



Mitochondrial Diagnostic Service, Neurosciences Directorate.

Dear Laboratory Service User,

The Mitochondrial Diagnostic Service (MDS) Laboratory at RVI Newcastle is a UKAS accredited medical laboratory **No.9027** Details of the Scope of our Accreditation and the testing performed is available via the UKAS website.

Available testing

A full list of available tests and turnaround times is stated in our User manual (Diagnostic Laboratory section):

Note on scheme providers used for EQA: From 1st January, 2018 Cytogenomics External Quality Assessment Service (CEQAS) and UK National External Quality Assessment Service (UK NEQAS) Molecular Genetics merged to become Genomics Quality Assessment (GenQA). GenQA is part of the UK NEQAS Consortium.

Quality Commitment to referring laboratories

To fulfil the requirements of ISO 15189:2012 in relation to referral laboratories we have compiled the following information. Due to the volume of requests and variety of forms we receive we are unable to complete individual forms. Our Quality commitment is detailed on page 2.

EQA Schemes and Performance

The department is registered with the EQA schemes listed below and participates in all rounds available covering our scope of service. This may include:

- EMQN scheme for Sanger sequencing (full scheme)
- GenQA for Molecular Genetics (4 schemes):
- 2020 Mitochondrial and POLG- related disorders 2020 Variant Validation
- 2020 Pathogenicity of germline sequence variants (Classification & Interpretation)
- 2020 Next Generation Sequencing (NGS) germline (pilot) - Pilot EQA so no performance rating given
- Inter-laboratory Comparison Scheme for Mitochondrial DNA Depletion (Newcastle-Oxford) – 2020:
- Histochemistry (UKNEQAS)

If at any time we achieve a 'persistent' poor performance we will inform the relevant referrers. Where an EQA scheme or interlaboratory comparison programme is not available for tests within the Laboratory's Scope of Accreditation the department has implemented



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alternative approaches including appropriate internal quality control procedures; these are documented as part of the quality management system.

North East and Yorkshire Genomic Laboratory Hub

Please also see [Genomic Laboratory Hub Services - NHS North East and Yorkshire Genomic Medicine Service \(ney-genomics.org.uk\)](https://www.nhs.uk/genomics/ney-genomics.org.uk)

Target turnaround times

These are documented in the User Manual.

The laboratory aims to report both urgent and non-urgent samples within the stated times however, due to staff shortages and higher than expected demand, there are backlogs and reporting delays for some tests in the MDS Laboratory.

We are working to address these issues as soon as possible. Please contact the laboratory if you require any further information.

Quality Commitment

Provided that we are sent samples and accompanying requests that are valid we make the following assurances to you:

1. We will inform you as quickly as possible if we believe that the results provided for any test/assay and clinical/interpretive service, are for any reason, unreliable.
2. We will inform you as soon as possible of any circumstances that adversely affect our turnaround times or the quality of services that we provide for your referred samples. **Please view our user handbook for up to date information.**
3. Wherever available, we are registered with an EQA scheme, or interlaboratory comparison programme, appropriate to the service provided.
4. We will inform you of any adverse EQA that results in persistent poor performance and/or if we were to be contacted by the scheme organisers.
5. Where no EQA scheme or interlaboratory comparison programme is available, we have alternative mechanisms in place to provide objective evidence for determining the acceptability of test/assay results.
6. We will inform you of any changes to sample requirements (including, but not limited to, sample volume, sample collection and transport conditions) for the testing we perform for you.
7. We will inform you of any changes that could lead to results or their interpretation being significantly different for the tests we perform for you.
8. We will notify you of any changes to our Quality Management System that could adversely influence the quality of results that we provide.
9. We will notify you of any change of contact details. **Please view our website for up to date information.**



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The above commitment applies to all referred tests and associated interpretations that we provide for you and includes all aspects that are pre-defined in any individual agreements.