Biomarker modules (Breast ER/PR IHC, Breast HER2 IHC, Gastric HER2 IHC, NSCLC ALK IHC and Breast HER2 ISH)

Because of the direct impact that the results of assays for biomarkers have on patient management, more stringent performance monitoring mechanisms are employed:

Status	When Triggered	Monitoring Procedure
GREEN	**1 underperformance** (scores <10/20) over 5 runs on NEQAS ICC slides	No issues with poor performance. Participant will be offered assistance to improve
AMBER	**2 underperformances** (scores <10/20) over 5 runs on NEQAS ICC slides	Participant and Head of Department will be notified of continued underperformance and will be sent a **'Warning letter'** indicating that they are close to being deemed a poor performer and to contact the scheme Director. The scheme Director will then provide advice and assistance on how the laboratory concerned might improve their results
RED	**3 underperformances** (scores <10/20) over 5 runs on NEQAS ICC slides	Participant and Head of Department will be notified that they have been deemed a **'poor performer'** and to contact the scheme Director to discuss the situation. The scheme is also obliged to refer the laboratory to NQAAP

Although in-house sections are not part of the poor performance monitoring system of modules, in-house material may also be used to gauge overall performance status. Laboratories should make every effort to submit well-preserved composite tissue with the full range of tumours of varying expression levels (as outlined in sections 2.3.2 and 2.3.3). Participants not using the correct controls will be scored a maximum borderline score of 12/20. In-house cell lines are an acceptable substitute to be used alongside a participants' own tissue, but the multi-control still must show the full range of expression. Commercial kit control cell lines, such as those used with the Dako HercepTest, Leica Oracle, and Ventana Pathway, are not acceptable as in-house controls for EQA.

N.B. Poor performance is carried out over the previous 5 runs. Participants may receive a letter to confirm their current status (e.g. Amber or Red) even if this may have been sent previously.

If a laboratory's status changes following an appeal (reassessment), a revised letter will be sent to confirm the new status.

Breast HER2 ISH

The value of ISH to determine HER2 gene amplification in breast cancer is evident. Published studies have also highlighted the importance of quality control to monitor this testing (1-5), and because of the direct impact that the results of assays for HER2 have on patient management, more stringent performance monitoring mechanisms are in place for NEQAS ICC and ISH to oversee the testing being carried out by laboratories.

Status	When Triggered	Monitoring Procedure
GREEN	**1 inappropriate score** over 5 runs on NEQAS ISH slides	No issues with poor performance. Participant will be offered assistance to improve
AMBER	**2 inappropriate scores** over 5 runs on NEQAS ISH slides	Participant and Head of Department will be notified of continued underperformance and will be sent a **'Warning letter'** indicating that they are close to being deemed a poor performer and to contact the scheme Director. The scheme Director will then provide advice and assistance on how the laboratory concerned might improve their results
RED	**3 inappropriate scores** over 5 runs on NEQAS ISH slides	Participant and Head of Department will be notified that they have been deemed a **'poor performer'** and to contact the scheme Director to discuss the situation. The scheme is also obliged to refer the laboratory to NQAAP