

Technical Bulletin: UKAS policy on accreditation of medical laboratories performing genomic tests

31 October 2025

LAB 60 *UKAS policy on accreditation of medical laboratories performing genomic tests* was published on 31 October 2025, following review of comments received during a 30-day consultation period. This policy outlines accreditation options for medical laboratories performing any genomic tests, whether as part of a broader repertoire of tests or as a dedicated genomic testing laboratory.

Flexible scope of accreditation is encouraged for laboratories with a large genomic testing repertoire, as the rate of change in these laboratories is high. Flexible scope reduces the number of extension to scope applications required and enables accredited laboratories to claim accreditation for new tests, within the boundaries of their flexible scope, quickly. The requirements for flexible scope accreditation are detailed in **GEN 4** *UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation*.

This technical bulletin details how UKAS will roll out implementation of LAB 60.

Genomic laboratories that have already been assessed using the informal “semi-flexible” approach will be transferred to a flexible scope of accreditation without submitting an application form or incurring any charges for the transfer, unless they inform UKAS that they want to revert to a fixed scope of accreditation. Laboratories being transferred to a flexible scope will be contacted by the UKAS project team to request relevant documentation and arrange a meeting to discuss the boundaries of accreditation to be recorded on their schedule of accreditation and in their UKAS record.

Genomic laboratory services that do not hold a “semi-flexible” scope of accreditation are required to submit an extension to scope application if they want to transfer to a flexible scope for part/all of their accreditation. The flexible scope application will be assessed alongside the laboratory’s annual accreditation assessment unless the application specifically requests assessment before the annual assessment is due to take place. *Please note, requests to perform the extension to scope outside of the annual assessment will be considered but may not be able to be honoured, due to limited technical assessor resource.* Extension to scope applications must be submitted in good time before the annual assessment, ideally at least 4 months ahead, and include the documentation listed in GEN 4.

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