

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

Physician: Doctor, Example

Patient: Patient, Example

DOB 3/15/1958

Gender: Male

Patient Identifiers: 01234567890ABCD, 012345

Visit Number (FIN): 01234567890ABCD **Collection Date:** 00/00/0000 00:00

FOXO1 (FKHR) (13q14) Gene Rearrangement by FISH

ARUP test code 3001297

FOXO1 FISH Result Positive

Controls were run and performed as expected. This result has been reviewed and approved by

Total Cell Count 50

Scoring Method Manual

FOXO1 FISH Reference Number SCHS22-7145 E11

FOXO1 FISH Source R Maxillectomy

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

4848



INTERPRETIVE INFORMATION: FOXO1 (FKHR) (13q14), FISH

Fluorescence in situ hybridization (FISH) analysis was performed on a section from a paraffin embedded tissue block using differentially labeled fluorescent probes targeting the upstream (5') and downstream (3') flanking regions of the FOXO1 (FKHR) gene (Abbott Molecular). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin and eosin stained section. Controls performed appropriately.

This test is designed to detect rearrangements involving the FOXO1 gene, but it does not identify a specific partner gene. An abnormal signal pattern seen in 25 percent or more of the evaluated tumor cells is considered a positive result. Based on the assay performance during test validation, the test is expected to detect 94 percent of FOXO1 rearrangements in patients with FOXO1 rearranged tumors, except for rare instances of cryptic rearrangements. Assay range and limit of detection were generated using normal and known positive cases respectively.

Identification of a rearrangement of the FOXO1 gene is useful in the diagnosis of alveolar rhabdomyosarcoma.

Reference:

Fletcher DM, Bridge JA, Hogendoorn P, Mertens F, Eds. WHO Classification of Tumours of Soft Tissue and Bone, 4th Ed. Lyon, France: IARC, 2013.

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
FOXO1 FISH Result	22-081-400689	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	22-081-400689	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	22-081-400689	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
FOXO1 FISH Reference Number	22-081-400689	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
FOXO1 FISH Source	22-081-400689	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

Patient: Patient, Example ARUP Accession: 22-081-400689 Patient Identifiers: 01234567890ABCD, 012345 Visit Number (FIN): 01234567890ABCD Page 2 of 2 | Printed: 8/15/2022 3:36:09 PM