PRECIPIO EXPECT MORE.
203-787-1717
203-901-1289

MOLECULAR

Patient: John A. Doe
DOB/Gender: 10/10/44 (74 yrs) - Male
Patient ID/MRN: 123456
Date Collected: 12/05/2023 11:06

Case# XX-00001
Status: Final

Report Category:
Not Detected

Provider: Jane Smith, M.D.

Oncology Hematology
Associates Tel: 800-123-4567
Fax: 800-765-4321

DIAGNOSIS:

Peripheral blood:
There is no evidence of mutations in any of the tested genes.

COMMENT

- The absence of mutations should not be a method to rule out hematologic neoplasm.
- Clinical and laboratory correlation is recommended.
- Other mutations are detected consistent with germline abnormalities but not reported. Mutations lead to early termination (loss of function), but there is no adequate data on their clinical relevance and should be classified as of "uncertain significance" at this time are not reported.

INTERPRETATION

This assay is limited to the detection of SNVs and indels within the 741 target amplicons contained within the Panel down to a level of 5% mutant allele frequency (MAF). The assay can detect internal tandem duplications (ITD) up to 126 bases in the FLT3 gene using paired end sequencing at read lengths of 150 bp (2x150).

The hematologic malignancy Panel was designed to target 58 genes known in the peer-reviewed literature to be frequently mutated in hematologic malignancies (i.e. tumor suppressor genes and oncogenic hotspots). These targets are based on data from ongoing clinical trials along with sources that include the College of American Pathologists (CAP), the Association for Molecular Pathology
(AMP), the National Comprehensive Cancer Network (NNCN), and the Catalog of Somatic Mutations in Cancer (COSMIC) database. Mutations within the panel's targets have potential involvement in myeloid cancers, including but not limited to acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), myeloproliferative neoplasms (MPN), chronic myelogenous leukemia (CML), chronic myelomonocytic leukemia (CMML), and juvenile myelomonocytic leukemia (JMML).

This is a next generation sequencing (NGS) test that analyzes DNA for abnormalities in 58 genes that are reported to be altered in various types of hematologic neoplasms. Nucleic acid is isolated from peripheral blood cells or bone marrow. Testing is performed using massive parallel sequencing of the coding DNA of the listed genes. Data was analyzed by the Pillar Variant Analysis Toolkit (PiVAT). The test is intended to provide information on somatic mutations (point mutations as well as small insertions and deletions) for use by qualified health care professionals in accordance with professional guidelines. This assay is not conclusive or prescriptive for labeled use of any specific therapeutic product or germline mutations. This assay is a single-site assay performed at Precipio. This test is for in vitro complementary diagnosis and classification. It should not be used as the primary diagnosis of hematologic neoplasm or for managing therapy in patients with hematologic neoplasms. Our sequencing method has a typical sensitivity of 5% for detecting hot-spot specific mutations and other mutations.

ABL1	BRAF	CEBPA▲	ETV6▲	HRAS	KDM6A▲	NPM1	PTEN	SMC1A	TP53▲
ANKRD26	CALR	CSF3R	EZH2▲	IDH1	KIT	NRAS	PTPN11	SMC3	U2AF1
ASXL1	CBL	CUX1	FLT3	IDH2	KMT2A	PDGFRA	RAD21▲	SRSF2	WT1
ATRX	CBLB	DDX41	GATA1	IKZF1▲	KRAS	PHF6▲	RUNX1▲	STAG1	ZRSR2▲
BCOR▲	CBLC	DNMT3A▲	GATA2▲	JAK2	MPL	PIGA▲	SETBP1	STAG2▲	
BCORL1▲	CDKN2A▲	ETNK1	GNAS	JAK3	NF1	PPM1D	SF3B1	TET2▲	

Full CDS coverage in genes indicated by▲

Electronically Signed By: Frank Bauer, MD (12/15/2024 15:09)

CLINICAL DATA

ICD-10: D75.89, R77.8, D75.9. Other specified diseases of blood and blood-forming organs. Other specified abnormalities of plasma proteins.

Received CBC, reported on 11/30/2023: WBC 5.5; RBC 4.91; HGB 14.6; HCT 46.1; MCV 94; MCH 29.8; MCHC 31.8; RDW 14.5%; PLT 288; MPV 6.9; LYM 36.7%; GRAN 58.0%; MID NP; MON 5.3%; NEU NP; EOS NP; BAS NP; (NP = not provided)

Disclaimer: The adequacy of staining is verified by the appropriate LSI controls. The reagents used for these assays are for research use only (RUO). Their performance characteristics have been initiated by Precipio, Inc. in its location in Omaha, NE (CLIA#: 28D2215036). They have not been reviewed by the FDA. The FDA has deemed that such approval is unwarranted for clinical use. These assays should be viewed as experimental and/or research use only.

Patient: John A. Doe
Case #: XX-00001
Received Information: 1 lavender-top tube(s)
Received: 12/06/2023 13:20
Reported: 12/15/2023 15:38