ARUP LABORATORIES
800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Chief Medical Officer

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

Physician: Doctor, Example

Patient: Patient, Example

DOB	12/19/1950
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

TFE3 Gene Rearrangement by FISH

ARUP test code 3002633

TFE3 Result	Negative Controls were run and performed as expected. This result has been reviewed and approved by [redacted]
TFE3 Ref Number	S23-34423 A1
Total Cell Count	100
Scoring Method	Manual
TFE3 Source	LKidney/Adrenal

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

INTERPRETIVE INFORMTION: TFE3 Gene Rearrangements by 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 TFE3 gene (ZytoVision GmbH). 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 translocations involving the TFE3 gene but does not identify a specific translocation partner. An abnormal signal pattern seen in 15 percent or more of the tumor cells evaluated is considered a positive result. While this test can detect most rearrangements it may not be able to detect rare cryptic rearrangements and intrachromosomal inversion events, such as a RBM10-TFE3 fusion. Based on the assay performance during test validation, the test is expected to detect 100 percent of TFE3 rearrangements in patients with TFE3 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 TFE3 gene locus is useful for the diagnosis of Alveolar Soft Part Sarcoma (ASPS) and Xp11 Translocation Renal Cell Carcinoma. TFE3 rearrangements are also identified in other neoplasms, including perivascular epithelioid cell tumors (PEComa) and epithelioid hemangioendotheliomas (EHE).

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
TFE3 Result	23-286-402095	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TFE3 Ref Number	23-286-402095	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	23-286-402095	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	23-286-402095	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TFE3 Source	23-286-402095	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