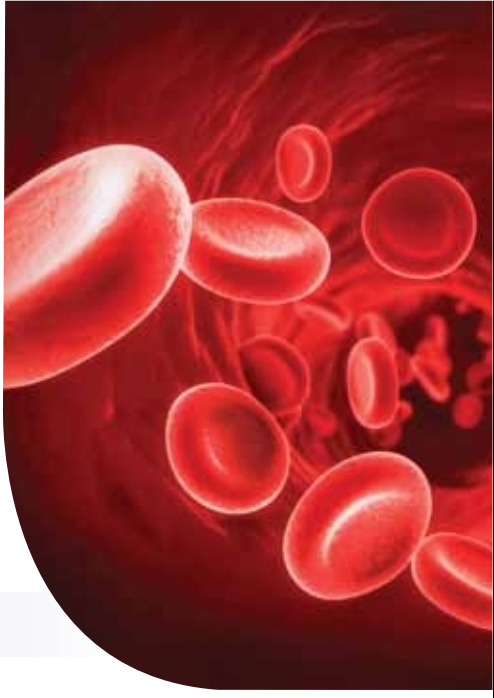
Unipath
SPECIALTY LABORATORY Ltd.



MYELOPROLIFERATIVE NEOPLASMS

Department of Molecular Biology

JAK2 V617F MUTATION

Detection of the JAK2 c.1849G>T (V617F) mutation in myeloproliferative neoplasms: polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF). This test is indicated for evaluation of patients with unexplained and sustained elevation of red blood cell or platelet counts, splenomegaly or bone marrow fibrosis of undetermined causation, and patients in whom a diagnosis of a chronic myeloproliferative disorder is a consideration. The JAK2 V617F mutation is detectable in approximately 95% PV, 55% ET, and 65% PMF patients. A negative result does not rule out a diagnosis of PV, ET, or PMF.

JAK2 EXON 12 MUTATION

Mutations within exon 12 of the JAK2 gene occur in most cases of JAK2 V617F-mutation negative polycyt emia vera. Testing for JAK2 exon 12 mutations may aid in the diagnosis of polycythemia vera, and is recommended in patients with JAK2 V617F-negative erythrocytosis. This test will qualitatively detect JAK2 exon 12 mutations in peripheral blood or bone marrow specimens with sensitivity down to 5% mutant allele. This is a second order test and should be used only following a JAK2 V617F-negative result.

MPL MUTATION

MPL gene mutations occur in cases of primary myelofibrosis (PMF) and essential thrombocythemia (ET) at a frequency of ~10% and 3% respectively. Testing for MPL mutations may aid in the diagnosis of these myeloproliferative neoplasms. MPL mutations are usually found in cases that test negative for the JAK2 V617F mutation, although a small number of patients have been reported with both mutations. This test will qualitatively detect MPL mutations (W515L, W515K, W515A, and S505N) in peripheral blood or bone marrow with a sensitivity down to 5% mutant allele.

CAL R MUTATION

Calreticulin (CALR) mutations have been reported in 50-71% of essential thrombocythemia (ET), and 56-88% of primary myelofibrosis (PMF) that are negative for JAK2 and MPL mutations. ET and PMF with CALR mutations are associated with distinct clinical features and can have superior outcome to MPL-mutated and JAK2-mutated ET and PMF in initial studies. Testing for this mutation can assist in the diagnosis of myeloproliferative neoplasms, and provide a marker for monitoring response to therapy and disease recurrence.

	JAK2 V617F	JAK 2 EX 12	MPL	CALR
PV	95-100	3-5	0	0
ET	50-64	0	3-5	24-25
PMF	40-69	0	5-8	32-35

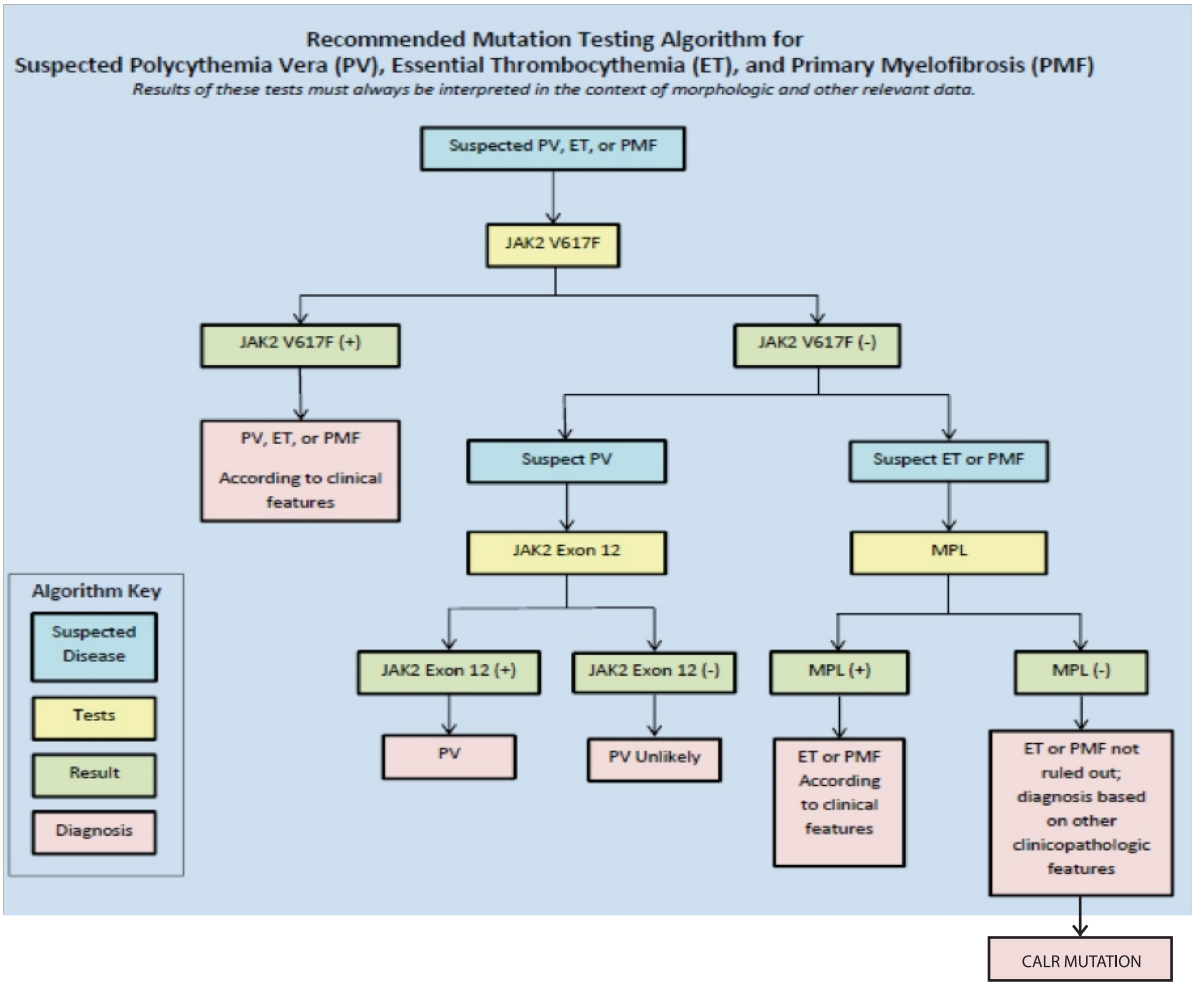
MYELOPROLIFERATIVE NEOPLASMS (MPN) ALGORITHM

In keeping with our commitment to develop and offer the critical tests necessary for clinicians to care for their CMPD patients, the Department of Molecular Biology at Unipath Specialty Laboratories Ltd, Ahmedabad utilizes the following mutation testing algorithm for suspected PV, ET, or PMF cases.

MPN algorithm will:

- Consolidate MPN mutation testing within a single source laboratory.
- Streamline efficiency of testing, decreasing turn around time.
- Provide highly accurate diagnostically relevant results.
- Improve cost efficiency.

As a leader in the rapidly evolving molecular diagnostic field, we hope that the following MPN Testing Algorithm will aid in your selection of the most informative and diagnostically-relevant tests.



TAT AND ORDERING INFORMATION:

TEST NAME	METHOD	SPECIMEN	REPORTING TIME
JAK 2 V617FMutation Detection	PCR	EDTA WB/BM	NEXT DAY
JAK 2 EXON 12 Mutation Detection	PCR SEQUENCING	EDTA WB/BM	10 DAYS
MPL Mutation Detection	PCR SEQUENCING	EDTA WB/BM	10 DAYS
CAL R Mutation Detection	PCR SEQUENCING	EDTA WB/BM	10 DAYS

Unipath specialty Laboratories ltd
102 Sanoma Plaza, B/S JMC House, Opp. Parimal Garden, Ellis Bridge, Ahmedabad – 380006
Phone No -079-49006800/31
Mail to: unipathmdx@gmail.com