Myeloproliferative Neoplasms Diagnostic Testing (Not Accredited)

TRIAL No:232401 **Participant:** **ISSUED:** 19/06/2023 **CLOSING:** 11/08/2023

Please note this programme was previously titled Myeloproliferative Neoplasms Gene Panels (Pilot - Not Accredited) programme. It is designed for laboratories performing Myeloproliferative Neoplasms (MPN) testing using current diagnostic algorithms (Tefferi & Pardanani, 2014) to diagnose and subtype the disease. **Participants are expected to test the sample according to their current testing pathways and from April 2022 this programme has been limited (according to WHO/NCCN guidance for the testing of MPN patients) to testing of the core clinically significant MPN variants: *JAK2* p.Val617Phe and clinically significant variants within *JAK2* exon 12, *CALR* exon 9 and *MPL* exon 10.** Extended next generation sequencing panel data is no longer included; such testing is now incorporated in the Myeloid Gene Panels (Pilot - Not Accredited) programme.

Please find enclosed one vial containing DNA for MPN diagnostic testing analysis. Please note that samples are representative of **diagnostic** samples and not follow-up samples. Sample ID (approximate amount and concentration) and relevant clinical details:

- MPN DT 110 (20µl of genomic DNA @ 172ng/µl in 1x TE) from a 45 year old male patient with a high haematocrit, ?polycythemia vera

Please analyse this sample with your in-house strategy for routine diagnostic testing of MPN patients. The scope of this programme is limited to the gene regions listed below and additional results (e.g. from extended NGS panel testing) are not submissible. Please note that testing of all four gene regions is not mandatory and testing should be performed according to your testing strategy as well as your laboratory test repertoire.

- *JAK2* c.1849G>T p.Val617Phe (V617F)
- *JAK2* exon 12
- *CALR* exon 9
- *MPL* exon 10

Exon numbering and variant nomenclature based on reference sequences: NM_004972.4(*JAK2*); NM_004343.4(*CALR*); NM_005373.3(*MPL*).

Wherever possible please treat samples as routine specimens adhering to standard operating procedures and local quality controls. There are no specific environmental conditions that need to be considered for this EQA trial.

Tefferi, A & Pardanani, A (2014) *Nat Rev Clin Oncol* **11**: 125-126

SAMPLE STABILITY, STORAGE AND PROCESSING

Please store samples at 2 - 8°C and avoid freeze/thawing.
The DNA provided should be subjected to local quality control and clean up procedures. The source sample has been subject to extraction using a magnetic (M-PVA) based method.
Samples have been eluted in 1xTE. If the nucleic acid provided does not meet local quality control procedures a repeat sample should be requested as soon as possible (see the section below for guidance on requesting a repeat sample).
Spin the tube briefly to ensure content is at the bottom of the tube prior to opening the cap.
Materials used in the production of samples for UK NEQAS LI EQA programmes are obtained from a variety of sources. In all cases these materials (patient samples, cell lines, blood products etc) are provided under the conditions that they be used only for the educational purpose of EQA. **Participants must only use the samples provided for the purpose intended**. UK NEQAS LI, Sheffield Teaching Hospitals NHS Foundation Trust and any of its employees will not be responsible for any misuse of samples issued in this programme.

COSHH (Control of Substances Hazardous to Health):
The nucleic acid supplied is not known to contain any agents capable of harm; it should be handled in accordance with local laboratory Health & Safety practices.

Packaging: UK NEQAS LI sample(s) are sent by first class post or courier accordingly. Packaging is guided by Package Instruction P650.

Disposal/Spillage: The sample(s) cannot be assumed to be free from infectious agents therefore the material should be assessed as potentially infectious (refer to COSHH). If found to be damaged the packaging and sample(s) should be disposed of in accordance with local Health & Safety and waste management practices. If no specific protocol is available, UK NEQAS LI suggests liberally covering the area with a suitable disinfectant (allowing sufficient contact time for effective action), absorbing the treated spillage with a paper towel before rinsing the area with water and drying thoroughly. See the section below for guidance on requesting a repeat sample.

REPEAT SAMPLES

Requests for repeat samples should be made by email (repeatsamples@ukneqasli.co.uk). Should this not be possible please telephone our Administration team on the number provided below. **Please make a repeat sample request as soon as possible. If following repeat sample(s) processing, results obtained still do not pass local internal QC please contact UK NEQAS LI.**

RESULTS SUBMISSION

Please only submit results applicable to the scope of this EQA programme.
The online results submission pages for this programme are currently hosted externally by the data entry system JotForm. **Participants are encouraged to carefully read and follow the instructions provided on the individual submission pages.**

The JotForm data entry pages can be accessed from the UK NEQAS LI website (www.ukneqasli.co.uk) via the **Participant Hub**. Participants are required to log into this area of the website using their Lab number (also known as PRN, participant reference number), Identity and Password. (Trials/Data Entry>Myeloproliferative Neoplasms Diagnostic Testing (Not Accredited). Click the link symbol adjacent to the trial (MPN DT 232401). URL: https://form.jotform.com/UKNEQASLI/232401MPNDT

Please note, all numerical fields must be completed using only decimal points to separate numbers, and not commas (e.g. enter 6.3 not 6,3).

If you experience any problems submitting your trial results, please do contact us (see contact details section) for assistance. Participants can make changes to existing laboratory contact details, request a password reminder or add a new contact at any time via the Participant Hub. Alternatively, please email (admin@ukneqasli.co.uk) or telephone the number provided below for assistance.

Failure to return your results will be recorded as a non-return and for an accredited programme impact upon your performance status. If you have any queries with regards to online data entry, please do not hesitate to contact us. It is the responsibility of participants to ensure that their results have been received by UK NEQAS LI. Further information can be found in the associated trial issue email and on our website (www.ukneqasli.co.uk).

REPORT DISTRIBUTION

The trial report for this programme will be available online at the UK NEQAS LI website (www.ukneqasli.co.uk). Participants are required to log into the **Participant Hub** (using their web user details) to retrieve PDF report(s). Participants will be notified regarding the availability of an issued report by email. To ensure you receive such emails please check the contact details we hold for your laboratory are accurate and current at re-registration. Participants can make changes to existing laboratory contact details, request a password reminder or add a new contact at any time via the Participant Hub. Alternatively, please email (admin@ukneqasli.co.uk) or telephone the number provided below for assistance.

CONTACT DETAILS

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Please state PRN (participant reference number) on all correspondence.