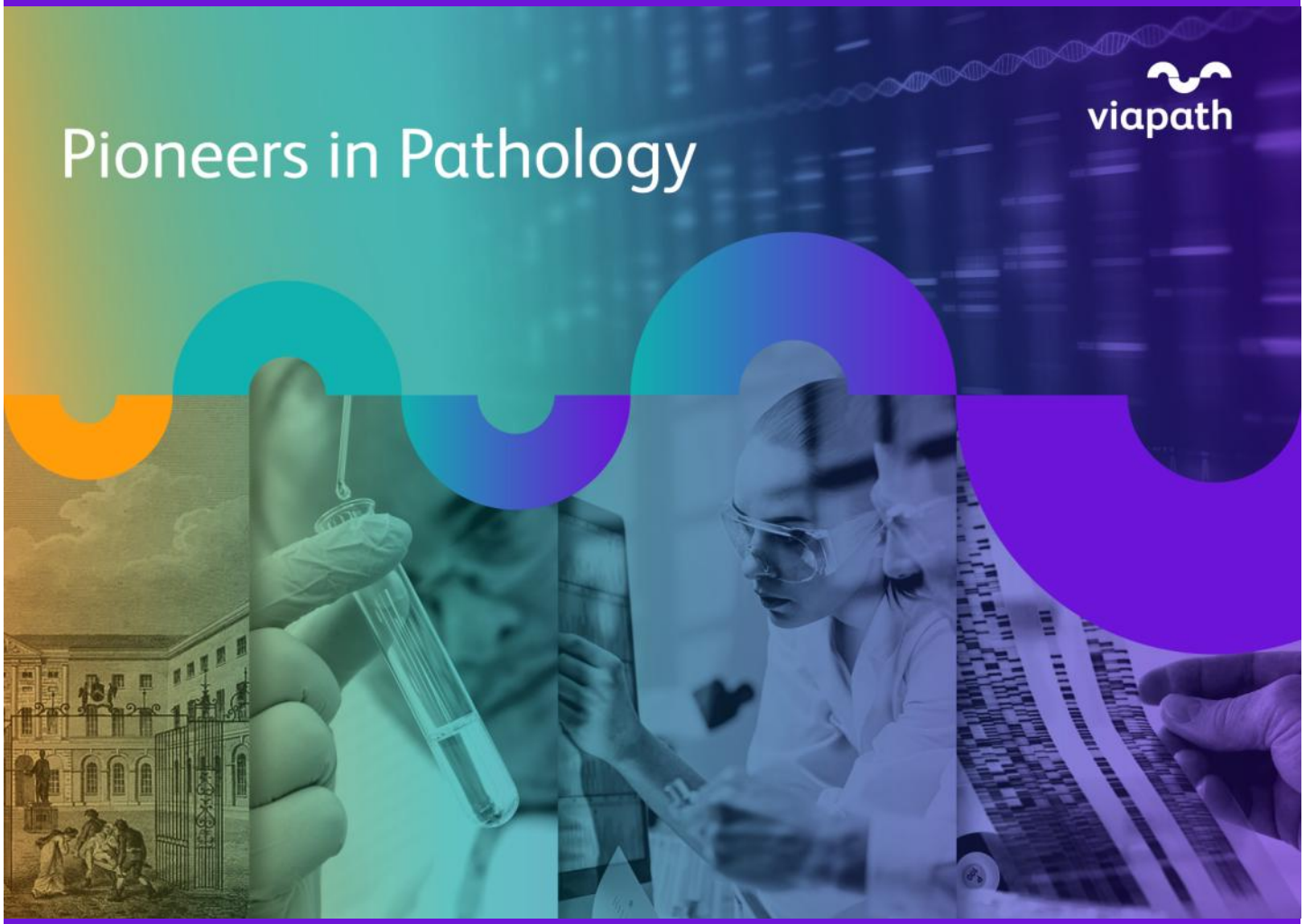
Issue 10 September 2017

Quality Matters



Welcome

Welcome to our tenth edition of Quality Matters which focuses on assessment. On page five, we describe the transition cycle from CPA (Clinical Pathology Accreditation) to ISO15189 accreditation and what the ISO15189 four year cycle consists of.

Jeremy Skinner Quality Manager from Genetics services at GSTT, talks about how they extended their scope and repertoire accredited by UKAS. You can read about the team's success on page two.

A very important focus for all our laboratories is being reassured that their work is meeting the required quality standards. All our laboratories belong to External Quality Assessment (EQA) schemes, where they exist, which assess the assays and give feedback on their performance compared with other scheme participants. Performance in EQA schemes is a very important component of UKAS assessments. Michelle James, a Biomedical Scientist from histology at the PRUH, explains why EQA is so important for patients, on page four.

Finally, we welcome Siobhan Holland who is the new Quality Manager for Bedford services.

Let's Talk Quality

Genetics Laboratories - Accreditation & Extension to Scope

Jeremy Skinner - Quality Manager in Genetics at Guy's Hospital

The Genetics Service at Viapath is composed of the following laboratories:

- Constitutional Genetics
- Biochemical Genetics
- Cancer Genetics

ISO15189 accreditation is granted to the scope or schedule that the laboratory applies for. In 2015 the Monogenics (sub-section of Constitutional Genetics) and Biochemical Genetics laboratories were successful in obtaining ISO15189 accreditation under a single scope.

Previously, Monogenics, Biochemical Genetics and the former Cytogenetics laboratory (which is now integrated into Constitutional Genetics and Cancer Genetics) were on two different CPA accreditation numbers, which means they were assessed separately.

The Genetics Laboratory had an objective to bring all the laboratories under one UKAS accreditation reference number, to support their new model of operating as a fully integrated Regional Genomics Service. In 2017 the remaining sections and sub-sections of the Genomics service (Cancer Genetics, Developmental Disorders, Prenatal and Reproductive Genetics and Bioinformatics) were ISO15189 accredited by "Extension To Scope" (ETS).

A scope (or schedule) is the official statement of activities for which the laboratory is granted accreditation. UKAS offers an extension to scope service for customers who wish to add to, or change, their range of accredited activities. This process may cover a number of changes to an existing scope, including:

- Addition of new conformity assessment activities (tests, inspections, calibrations, areas of certification, etc.)
- Addition of new locations (UK or overseas)
- Expansion into a new area of accreditation

All the laboratories had previously completed the gap analysis and there had been a great deal of learning from the initial assessments and from findings raised at other UKAS visits within Viapath.

When laboratories are brought into an existing scope, UKAS will want to see that there has been a genuine merger so the Genetics quality manual was amended to include all the Genetics laboratories, processes across the laboratory were harmonised (including competency assessments which were praised by the assessors), with pan-Genetics documents being produced and there were pan-Genetics meetings which included all staff meetings for the first time.

Well done Team Genetics!

Genetics Laboratory Teams @ Guy's & St Thomas' Hospital

Under the Microscope - External Quality Assessment (EQA)

What is EQA?

External Quality Assessment (EQA) evaluates the laboratory's performance compared with its peers, and is designed to assess the entire process of sample handling from receipt to reporting. EQA is undertaken periodically hence the use of the term assessment rather than control.

Laboratories should use EQA schemes accredited to ISO17043 where available, although it is recognised that schemes do not exist for every test in which case, alternative schemes should be sought (for example, NHS Screening Programmes, Royal College of Pathologists) or inter-laboratory comparisons. In some cases where no schemes are available, benchmarking internally or with peer laboratories takes place.

Laboratories sign up to specific schemes relevant to the techniques and processes they perform.

Definitions

- **EQA** - External Quality Assessment
- **NEQAS** - National External Quality Assessment Scheme
- **NHSSP** – National Health Service Screening Programmes
- **NQAAP** - National Quality Assurance Advisory Panel
- **RCPath** – Royal College of Pathologists
- **UKAS** - United Kingdom Accreditation Service
- **UKNEQAS** – United Kingdom National External Quality Assessment Scheme
- **WEQAS** - Welsh External Quality Assurance Scheme

? Why do we use UKNEQAS?

- UKNEQAS operate a Code of Practice which lays down scheme requirements including design, management obligations and responsibilities, clinical relevance and financial accountability.
- UKNEQAS has been in operation since 1969, operates both in the UK and internationally and provides a well established and regarded track record of EQA.
- UKAS require medical laboratories to participate in EQA schemes, where available, and requires UKNEQAS to offer assurance on laboratory quality performance on its behalf.

? What are the UKNEQAS scheme objectives?

- Provides regular, impartial and confidential assessments of a range of technical procedures performed by participating laboratories
- Provides data to assist participating laboratories audit their performance
- Contributes to the improvement of procedures used within participating laboratories.
- Contribute to the continuing professional development of staff within participating laboratories
- Assist participating laboratories in meeting accreditation standards relating to EQA
- The EQA Scheme findings and contractual arrangements are confidential between the scheme and the laboratory.

! UKNEQAS performance monitoring

The EQA Scheme Director/organiser is independent, external to Viapath and decides on frequency of monitoring. Performance is reviewed after each circulation and the results made available to the laboratory. Substandard/poor performance can trigger local or national support.

Poor performance is defined as a "low mark" (numeric's), or a persistent breach of the scheme's performance criteria, and each scheme has specified performance parameters contained in the scheme participants manual.

Non-submission of samples/slides will result in a score of zero (0), and will be included in poor performance monitoring, unless the laboratory has informed UKNEQAS of a valid reason for non-submission.

Poor performance will result in a letter being issued to the laboratory by UKNEQAS offering advice and assistance.

Under the Microscope

The importance of External Quality Assessments (EQA)

Michelle James - Quality Lead Senior Biomedical Scientist in Histology at the Princess Royal University Hospital & UKNEQAS Cellular Pathology Technique Assessor

It is an ISO15189 requirement for medical laboratories to participate in an External Quality Assessment (EQA) or proficiency testing programme that is ISO/IEC 17043 accredited. The reason for this is to ensure internal quality control for patient testing is standardised to achieve accurate results no matter where they are tested in the UK.

In-house optimisation of laboratory tests does not necessarily mean it is accurate. Standardisation of inter-laboratory testing is essential because procedures may vary which could influence result outcome.

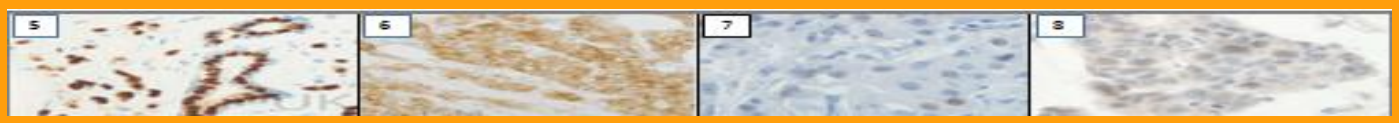
In Histology where tissue samples are tested, inter-laboratory variation may occur in Standard Operating Procedures (SOPs) which include specimen handling, fixation, processing, reagents used, staining and staff competencies. Such variation could have an effect on optimisation of staining techniques including Haematoxylin & Eosin (H&E), Immunocytochemistry and Special Stains.

The Histology department at the Princess Royal University Hospital takes part in two ISO/IEC 17043 accredited EQA schemes which are: the United Kingdom National Equality Services for Cellular Pathology Technique (UKNEQAS CPT) and the United Kingdom National Equality Services for Immunocytochemistry (UKNEQAS ICC). Both schemes assess participants across the UK and overseas and have a pool of professional non-biased assessors with expertise in verification and validation of diagnostic staining techniques. At the PRUH we use feedback from both schemes to continuously improve our staining techniques. We also use feedback to assess the scoring competency of our BMS staff who score our test slides before they are submitted for assessment.

The images below illustrate examples of variation in slides submitted for assessment from the UKNEQAS CPT Image gallery (Participants one-four) and UKNEQAS ICC image gallery (Participants five-eight).

Participants one and two illustrate variation in Grocott Hexamine Silver (GHS) staining which is used diagnostically to distinguish a fungal infection from a tumour in a lung cavitating lesion. One demonstrates optimal expression of fungi (black staining) whereas two demonstrates very weak fungal staining (pale grey staining) for the same test section.

Participants three and four illustrate variation in Ziehl Neelsen (ZN) staining for tuberculosis. Three demonstrates optimal staining of Mycobacterium tuberculosis (magenta staining) with light blue counter stain compared to four where a very strong blue counter stain masks the Mycobacterium tuberculosis for the same test section which could result in the Mycobacterium tuberculosis not being detected.



Participants five to eight illustrate variations in Oestrogen Receptor staining for breast cancer. Five demonstrates optimal nuclear staining (dark brown staining in the nuclei of the cell) in a high expressing tumour; Six demonstrates incorrect cytoplasmic staining (pale brown staining in the cytoplasm of the cell) which should be nuclear; Seven demonstrates very weak staining (limited pale brown nuclear staining) in a mid-expressing tumour; and eight demonstrates false positive nuclear staining in a negative control.

The variation in participants illustrated above is evidence that it is important for laboratories to take part in an accredited EQA scheme because in-house optimisation is not always accurate and could result in the misdiagnosis of a patient. UKNEQAS CPT and UKNEQAS ICC offer support to struggling participants and have an appeal process. UKNEQAS CPT also provides a validation service for laboratory in-house control material, as well as a validation service for staining procedures.

In summary, it is important to take part in EQA schemes and is an ISO15189 requirement. It provides confidence in accuracy of testing and reporting, staff competence, user satisfaction and ultimately optimal patient care.

Accreditation - Transition Process from CPA to ISO15189

SUBMIT APPLICATION TO UKAS

INITIAL ASSESSMENT

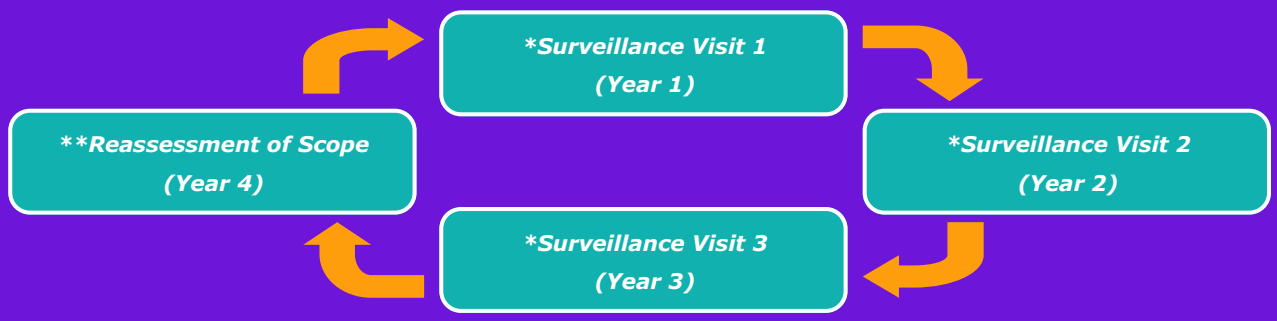
OUTCOME

NOT RECOMMENDED TO ISO15189

RECOMMENDED TO ISO15189
Pending satisfactory clearance of non-conformities which need to be submitted within 12 weeks

- UKAS consider non-conformities, evidence to clear them and have a formal process for sign-off
- UKAS Board revise recommendation and evidence and decide whether to grant accreditation to ISO15189 for laboratory
- UKAS writes formally to the laboratory informing them of decision
- Accreditation status is published on the UKAS website
- Viapath is able to announce success and place the accreditation mark by assays which have been accredited by UKAS.
- Laboratory moves to **ISO15189 four-year cycle**

ISO15189 FOUR-YEAR CYCLE



* Reassessment of Scope once every four years—full scope.

** Surveillance Visits aim to assess a third of scope each time i.e. the three surveillance visits will cover the complete scope.

!

UKAS look for learning across Viapath and between specialties

Quality Manager @ Bedford

Siobhan Holland - Quality Manager at Bedford

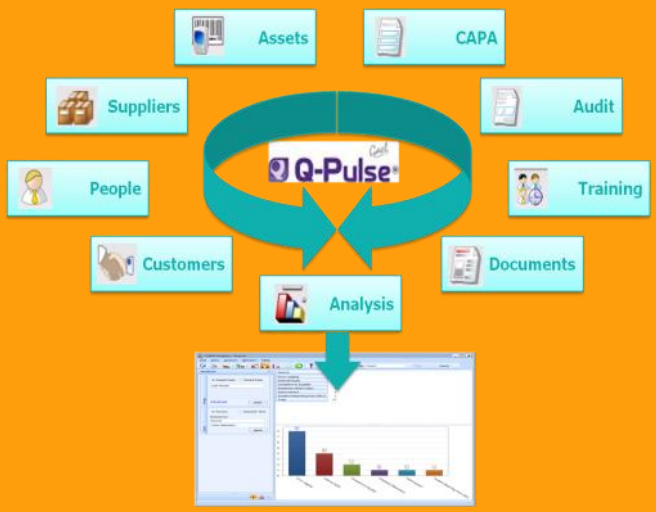
Siobhan Holland has been appointed as the Quality Manager for our Bedford laboratories and takes up her new role in early September. Siobhan is currently the Quality lead for Microbiology services at Bedford and is a key member of their team's continued success in achieving ISO15189 accreditation last year with a successful surveillance visit in October 2016.

Siobhan has previously worked at Addenbrookes hospital in Cambridge and has a long held interest in quality, recently being awarded her masters degree in Biomedical Sciences.

Siobhan is very much looking forward to supporting all of the Bedford services and working closely with site Clinical Director, Dr Fraser Mutch, and General Manager Guy Humphrey. All the Viapath Quality Managers want to welcome Siobhan to the team and look forward to working with her.

Did you know?

Q-Pulse is Viapath's electronic Quality Management System (QMS), which is a formalised system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. Q-Pulse helps coordinate and direct Viapath's activities to meet our customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. Q-Pulse is a very valuable tool to effectively managing our Quality, Risk and Safety management systems. The diagram above displays the various modules available in Q-pulse and how this is a fully integrated system which is capable of providing analysis reports with the available data.



ACTION: If you are not familiar with Q-Pulse speak to your line Manager for login and training.

In the next edition of Quality Matters...

We will be focusing on Incidents and Errors.

We would like to hear from you...

If you have any suggestions or feedback please contact the Head of Quality - Liz Adair or the Quality Hub Coordinator - Carolina Salgado via telephone 020 7188 7188 (Ext. 54885) or email to **QualityMatters@viapath.co.uk**.