

**Genomics and Molecular Medicine Service**  
City Hospital campus  
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Date 10/04/2024

**To all Service Users**

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**Re: Nottingham Genomics and Molecular Medicine Service ISO 15189 UKAS Accreditation:  
Suspension**

Dear Colleague

At a recent UKAS inspection visit, the recommendation of the assessment team was to fully suspend our accreditation of the Cytogenetic and Molecular Diagnostic services, part of the Genomics and Molecular Medicine Service at Nottingham University Hospitals NHS Trust. .

The key findings from this inspection and cause for suspension included:

- Delays in the quality management system with particular reference to audits, non-conformities and document control not being maintained in a timely manner.
- Significant backlogs and delays to turn around times (TATs) across a portion of tests, with little evidence available to provide assurance that actions put in place to reduce and improve the situation were effective, with subsequent risk to patients not evidenced.

It was concluded that these findings were as result of insufficient staffing resource.

During the assessment it was acknowledged there is a well-established management system in place with suitable procedures in place to manage all areas of the system. Assessors recognised the high level of knowledge and dedication of staff.

No specific concerns were raised in relation to examination results being compromised, recognising equipment and reagents are managed and maintained in line with documentation and manufacturer's specifications. Adequate External Quality Assurance, Internal Quality Control and alternative procedures are in place to demonstrate satisfactory performance.

This suspension is for a period of up to 6 months with a review, anticipated in July 2024. Reinstatement of accreditation will be on successful submission of evidence demonstrating improvement and implementation of findings raised at this assessment and a follow up reassessment against ISO 15189:2022 standards.

In order to ensure that the service is able to evidence the required improvements and continue to issue accurate results with sufficient resource to manage service and patient requirements, the following risk mitigation measures are planned:

- Full review of staffing requirements for current and future workload.
- Review of laboratory practices to identify efficiencies to support a reduction in backlogs and TATs.

- Review current procedures for timely management of Quality Management System activities.
- Work with other local Nottingham University Hospitals Pathology services and Wider East Genomics Laboratory Hub to learn from good practices.
- Update Quality Management System training to include changes to ISO standards.
- Additional business meetings with UKAS to support active schedule management.
- Clear governance route through Nottingham University Hospitals NHS Trust and working with partners in East Genomic Laboratory Hub

Please be assured that during this period of suspended accreditation the Nottingham University Hospitals' Genomics and Molecular Medicine Service will continue to provide a competent and accurate Cytogenetic and Molecular Diagnostic testing service. For further information regarding turnaround times please see [Service turnaround times | East Genomics](#)

If you have any specific concerns or queries relating to the content of this letter please contact the laboratory directly.

Yours sincerely

*Tom McCulloch*

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**Genomics and Molecular Medicine**

*Amanda Corkill*

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