

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](http://www.precipiodx.com), and the associated IFU (Instructions For Use), available upon request.

<b>Technology Overview</b>	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).				
<b>MPN</b>	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).				
<b>Genes Tested</b>	<b>Coverage</b>				
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				
<b>Results</b>	The results from HemeScreen® MPN are qualitative and DNA sequencing is required to identify specific isoforms.				
<b>Associated WHO/NCCN Guidelines<sup>1,2</sup></b>	<p><i>Per the WHO:</i> 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 { <a href="#">15837627</a> }. 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 { <a href="#">17267906</a> }. 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 { <a href="#">15837627</a> }. Mutations in the calreticulin (CALR) gene are found in 25-35% of ET patients { <a href="#">24325356</a> }. 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 { <a href="#">16868251</a> }.</p>				
<b>Assay Specifications</b>	<b>Specificity</b>	<b>Sensitivity</b>	<b>LOD</b>	<b>Storage</b>	
	>99%	95%	5%	-20 °C	
<b>SKU</b>	<b>Product Configuration</b>	<b>Assay Contents</b>			
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
<b>Instrument Required</b>	HRM-enabled RT-PCR (example ThermoFisher Quantstudio 3 or higher)				
<b>Contact</b>	For further questions, contact our technical support team at <a href="mailto:techsupport@precipiodx.com">techsupport@precipiodx.com</a> or call 203-787-7888				
<b>Disclaimer</b>	<p><i>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.</i></p>				

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

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