UK NEQAS
International Quality Expertise

50 Years as World Leaders in EQA 1969–2019

# UK NEQAS ICC & ISH

# PERFORMANCE CRITERIA

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## 1. Poor Performance Monitoring (UK Clinical Laboratories)

All UK NEQAS schemes are required by their accrediting body (UKAS ISO 17043/15189), to have in place a formal system whereby performance of their UK clinical laboratory-based participants is monitored.

UK NEQAS ICC & ISH is required to notify the appropriate Royal College of Pathologist National Quality Assurance Advisory Panel (RCPath NQAAP) of all instances of persistent substandard performance from participating UK clinical laboratories.

The Joint Working Group for Quality Assurance, which is the RCPath body with overall responsibility for clinical quality assurance, has instituted a 'traffic light' system for the grading of UK clinical laboratory-based participants' performance:

| Colour Code | Descriptor |
|---|---|
| **GREEN** | Participant has no issues with poor performance. |
| **AMBER** | Issues with poor performance, managed locally between the Scheme and the participant. |
| **RED** | Poor performance issues remain unresolved; participant is designated as a persistent poor performer and referred to NQAAP |

The UK NEQAS ICC & ISH Poor Performance monitoring covers the five most recent runs following the upload of reports after each assessment.

Each Module is treated as a separate entity; low scores from one Module **are not** combined with low scores from another to produce a poor performance.

It is important that a laboratory which has underperformed continues to participate at subsequent Assessment Runs in order that their continuing performance can be correctly judged (please note that un-sanctioned non-submission counts towards poor performance).

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.

## 2. Offer of Assistance letters

When a participant has a received one score (in Biomarker Modules) or two scores (in Generic Modules) indicative of underperformance(s), the scheme will contact the participant with 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. Performance status remains GREEN at this stage.

## 3. 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 (and an alternative could not be provided), not clinically testing or testing being outsourced.

Retrospective explanations following the production of results, and subsequent poor performance reports, may not be acceptable.

## 4. NON-BIOMARKER (GENERIC) MODULES

These include:

- General Pathology
- Cytology
- Neuropathology
- Lymphoid Pathology
- Alimentary Tract (GIST)
- Mismatch Repair (MMR) Proteins

| Action | Trigger Point | Monitoring Procedure |
|---|---|---|
| **Offer of Assistance Letter** | **Two** unacceptable scores (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact is notified of repeated underperformance.<br>Participant will be offered assistance to improve. |
| **AMBER STATUS** | **Three** unacceptable scores (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact and Head of Department are notified of repeated underperformance.<br>A 'Warning letter' is issued indicating that they are close to being deemed a poor performer. |
| **RED STATUS** | **Four** unacceptable scores (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact and Head of Department are notified of repeated underperformance.<br>A 'Red letter' is issued indicating that they are deemed to be a poor performer and are required to contact the Scheme Director. NQAAP is informed. |

## 5. BIOMARKER MODULES

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

Modules designated as assessing biomarker include:

- Breast Pathology Hormone Receptors (ER and PR)
- Breast Pathology HER2 IHC
- Breast Pathology HER2 ISH
- Gastric Pathology HER2 IHC
- NSCLC ALK

| Action | Trigger Point | Monitoring Procedure |
|---|---|---|
| **Offer of Assistance Letter** | **One** unacceptable score (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact is notified of repeated underperformance.<br>Participant will be offered assistance to improve. |
| **AMBER STATUS** | **Two** unacceptable scores (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact and Head of Department are notified of repeated underperformance.<br>A 'Warning letter' is issued indicating that they are close to being deemed a poor performer. |
| **RED STATUS** | **Three** unacceptable scores (≤8/20) over 5 runs on UK NEQAS Gold or second antibody assessments. | Participant nominated contact and Head of Department are notified of repeated underperformance.<br>A 'Red letter' is issued indicating that they are deemed to be a poor performer and are required to contact the Scheme Director. NQAAP is informed. |

Although in-house sections are not part of the poor performance monitoring system, they may also be used to gauge overall performance status in cases of poor performance. Participants should make every effort to submit appropriate control material for the antigen requested.

Poor performance monitoring is carried out over a rolling five-assessment period 5. Participants may receive a letter to confirm their current status or continuing (e.g. Amber or Red) even if this may have been triggered at a previous Assessment Run.

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

## 6. Poor Performance Monitoring (Non-UK Laboratories)

Following a review of the Poor Performance monitoring carried out by UK NEQAS ICC & ISH, it was decided that from the start of the 2019 – 2020 EQA year, (Run 126 onwards), that Non-UK laboratories would also be subject to Performance Monitoring.

Criteria for the Non-UK laboratories will be the same as for the UK Clinical Laboratories, but only Amber and Red letters will be generated; non-UK participants will not be sent 'Offer of Assistance' letters.

N.B. UK NEQAS ICC & ISH does not have the remit to informer any non-UK laboratory regulatory body when a non-UK participant is found to be Amber or Red rated using the criteria above, nor does the Scheme have the power to compel a participant to make contact; it is the responsibility of the participants' laboratory to act as they deem fit upon receipt of these letters.