HemeScreen® MPN Panel – Product Overview

This document provides a general product overview of the HemeScreen MPN Assay. Additional information can be found on Precipio's website at www.precipiodx.com, and the associated IFU (Instructions For Use), available upon request.

Technology Overview	HemeScreen® is a proprietary set of RUO (Research Use Only) reagents used to screen the wild type (Negative) from Mutated (Positive) genes in a simplified workflow relative to alternative molecular testing technologies (RT-PCR or NGS).
MPN	The myelodysplastic/myeloproliferative neoplasms (MDS/MPN) comprise a group of hematologic malignancies characterized by clonal hematopoiesis with altered proliferation and maturation with one or more cytopenias (i.e., thrombocytopenia).

Genes Tested	Coverage
JAK2 ex. 14 (V617F)	c.1849G>T;p.V617F
JAK2 ex. 13	c.1711G>A,p.G571S
JAK2 ex. 12	c.1611_1616delTCACAA; p.F537_K539delinsL c.1624_1629delAATGAA; p. N542_E543del c.1615_1616delAAinsTT; p.K539L
CALR	c.1099_1150del; p.L367fs*46 c.1154_1155insTTGTC; p.K385fs*47
MPL	c.1544G>T; p.W515L c.1543_1544TG>AA; p.W515K

Results	The results from HemeScreen® MPN are qualitative.
Associated WHO/NCCN Guidelines[1, 2]	*Per the WHO:* The JAK2 p.V617F mutation is detectable in over 95% of patients with PV. Valine 617 is located in the JH2 domain of JAK2, which acts to repress its kinase activity { 15837627 }. Many different mutations in exon 12 of the *JAK2* gene have been reported from almost all patients with JAK2 p.V617F-negative PV, usually small in-frame insertions or deletions, affecting the pseudokinase domain: these patients have a more isolated erythrocytosis { 17267906 }. The JAK2 p.V617F mutation is detectable in 50 to 60% of patients with ET. Valine 617 is located in the JH2 domain of JAK2, which acts to repress its kinase activity { 15837627 }. Mutations in the calreticulin (*CALR*) gene are found in 25-35% of ET patients { 24325356 }. CALR frameshift mutations are all predicted to result in a novel C-terminal protein sequence, the commonest being 52-bp deletion ("type 1") or 5-bp insertion ("type 2"). These are found with similar frequencies in ET. Activating point mutations in the thrombopoietin receptor gene, *MPL*, were identified in 2006 in 5-10% of patients with ET { 16868251 }.

	Specificity	Sensitivity	LOD	Storage
Assay Specifications	>99%	98%	2%	-20 °C

SKU	Product Configuration	Assay Contents			
HS-4P-MPN	4 sample pre-plated plate	Primers/MasterMix Mix	Positive controls	NTC	Wild Type
HS-8P-MPN	8 sample pre-plated plate	Primers/MasterMix Mix	Positive controls	NTC	Wild Type

Instrument Required	HRM-enabled RT-PCR (example ThermoFisher Quantstudio 3 or higher)
Contact	For further questions, contact our technical support team at techsupport@precipiodx.com or call 203-787-7888
Disclaimer	*The information in this document represents the company's best understanding of the technical and regulatory landscape; however, it should not serve as any guidance to any laboratory seeking to implement HemeScreen. Laboratory managers and medical directors should seek their own information independently through their CLIA inspector and any other state and federal regulatory body available.*

1 World Health Organization. World Health Organization. Available at: https://tumourclassification.iarc.who.int/chaptercontent/63/13

2 World Health Organization. World Health Organization. Available at: https://tumourclassification.iarc.who.int/chaptercontent/63/14