Hematologics, Inc.

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Medical Director: Denise A. Wells, MD

HLID#: **PATIENT NAME:**

PATIENT ID#: DOB: NPI: **ORDERING PHYSICIAN:**

SPECIMEN TYPE: Bone Marrow Aspirate

RECEIPT DATE: **COLLECTION DATE:**

ICD Code: REPORT DATE: UNITS: 1 FISH-MM Panel

+ Cell Enrichment

SEX:

CLINIC ID#:

NUMBER OF PROBES: 6 MP

CPT: 88368/88112/88377

ACCOUNT:

Patient Name HLID#

FISH REPORT

Specimen Type: CD138+ enriched cell population from Bone Marrow Aspirate

Clinical History/Indications: A xx-year-old fe/male with a clinical history of kappa light chain monoclonal gammopathy.

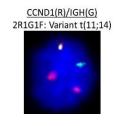
FISH (fluorescence in situ hybridization) Result: ABNORMAL – see comment* Positive for CCND1/IGH t(11;14) gene rearrangement with variant signal pattern

MM Panel	Loci	ISCN	Results
CDKN2C/CKS1B	1p32/1q21	nuc ish(CDKN2C,CKS1B)x2[200]	Normal
Trisomy 3/Trisomy 15	3p11.1-3q11.1/15p11.1-15q11.1	nuc ish(D3Z1,D15Z4)x2[200]	Normal
FGFR3/IGH	t(4;14)(p16;q32)	nuc ish(FGFR3x2,IGHx1,IGH dimx1)[139/200]	Partial Loss of 14q (IGH)
CCND1(BCL1)/IGH	t(11;14)(q13;q32)	nuc ish(CCND1x3,IGHx2)(CCND1 con IGHx1)[148/200]	ABNORMAL
del(13q)	13q14.2/13q34	nuc ish(D13S319,13q34)x2[200]	Normal
TP53/D17Z1	17p13/17p11.1-17q11.1	nuc ish(TP53,D17Z1)x2[200]	Normal

Interpretation:

- These findings reveal an abnormal cell clone characterized by CCND1/IGH t(11;14) gene rearrangements with variant signal pattern in the CD138 enriched cell fraction of this specimen.
 - CCND1/IGH t(11;14) has been associated with standard/good prognosis in plasma cell neoplasms.
 - *Comment: Venetoclax may improve outcomes in multiple myeloma patients harboring t (11:14). [Vaxman I, Sidiqi H, Gertz M. Expert Rev Hematol. 2018 Nov 14.]
- Clinical and hematopathologic correlation is recommended.

CD138+ plasma cells were isolated by magnetic-activated cell sorting using anti-CD138 immunobeads and a magnetic-activated cell sorter (StemCell Technologies TM) separation system. Interphase FISH (fluorescence in situ hybridization) was performed to assess this specimen for the presence of cytogenetic aberrations in the nondividing cell population. Hybridization was performed using the D13S319 (13q14.2), CDKN2C/CKS1B (1p32.3, 1q21) and TP53/D17Z1 (17p13) gene probes to look for deletion/loss of these regions or chromosomes. The D3Z1 and D15Z4 centromere probes were used to determine gains of chromosomes 3 and 15. The 13q34 probe was run as the control for D13S319 and to distinguish between deletion 13q and monosomy 13. FISH was also performed using the IGH/CCND1 and the IGH/FGFR3 probe sets, to look for t(11;14) and t(4;14) rearrangements, respectively, or alternate IGH gene rearrangements.



A total of 200 CD138+ interphase nuclei were examined for each probe. The IGH/CCND1 probe set was positive for a t(11;14) rearrangement with variant signal pattern (2R1G1F) in 74% of cells examined. The FGFR3/IGH probe set showed 2R1G1dimG in 69.5% of cells examined, revealing a partial loss of IGH (14q32) consistent with the positive IGH/CCND1 findings. The remaining analyses fell within normal limits for this specimen type. Please note, that this analysis cannot be used for quantification purposes of the aberrant cell population since only CD138+ purified cells were analyzed.

FISH Analysis Summary:

Number of Cells Analyzed: 200 / Cells Analyzed: Interphase / Probes Utilized: CDKN2C,CKS1B, D3Z1+D15Z4, FGFR3/IGH, CCND1/IGH, D13S319,13q34, TP53-P / Source and Lot Number: Cytocell, 181122-001, 190314-013/190228-006, 181002-011, 180927-021, 190405-005, 181127-001 / Control Probe Utilized: database

Electronically signed by: Barbara K. Zehentner, Ph.D., HCLD (ABB), Director of Molecular Analysis - 09/10/2019 14:00 PT; Denise A. Wells, MD, Medical Director - 09/10/2019 14:05 PT

This test was developed and its performance characteristics determined by HematoLogics, Inc. It has not been cleared or approved by the US Food and Drug Administration