SUCCESS AND FAILURE RATE IN EGFR MUTATION ASSESSMENT IN PATIENTS WITH NON-SMALL CELL LUNG CANCER (NSCLC)

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Biomarker-driven targeted therapy of NSCLC with EGFR tyrosine kinase inhibitors provides exciting treatment outcomes for that group of patients but also necessitates molecular diagnostic of tissue material.

Our aim was to assess the frequency of success and failure rate in samples from NSCLC patients referred for epidermal growth factor receptor **(**EGFR**)** mutations diagnostics.

Analysis included results of 2,126 consecutive specimens from NSCLC patients referred for evaluation of EGFR mutations status between January 2014 and August 2016. Testing was performed by means of real-time PCR assay (CE-IVD). 1199/2126 (56%) samples were collected and processed in our hospital (in-house) while 934/2126 (44%) were referred from external hospitals. Diagnostic samples consisted of: 75.4% formalin-fixed paraffin-embedded tissues, 21.9% biopsy and 2.7% fine needle aspiration (FNA) specimens.

In total, the failure rate directly resulting from the inadequate specimen quality was 1,4% (29/2126). It was higher in referred (2.4%) than in-house samples (0.6%). Assay feasibility in in-house materials was 99,6% for resection samples, 99% for biopsy and 97,8% for FNA specimens. For referred materials, assay feasibility was 97% for resection specimens 99% for biopsy and 100% for FNA biopsy.

In conclusion, current quality of in-hospital diagnostic procedures enables the high success rate of EGFR mutation analysis in NSCLC samples.