| New Test Available Now | 3002737 | **FISH, Interphase, CD138+ Cells** | **FISHICD138** |

Time Sensitive

Oncology Test Request Form Recommended (ARUP form #43099)

Additional Technical Information

Methodology: Fluorescence in situ Hybridization
Performed: Sun-Sat
Reported: 3-10 days

Specimen Required: <u>Collect:</u> Non-diluted bone marrow aspirate collected in a heparinized syringe. Also acceptable: Whole blood collected in Green (Sodium Heparin).
<u>Specimen Preparation:</u> Transfer 3 mL bone marrow to a green (sodium heparin) (Min: 1 mL). **OR** transport 5 mL whole blood (Min: 2 mL)
<u>Storage/Transport Temperature:</u> Room temperature.
<u>Remarks:</u> Desired FISH probe and pertinent clinical diagnosis required with test order. **Testing will not be performed until probe and diagnosis are provided**; absence of this information will delay turnaround time.
<u>Unacceptable Conditions:</u> Paraffin-embedded specimens. Clotted specimens.
<u>Stability (collection to initiation of testing):</u> Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: Fluorescence in situ hybridization (FISH) is performed on CD138+ sorted cells (assuming specimen is sufficient for sorting) for multiple myeloma prognosis-specific genomic abnormalities. The comprehensive multiple myeloma panel is available under mnemonic FISHMMP (3002063). The following probes may be ordered individually or in any combination: 1q (*CKS1B*) gain/amplification/17p (*TP53*) loss/deletion, t(4;14) (*IGH*/*FGFR3* and *MMSET* fusion), 8q (*MYC*) break apart, t(8;14) (*IGH/MYC* fusion), +9/9q (*ASS1*) trisomy/gain, t(11;14) (*IGH/CCND1* fusion and/or +11), 13q (D13S319) deletion, 14q (*IGH*) break apart, t(14;16) (*IGH*/*MAF* fusion)*,* t(14;20) (*IGH*/*MAFB* fusion), +15/15q,+17/17q (*PML/RARA* gain).

When this test is ordered in conjunction with a chromosome analysis, specimen prioritization will be given to FISH for the sorting of CD138+ cells. This could impact the successful completion of the chromosome analysis.

If sorting fails to yield sufficient CD138+ cells, testing will be performed using unsorted cells, if available.

If more than one probe is ordered, additional charges will apply.

Contact ARUP Genetics Processing (extension 3301) to add a probe to a current specimen.

Other specimen types may be acceptable, contact Genetics Processing (extension 3301) for specific specimen collection and transportation instructions. ** other sample types acceptable (if reported **without disclaimer** should be added to the OMS build, but not viewable in WOE/CONNECT.

This test must be ordered using Oncology test request form #43099 or through your ARUP interface.

CPT Code(s): 88271; 88275; 88291

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.