

# Technical Bulletin: Accreditation options for genomic testing services - fixed vs flexible scope

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## Accreditation options for genomic testing services: fixed vs flexible scope

Over the last few years UKAS has been trialling options to determine how best to support our accredited customers who offer any genomic/molecular testing. Due to the continuous development of genomic tests, a fixed scope of accreditation may not be the most appropriate option for accredited services as the need to submit multiple extension to scope (ETS) applications each year can be time consuming and resource heavy.

An approach has been trialled whereby some accredited genomic laboratories have been offered a level of flexibility in their accredited scope, reducing the need for so many extension to scope applications. On review, this approach has presented some challenges. For example, some laboratories have not always ensured that they have been able to demonstrate to UKAS that appropriate records are available of method validation and/or verification, EQA participation and performance, and staff training and competency.

To support laboratories that may wish to pursue a flexible scope some example scenarios are included below. Please note, medical laboratories considering applying for a flexible scope of accreditation must also read, and implement the requirements of, UKAS publication [GEN 4](#).

## Examples

### *Next generation sequencing panels*

NGS panels may detect numerous gene mutations. Laboratories are only likely to verify commonly detected mutations initially but may expand their repertoire of verified mutations over time.

If laboratories use NGS panels to detect or confirm mutations in specific genes, and are unlikely to expand their test repertoire, a fixed scope of accreditation is likely to be the most appropriate option.

If laboratories are using NGS panels more broadly, and wish to detect mutations in any of the genes covered by an NGS panel, add targets to a custom panel or add target types (e.g. fusion genes, CNVs, tandem repeats), a flexible scope of accreditation may be a suitable option. Changes to library preparation and enrichment methodology could also be managed under a flexible scope.

Example representation on the UKAS schedule of accreditation:

- + Fixed scope: "Detection of mutations in genes XXX, YYY, ZZZ, AAA using NGS panel name"
- + Flexible scope: "Detection of mutations (eg SNVs, small indels, fusion genes, CNVs) using NGS panel name"

### ***Sanger sequencing***

Sanger sequencing may be used to detect specific or denovo mutations in specific genes using commercially sourced primers or in-house designed primers (manufactured outside of the accredited laboratory). Applications may be for detection of known mutations, minimal residual disease monitoring (e.g. IgH/TCR), cascade testing or confirmatory testing.

If laboratories have a stable repertoire of detected mutations, a fixed scope is likely to be the most appropriate option. If a laboratory regularly designs primers to detect de novo mutations or for minimal residual disease monitoring, a flexible scope may be a suitable option.

Example representation on the UKAS schedule of accreditation:

- + Fixed scope: "Detection of mutations in gene XXX using name commercial primer and sanger sequencing"
- + Flexible scope: "Detection of rare/de novo mutations using in-house designed primers and sanger sequencing"

### **Other potential scenarios**

#### ***Fragment Analysis (in MLPA, gel electrophoresis), Pyrosequencing, Real-time PCR, QPCR, High resolution melt analysis, melt analysis***

Where laboratories expect to expand their scope on an on-going basis through verification of additional primer sets a flexible scope is likely to be the most appropriate option.

#### ***Cartridge based technology***

As molecular testing and technology develops, traditionally non-molecular services (haematology, cellular pathology, etc) are implementing a wide range of molecular tests. This is usually relatively simple, cartridge-based technology used to detect known mutations in a limited number of clinical scenarios (e.g. JAK2, EGFR, KRAS). These laboratories are unlikely to benefit from a flexible scope unless regular changes to the test repertoire are expected.

### **Next steps**

Accredited laboratories with a UKAS schedule which has been updated to include a flexible approach, without having applied for a flexible scope, will either need to apply for a flexible scope of accreditation or will revert to a fixed scope of accreditation.

If you are interested in applying for a flexible scope of accreditation, please contact your UKAS Assessment Manager for more information.

[Link to Medical laboratories flexible scope guidance presentation](#)