Changes to Diagnosis Classification in the Leukaemia Diagnostic Interpretation Programme

The diagnosis of haematological malignancy has evolved in the last few decades aided by the greater understanding of the genetic basis of oncogenesis. Today the tools developed during that era, including monoclonal antibodies, genetic probes used in hybridisation and amplification techniques through to next generation sequencing techniques, can all be utilised in the classification of haematological neoplasms. Indeed the detection of specific genetic markers can completely change the immediate treatment and outcome of patients.

The results of these investigations are now incorporated into the extensive descriptions that underpin the disease classifications described in the 'WHO Classification of Tumors of Haemopoietic and Lymphoid Tissues' a classification which has been adopted worldwide as the defining criteria for establishing the diagnosis of haematological neoplasms.

UK NEQAS LI and the steering committee have been committed to developing quality assessment schemes that would not only allow laboratories and diagnosticians to benchmark the results of their analyses with others, but also to develop schemes that would allow the incorporation of all testing modalities in developing an overall diagnosis. UKNEQAS LI now runs various QA schemes for leucocyte immunophenotyping and molecular analysis. However these schemes have a necessity to develop and evolve so that they can provide laboratories with useful tools that can be used to prove accuracy and competence in the tasks that they undertake and provide for the patients that they serve.

UK NEQAS LI and the steering committee believe that the Leukaemia diagnostic interpretation scheme now needs to evolve to drive greater diagnostic accuracy within the field. Greater accuracy in the diagnosis of haematological neoplasms is in part the subject of the National Institute for Health and Care Excellence (NICE) publication Haematological cancers: improving outcomes (Published May 2016 available at https://www.nice.org.uk/guidance/ng47) which mandates the use of integrated technologies and multi-disciplinary teams to review all diagnoses of haematological neoplasm's in the UK.
The steering committee has recommended that the scoring scheme used for the assessment of the Leukaemia diagnostic interpretation be changed to three new categories;

- The **Correct Diagnosis -** This will be established by an expert panel/committee from all of the data provided including; clinical presentation, morphology, immunophenotype, cytogenetic and molecular genetic data. On rare occasions this may not be the consensus diagnosis.
- A **Differential Diagnosis** classification is such that the diagnosis is deemed plausible in the absence of further pathological tests, and the majority of the Expert Committee is in agreement. If your diagnosis falls into this category you will not be penalised.

- The classification of an **Incorrect Diagnosis** is one that does not utilise all of the available information to establish either the correct or differential diagnosis. It could also be a diagnosis that may lead clinicians to give sub-optimal therapy. This classification would also be used where a submitted diagnosis has either assumed or introduced pathologies other than those provided in the trial data set e.g. stating there is a t(15;17).

By making these changes the steering committee believe that the scheme will remain fit for purpose and can be used as part evidence for proving competency to regulatory bodies such as UKAS/CAP etc.