FGFR Mutation Testing by RT-PCR, BALVERSA®

CPT Code: Please inquire.

Test Details

Synonyms
erdafitinib, fibroblast growth factor receptor, FGFR3, FGFR2

Use
Urothelial Carcinoma (Bladder Cancer)
The U.S. Food and Drug Administration (FDA) has granted accelerated approval to BALVERSA® (erdafitinib), a treatment for adult patients with locally advanced or metastatic urothelial carcinoma (UC) containing carcinogenic FGFR mutations and that has progressed during or following prior platinum containing chemotherapy. Insight Molecular Labs offers the FDA-approved companion diagnostic test, QIAGEN *therascreen*® FGFR RGQ RT-PCR Kit, to simultaneously detect 9 known carcinogenic aberrations in the FGFR3 and FGFR2 genes to identify patients more likely to respond to BALVERSA®.

Methodology
RT-PCR

Specimen Details

Specimen Type
Formalin-fixed, paraffin-embedded (FFPE) tissue.

Quantity
A sufficient number of FFPE sections 4-5 µm thick, less than three months old, from which tumor area has been circled by a pathologist on a serial H&E slide and contains 100 to 500 mm^2 of tumor area.

Sample Processing
Recommended fixative is 10% neutral buffered formalin for a fixative time of at least 6 hours. FFPE specimens may be stored at ambient temperature following fixation.

Causes for Rejection
Insufficient tissue, unidentified tumor area, missing pathology report. If pathology services are required, please contact client services at (615) 255-8880 or inquire here.

Clinical Information

Special Instructions

Associated clinical diagnosis and pathology report should be included with the specimen. If assistance is required to attain sufficient quantities and a marked H&E slide please inquire with client services at (615) 255-8880 or inquire here. The FGFR mutation test requisition form can be found here.

References

FDA Drug Trials Snapshots: BALVERSA® website:
https://www.fda.gov/Drugs/InformationOnDrugs/ucm636149.htm

An Efficacy and Safety Study of JNJ-42756493 in Participants With Urothelial Cancer:
https://clinicaltrials.gov/ct2/show/NCT02365597

FDA Approves First Targeted Therapy for Metastatic Bladder Cancer, press release:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635906.htm

QIAGEN Launches First FDA-Approved Companion Diagnostic Using FGFR Alterations to Help Guide the Treatment3 of Metastatic Urothelial Cancer:
https://corporate.qiagen.com/newsroom/press-releases/2019/20190412_fgfr_fda_approval