

## Pilot Myeloproliferative Neoplasms (MPN) Gene Panels (Not Accredited)

Distribution – 202101

Participant -

Date Issued - 09 Sep 2020

Closing Date - 30 Oct 2020

### Trial Comments

FINAL VERSION: This trial was issued to 86 participants; 82 participants (95.3%) have returned results. Of the four participants that did not return results, one pre-notified us regarding their non-return and one requested an extension to results submission in light of the ongoing COVID-19 pandemic.

### Sample Comments

A single sample of lyophilised cells (ref: MPN GP 106) was issued by UK NEQAS LI.

Participants were asked to analyse the sample provided with their 'in house' strategy for testing patients with a Myeloproliferative Neoplasm. The analysis of standard markers (e.g. *JAK2* p.Val617Phe, *JAK2* exon 12, *CALR* exon 9, *MPL* exon 10), as performed in the same succession as for clinical referrals, was requested. We would like to acknowledge and greatly thank Professor Kiyoi (Nagoya University) for permitting the use of MARIMO cell line material in this pilot programme.

### Sample MPN GP 106

Did you detect a pathogenic variant in Sample MPN 106: Test lab

### Your Results - Pathogenic variant(s)

Gene/Region	Your DNA sequence variant detected	Your protein variant

### All Participant Results

Please note, in the interests of clarity we will only summarise variants detected by >2 participants and which are identifiable by Human Genome Variation Society (HGVS) derived nomenclature in the table below (other than the core requested variants of JAK2 p.Val617Phe, JAK2 exon 12, CALR exon 9, MPL exon 10). Please refer to the additional individual gene/region table(s) for a more detailed nomenclature breakdown of results received, as appropriate.

Gene region/marker	Participants detecting a variant/total number who tested the gene	Consensus DNA sequence variant*	Consensus protein variant*	Median Mutation Load(%)/Variant Allele Frequency (%) <sup>†</sup>
JAK2 p.Val617Phe	0/81	No variant detected	No variant detected	n/a
JAK2 Exon 12	0/76	No variant detected	No variant detected	n/a
CALR Exon 9	77/81	c.1099_1159del	p.(Leu367Metfs*43)	39.4/28.9
MPL Exon 10	64/81	c.1514G>A	p.(Ser505Asn)	24.5/25.0

\*Results returned by participants (at both the DNA and protein level) may have been harmonised to the equivalent Human Genome Variation Society (HGVS) approved nomenclature (<http://varnomen.hgvs.org/>) during the compilation of 'All Participants' results tables. Protein nomenclature includes parenthesis as it represents a prediction from analysis at the DNA level. Please contact UKNEQAS LI for reference sequence information.

<sup>†</sup>Descriptive statistics calculated for any variant with >2 quantification data points. Percentage values quoted have been subjected to rounding up/down to 1 decimal point.; mutation load represents information returned from non-NGS users, whereas VAF represents data returned from NGS users.

### Your Performance

Performance	Performance status for this sample	Performance status classification over 12 sample period	
		Satisfactory	Critical
n/a	n/a	n/a	n/a

Please note: this programme is not currently performance monitored. We will work towards a performance monitoring system as the programme develops.

**Detailed breakdown of CALR exon 9 variant(s) detected.**

Please note the LRG is public for CALR: <https://www.lrg-sequence.org/search/?query=CALR>

DNA Sequence Change	n	Nomenclature guidance comments (as applicable)
c.1099_1159del	53	Compliant with current HGVS recommendations <sup>1,2</sup> (as per NCBI RefSeq Transcript NM_004343.3).
61bp deletion	3	No HGVS based nomenclature provided. However, result is in line with the consensus reported deletion size for this trial.
Variant in exon 9 (not type 1 or 2)	1	No HGVS based nomenclature provided. However, result is in line with the consensus reported for this trial.
Not provided	2	
c.1099_1159delCTTAAGGAGGAGGAA GAAGACAAGAAACGCAAAGAGGAGG AGGAGGCAGAGGACAAGGAGG	4	Please note, listing the nucleotides was optional in the previous version of the HGVS; however, v20.05 <sup>2</sup> does not recommend this. They cite it as redundant information increasing the chance of error: <a href="https://varnomen.hgvs.org/recommendations/DNA/variant/deletion/">https://varnomen.hgvs.org/recommendations/DNA/variant/deletion/</a>
c.1099_1159del61	1	The number of deleted nucleotides can be deduced from the positional limits of the deletion; including redundant information increases the chance of error.
c.1099_1150del	2	Out of consensus variant identified.
c.1092_1143del	2	Out of consensus variant identified. Nomenclature error at the c.DNA level; please note current HGVS recommendations <sup>1,2</sup> which state the most 3' (downstream) nucleotide positions are to be arbitrarily assigned when describing the deleted region.
60 bp deletion	2	Out of consensus variant identified.
c.1099_1159delCTTAGGAGGAGGAA GAAGACAAGAAACGCAAAGAGGAGG AGGAGGCAGAGGACAAGGAGG	1	Nomenclature error at the c.DNA level; please note current HGVS recommendations <sup>1,2</sup> to not describe the deleted nucleotides as including redundant information increases the chance of error.
c.1099_1158del	1	Out of consensus variant identified.
c.1099_1059del	1	Positional numbering error; likely a transcription error.
50bp deletion	1	Out of consensus variant identified.
52 bp deletion	1	Out of consensus variant identified.

Colour coding reflects the level of compliance with current HGVS recommendations: **green** = fully compliant, **amber** = generally compliant with some omission(s) and **red** = nomenclature error(s)/ fails to comply with the recommendations.

Protein Sequence Change	n	Nomenclature guidance comments (as applicable)
p.(Leu367Metfs*43)	25	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description.
p.(Leu367MetfsTer43)	6	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description.
p.(Leu367fs)	1	Compliant with HGVS recommendations (short form) <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description.
p.(Leu367fs*43)	1	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description.
Not provided	12	
p.Leu367fs	5	Compliant with HGVS recommendations (short form) <sup>1,2</sup> . Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.Leu367MetfsTer43	4	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.Leu367Metfs*43	3	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.L367Mfs*43	3	Compliant with HGVS recommendations <sup>1,2</sup> ; however, use of three letter amino acid codes is preferred. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.(L367Mfs*43)	2	Compliant with HGVS recommendations <sup>1,2</sup> ; however, use of three letter amino acid codes is preferred.
p.L367fs*43	2	Compliant with HGVS recommendations <sup>1,2</sup> ; however, use of three letter amino acid codes is preferred. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material. When using short form, neither the '*' nor the position of the new translation termination (stop) codon is required.
p.Leu367fs*	1	Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material. When using short form, the '*' is not required.
p.(Leu367_Metfs*43)	1	Generally compliant with HGVS recommendations <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description. However, the unnecessary '_' should not be included.
(p.Leu367Metfs*43)	1	Generally compliant with HGVS recommendations <sup>1,2</sup> ; however, the first of the parentheses should be positioned following 'p'.
(p.Leu367MetfsTer43)	1	Generally compliant with HGVS recommendations <sup>1,2</sup> ; however, the first of the parentheses should be positioned following 'p'.
p.(Leu367Metfs*?)	2	Nomenclature error at the protein level. The new reading frame does encounter a new translation termination (stop) codon, therefore '?' is not appropriate for this variant description at the protein level.

p.(Leu367fs*46)	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> . Incorrect position of the new translation termination (stop) codon.
p.(L367Tfs*46)	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> . Incorrect single letter amino acid code used and incorrect position of the new translation termination (stop) codon. Three letter amino acid codes are preferred.
Leu367Metfs*43	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> , which state that a letter prefix is mandatory to indicate the type of reference sequence used. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
L367fs*43	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> , which state that a letter prefix is mandatory to indicate the type of reference sequence used. Three letter amino acid codes are preferred. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
L367fs*46	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> , which state that a letter prefix is mandatory to indicate the type of reference sequence used. Incorrect position of the new translation termination (stop) codon. Three letter amino acid code preferred. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.Lys367Met fs*43	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> . Incorrect three letter amino acid code used. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.

Colour coding reflects the level of compliance with current HGVS recommendations: **green** = fully compliant, **amber** = generally compliant with some omission(s) and **red** = nomenclature error(s)/ fails to comply with the recommendations.

**Detailed breakdown of MPL exon 10 variant(s) detected.**

Please note the LRG is public for MPL: <https://www.lrg-sequence.org/search/?query=MPL>

DNA Sequence Change	n	Nomenclature guidance comments (as applicable)
c.1514G>A	61	Compliant with current HGVS recommendations <sup>1,2</sup> (as per NCBI RefSeq Transcript NM_005373.2).
Variant in exon 10	1	No HGVS based nomenclature provided. However, result is in line with the consensus reported for this trial.
Not provided	2	

Colour coding reflects the level of compliance with current HGVS recommendations: **green** = fully compliant, **amber** = generally compliant with some omission(s) and **red** = nomenclature error(s)/ fails to comply with the recommendations.

Protein Sequence Change	n	Nomenclature guidance comments (as applicable)
p.(Ser505Asn)	38	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses appropriately reflect the analysis of DNA and the predicted status of the protein level description.
Not provided	3	
p.Ser505Asn	12	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
p.S505N	5	Compliant with HGVS recommendations <sup>1,2</sup> . Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material and the use of three letter amino acid codes is preferred.
p.(S505N)	2	Compliant with HGVS recommendations <sup>1,2</sup> however use of three letter amino acid codes is preferred.
(p.Ser505Asn)	1	Generally compliant with HGVS recommendations <sup>1,2</sup> however the first of the parentheses should be positioned following 'p.'
Ser505Asn	2	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> , which state that a letter prefix is mandatory to indicate the type of reference sequence used. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.
S505N	1	Nomenclature error at the protein level. Please note current HGVS recommendations <sup>1,2</sup> , which state that a letter prefix is mandatory to indicate the type of reference sequence used. Three letter amino acid codes are preferred. Parentheses to indicate predicted status of the protein level description are absent and should be used when DNA is input material.

Colour coding reflects the level of compliance with current HGVS recommendations: **green** = fully compliant, **amber** = generally compliant with some omission(s) and **red** = nomenclature error(s)/ fails to comply with the recommendations.

**Testing strategy used by participants for patient samples**

Strategy	n
Targeted Next Generation Sequencing panel testing	43
Sequential single gene testing	30
Parallel single gene testing	8
Targeted NGS panel and single gene testing	1

**NGS platform(s) used by participants performing targeted gene panel testing in this study**

Platform	n
Illumina MiSeq	24
Life Tech Ion S5	8
Illumina MiniSeq	5
Illumina NovaSeq	3
Life Tech Ion PGM	3
Illumina NextSeq	1
Life Tech Ion S5 XL	1

**NGS approaches used by participants in this study**

Methods	n
In house (amplicon based)	9
Oncomine Myeloid Research Panel	7
Illumina TruSight Myeloid Sequencing Panel	6
Qiagen QiaSeq Custom Panel	5
Myeloid Solution, Sophia Genetics	4
Archer DX VariantPlex Myeloid Panel	3
In house (capture based)	2
In house (no further information provided)	2
Agilent Haloplex HS Panel	1
AmpliSeq for Illumina - Myeloid panel	1
AmpliSeq for Illumina - Custom panel	1
Fluidigm Access Array	1
Qiagen GeneRead DNAseq Targeted Myeloid Panel	1
Roche Kappa Capture	1
Other	1

**Annotation database used to interpret variant**

Database	n
COSMIC (Catalogue Of Somatic Mutations In Cancer)	41
ClinVar(NCBI)	36
dbSNP (Short Genetic Variations, NCBI)	28
The Genome Aggregation Database (gnomAD)	24
WHO International Agency for Research on Cancer (IARC) TP53 Database	20
My Cancer Genome (Vanderbilt-Ingram Cancer Center)	17
Varsome (Aggregation tool)	14
HGMD (The Human Gene Mutation Database)	10
OMIM (NCBI)	9
The Cancer Genome Atlas (TCGA)	6
OncoKB	3
SESHAT	2
ALAMUT	1
Annova	1
ensembl	1
Sophia DDM	1
The Belgian algorithm	1

**Minimum variant allele frequency reported by participants using NGS**

% Value	n
10	1
5	28
4	1
3	2
2	8
1	4
0.5	1



**Analysis methods used by participants performing single gene testing**

<b>Methods</b>	<b>JAK2 p.Val617Phe</b>	<b>JAK2 Exon 12</b>	<b>CALR Exon 9</b>	<b>MPL Exon 10</b>
Agarose Gel Electrophoresis	7	1	1	3
Capillary Electrophoresis	5	8	23	6
Digital PCR (Bio-Rad)	4	-	-	1
High Resolution Melt	1	3	2	6
NGS (Illumina)	2	3	2	3
Real-Time PCR Fluorescent Detection	17	4	2	8
Sanger Sequencing	-	12	9	10

Uncontrolled Copy

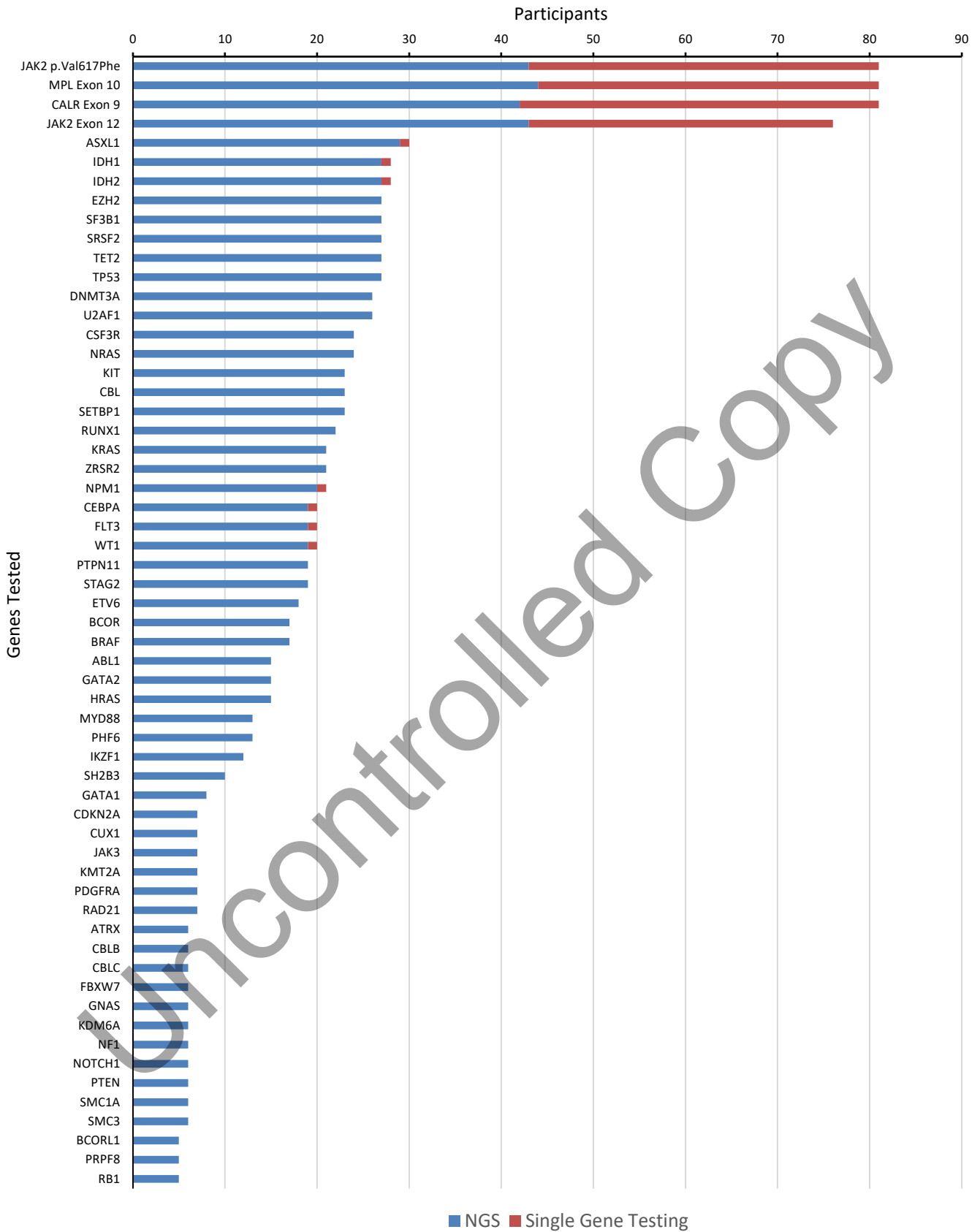


Figure: Histogram to show the genes tested by all participants for sample MPN GP 106. Only the genes tested by ≥5 participants are shown here.

### Trial Comments

- Overall, there was variability seen in variant detection and the nomenclature used to describe variants in this trial distribution.
- MPN GP 106 was a sample formulated from a cell line previously characterised to harbour NM\_004343.3 (*CALR*): c.1099\_1159del; p.(Leu367Metfs\*43) ; a 61bp deletion mutation in exon 9 alongside a missense change in the *MPL* gene; NM\_005373.2(*MPL*): c.1514G>A, p.(Ser505Asn). A second cell line was used to lower the variant allele frequency of these variants which harboured a number of pan myeloid and pan leukaemic variants.
- 82/82 participants identified a pathogenic variant in sample MPN GP 106.
- No participants reported a *JAK2* p.Val617Phe or *JAK2* Exon 12 variant.

#### ***CALR* c.1099\_1159del; p.(Leu367Metfs\*43)**

- 77/81 participants who tested the *CALR* gene detected a deletion. The size of the reported deletion ranged from 50bp-61bp (see tabulated details, page 3).
- Of the four participants who did not detect a *CALR* Exon 9 variant in sample MPN GP 106, all used targeted NGS with differing approaches (one used the Illumina MiSeq with the Illumina Ampliseq custom panel; one used the Illumina Novaseq and Roche Kappa Capture method; one used the Life Tech Ion PGM with an in house (amplicon based) approach; and one used the Life Tech Ion S5 with an in house (amplicon based) approach).
- None of the participants who failed to detect the *CALR* variant reported sub optimal coverage in the region.
- In line with expectation, 58/64 participants who sequenced the variant and provided HGVS nomenclature detected a *CALR* c.1099\_1159del; p.(Leu367Metfs\*43); a 61bp deletion mutation in exon 9.
- The 61 bp deletion identified in this study has been well characterised in the literature (COSMIC Genomic Mutation ID: COSV57127153; Legacy Identifier COSM1738367) and, in line with other *CALR* variants, leads to a +1 shift to an alternate reading frame, ultimately altering the charge of the c terminus of the *CALR* protein<sup>3</sup>.
- Four participants erroneously reported the *CALR* c.1099\_1150del; p.(Leu367Metfs\*46) (Type 1) variant; (COSMIC Genomic Mutation ID: COSV57116546; Legacy Identifier COSM1738055). Two of these participants used single gene testing approaches (one used an in-house capillary electrophoresis assay and one used Qiagen/Ipsogen *CALR* RGQ PCR Kit and Real-Time PCR. The remaining two participants used targeted NGS panels on the Illumina MiSeq platform (TruSight Myeloid Sequencing Panel and Qiagen QiaSeq Custom Panel respectively).
- Application of the Human Genome Variation Society (HGVS) recommendations<sup>4,5</sup> for the description of sequence variants was inconsistent for this trial. Positional errors were apparent at both the c.DNA and protein level. Care should be taken to state the most 3' (downstream) nucleotide positions when describing the deleted region. NGS based variant calling algorithms may not apply this HGVS convention (often referred to as the 3' rule). It is acknowledged that laboratories performing allele sizing or melt curve based assays to analyse *CALR* will lack sufficient sequence information from their results to provide HGVS based nomenclature.

#### ***MPL* c.1514G>A, p.(Ser505Asn)**

- 64/81 participants who tested the *MPL* gene detected a pathogenic variant in the *MPL* gene in sample MPN GP 106.
- 61/81 participants who tested the *MPL* gene detected a missense sequence change in the *MPL* gene; NM\_005373.2(*MPL*): c.1514G>A, p.(Ser505Asn).
- 3/81 did not specify the variant they detected (all used melt curve analysis).
- 17/81 who tested *MPL* did not detect a variant.
- Of these 17, seven participant's assays targeted the p.W515K/L only.
- Of the remaining ten participants, four used targeted next generation sequencing, with all of their panels seemingly encompassing the relevant codon. These participants used the Life Tech Ion S5 and an in house (amplicon based) assay, the Illumina MiniSeq with the Archer DX VP Myeloid kit,

the Illumina MiSeq with in-house (amplicon based) assay and the Illumina MiniSeq with the Qiagen QiaSeq Custom Panel.

- Six used single gene testing approaches (three used an in-house capillary electrophoresis approach, one used an in-house agarose gel approach, one used a high-resolution melt approach and one used Real-Time PCR but did not state whether it was in-house, or kit based).
- There was much better adherence to the Human Genome Variation Society (HGVS) recommendations for the description of this variant, at both the c.DNA and protein level. However, please note, where gDNA represents the assay input material parenthesis should be included in the nomenclature description to indicate the amino acid change is predicted from DNA level data.
- The lower detection rate for this variant possibly reflects the targeting of the more widely cited MPL p.(Trp515Leu/Lys) variant during assay design.
- The MPL p.(Ser505Asn) variant is a rare but well reported variant in MPN that has been seen to be both acquired MPNs and familial essential thrombocythemia. It has also been reported concurrently with *CALR* deletions<sup>6</sup>.

### Other Variants

Other variants detected by >1 participant		n
<i>TP53</i>	c.404G>A	28
<i>NRAS</i>	c.181C>A	27
<i>NRAS</i>	c.182A>T	25
<i>SH2B3</i>	c.1696C>T	5
<i>CUX1</i>	c.983G>A	5
<i>TP53</i>	c.1051_1055del	3
<i>ASXL1</i>	c.1954G>A	3
<i>JAK3</i>	c.2609G>A	3
<i>CDKN2A</i>	c.238C>T	2

- It is currently beyond the scope of this programme to comment extensively on the likely clinical significance of these variants in an MPN context. However, please note at the time of trial reporting available evidence for the *ASXL1* c.1954G>A p.(Gly652Ser) variant suggests it represents a likely neutral polymorphism of germline origin (COSMIC: COSM4799337, COSM1716555; ClinVar: 133592 (benign); dbSNP: rs3746609; MAF = 1.7% (1000 Genomes) and 1.8% (ExAC)).

### Methodology

- Targeted NGS panel testing is the most commonly employed strategy by participants (n=43), compared to 38 participants using single gene testing (either sequential or parallel). This is a reverse of the previous trial (192001) where most participants were using single gene testing.
- A wide range of methods were used to detect the core MPN associated genes, the majority of which have a theoretical limit of detection (LoD) adequate to detect them in the context of MPNs. However, a small subset of laboratories were using techniques with an inadequate limit of detection such as Sanger sequencing.
- Whilst the recommended LoD for *JAK2* p.(Val617Phe) is 1-3%<sup>7</sup> mutation load, no such published guidelines exist for *JAK2* Exon 12, *CALR* or *MPL* variants. Low level *CALR* and *MPL* variants appear to be uncommon but are occasionally found at mutation loads <5%<sup>8,9</sup>.
- For NGS panel users, 73.3% of participants employed bridge amplified reversible dye terminator based platforms from Illumina (n=33). The remaining participants used the Life Technologies Ion semiconductor based technology (n=12).

- Twenty-five participants used a kit based NGS solution; six participants used a custom kit solution and thirteen participants used an in-house solution.
- Thirty-nine participants referenced the GRCh37/hg19 genome assembly; six participants referenced the GRCh38 genome assembly.
- For participants employing a single gene testing approach, the most commonly used approach was Real-Time PCR Fluorescent Detection (n=17) for the *JAK2* p.Val617Phe variant; Sanger Sequencing (n=12) for *JAK2* exon 12 variants; Capillary Electrophoresis (n=23) for *CALR* exon 9 variants; and Sanger Sequencing (n=10) for *MPL* exon 10 variants.

## References

1. den Dunnen, J. T. *et al.* HGVS Recommendations for the Description of Sequence Variants: 2016 Update. *Hum Mutat* **37**, 564–9 (2016).
2. den Dunnen, J. T. Sequence Variant Nomenclature Version 20.05. Available at: <https://varnomen.hgvs.org/>. (Accessed: 16th July 2020)
3. Kollmann, K. *et al.* MARIMO cells harbor a *CALR* mutation but are not dependent on *JAK2/STAT5* signaling. *Leukemia* **29**, 494–497 (2015).
4. den Dunnen, J. T. & Antonarakis, S. E. Mutation nomenclature extensions and suggestions to describe complex mutations: a discussion. *Hum Mutat* **15**, 7–12 (2000).
5. Sequence Variant Nomenclature. (2018). Available at: <http://varnomen.hgvs.org/>. (Accessed: 9th February 2018)
6. Tashkandi, H., Moore, E. M., Tomlinson, B., Goebel, T. & Sadri, N. Co-occurrence of type I *CALR* and two *MPL* mutations in patient with primary myelofibrosis. *Ann Hematol* **96**, 1417–1418 (2017).
7. Bench, A. J. *et al.* Molecular diagnosis of the myeloproliferative neoplasms: UK guidelines for the detection of *JAK2* V617F and other relevant mutations. *Br J Haematol* **160**, 25–34 (2013).
8. Jones, A. V, Cross, N. C. P., White, H. E., Green, A. R. & Scott, L. M. Rapid identification of *JAK2* exon 12 mutations using high resolution melting analysis. *Haematologica* **93**, 1560–1564 (2008).
9. Jones, A. V. *et al.* The *JAK2* 46/1 haplotype predisposes to *MPL*-mutated myeloproliferative neoplasms. *Blood* **115**, 4517–4523 (2010).

**Information with respect to compliance with standards BS EN ISO/IEC 17043:2010**

4.8.2 a) The proficiency testing provider for this programme is:

UK NEQAS for Leucocyte Immunophenotyping  
Pegasus House, 4<sup>th</sup> Floor Suite  
463A Glossop Road  
Sheffield, S10 2QD  
United Kingdom  
Tel: +44 (0) 114 267 3600, Fax: +44 (0) 114 267 3601  
e-mail: nicola.rose@ukneqasli.co.uk

4.8.2 b) The coordinators of UK NEQAS LI programmes are Mr Liam Whitby (Director) and Mr Stuart Scott (Centre Manager).

4.8.2 c) Person(s) authorizing this report:  
Mr Liam Whitby (Director) or Mr Stuart Scott (Centre Manager) of UK NEQAS LI.

4.8.2 d) Pre issue testing of samples for this programme is subcontracted, although the final decision about sample suitability lies with the EQA provider; no other activities in relation to this EQA exercise were subcontracted. Where subcontracting occurs it is placed with a competent subcontractor and the EQA provider is responsible for this work.

4.8.2 g) The UK NEQAS LI Confidentiality Policy can be found in the Quality Manual which is available by contacting the UK NEQAS LI office. Participant details, their results and their performance data remain confidential unless revealed to the relevant NQAAP when a UK participant is identified as having performance issues.

4.8.2 i) All EQA samples are prepared in accordance with strict Standard Operational Procedures by trained personnel proven to ensure homogeneity and stability. Where appropriate/possible EQA samples are tested prior to issue. Where the sample(s) issued is stabilised blood or platelets, pre and post stability testing will have proved sample suitability prior to issue.

4.8.2 l), n), o), r) & s) Please refer to the UK NEQAS LI website at [www.ukneqasli.co.uk](http://www.ukneqasli.co.uk) for detailed information on each programme including the scoring systems applied to assess performance (for BS EN ISO/IEC 17043:2010 accredited programmes only). Where a scoring system refers to the 'consensus result' this means the result reported by the majority of participants for that trial issue. Advice on the interpretation of statistical analyses and the criteria on which performance is measured is also given. Please note that where different methods/procedures are used by different groups of participants these may be displayed within your report, but the same scoring system is applied to all participants irrespective of method/procedure used.

4.8.2 m) We do not assign values against reference materials or calibrants.

4.8.2 q) Details of the programme designs as authorized by The Steering Committee and Specialist Advisory Group can be found on our website at [www.ukneqasli.co.uk](http://www.ukneqasli.co.uk). The proposed trial issue schedule for each programme is also available.

4.8.2 t) If you would like to discuss the outcomes of this trial issue, please contact UK NEQAS LI using the contact details provided. Alternatively, if you are unhappy with your performance classification for this trial, please find the appeals procedure at [www.ukneqasli.co.uk/contact-us/appeals-and-complaints/](http://www.ukneqasli.co.uk/contact-us/appeals-and-complaints/)

4.8.4) The UK NEQAS LI Policy for the Use of Reports by Individuals and Organisations states that all EQA reports are subject to copyright, and, as such, permission must be sought from UK NEQAS LI for the use of any data and/or reports in any media prior to use. See associated policy on the UK NEQAS LI website: <http://www.ukneqasli.co.uk/eqa-pt-programmes/new-participant-information/>