

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 10/23/1959
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

IGH-CCND1 Fusion, t(11;14) by FISH

ARUP test code 3001306

CCND1 FISH Result	Positive
	Controls were run and performed as expected. This result has been reviewed and approved by [REDACTED]
Total Cell Count	734
Scoring Method	Computer Assisted
CCND1 FISH Reference Number	MS24-2005 A1
CCND1 FISH Source	R Axillary LN

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

INTERPRETIVE INFORMATION: IGH-CCND1, FISH

IGH-CCND1 fluorescent in situ hybridization (FISH) analysis is designed to detect the IGH-CCND1 fusion associated with t(11;14)(q13;q32). Differentially labelled fluorescent probes directed against IGH and CCND1 were used (Agilent Technologies).

Fused signals within a cell are considered abnormal signal patterns and are consistent with IGH-CCND1 fusion. If a sample contains fused signals seen in 21 percent or more of the cells evaluated, it is considered a positive result. Based on the assay performance during test validation, the test is expected to detect 95 percent of IGH-CCND1 rearrangements in patients with IGH-CCND1-rearranged lymphomas, except for rare instances of cryptic rearrangements. Assay range and limit of detection were generated using normal and known positive cases respectively.

IGH-CCND1 fusion is primarily found in mantle cell lymphoma, but this fusion is also found in other B-cell lymphoproliferative disorders including plasma cell neoplasms. Results should be correlated with clinical, morphologic, and immunophenotypic data.

Fluorescence in situ hybridization (FISH) analysis was performed on a section from a paraffin-embedded tissue block. The area(s) for analysis were selected by histopathologic review of a matching hematoxylin- and eosin-stained section.

Controls performed appropriately.

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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
CCND1 FISH Result	24-075-401825	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	24-075-401825	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	24-075-401825	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
CCND1 FISH Reference Number	24-075-401825	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
CCND1 FISH Source	24-075-401825	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at: