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Medical Director: Denise A. Wells, MD

HLID#: PATIENT NAME:
PATIENT ID#: DOB :
NPI: ORDERING PHYSICIAN:
SPECIMEN TYPE: Bone Marrow Aspirate
COLLECTION DATE: RECEIPT DATE:
REPORT DATE: ICD Code: UNITS: 1 FISH-MM Panel
+ Cell Enrichment
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™) separation system. Interphase FISH (fluorescence in situ hybridization) was performed to assess this specimen for the presence of cytogenetic aberrations in the non-dividing 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

CCND1(R)/IGH(G)
2R1G1F: Variant t(11;14)

