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## A performance comparison PCR-based approaches for *EGFR* mutations status detection in plasma and FFPE tissue of patients with advanced NSCLC

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The presence of activating mutations in the *EGFR* gene is a prognostic marker of susceptibility to target therapy by Tyrosine Kinase Inhibitors (TKI). Now it is possible to determine in the plasma activating mutation in 19-21 exon as well as *T790M* mutations in exon 20, which is marker refractory to TKI. The aim of this study was to compare mutation status in FFPE tissue and plasma samples and the evaluate diagnostic characteristics of real-time wild-type blocking PCR (LNA-clamp) assay, digital PCR approach (dPCR) and routine approaches, which are used for tissue analysis – Sanger sequencing and real-time PCR. The study included 89 patients with advanced NSCLC with known mutation status in FFPE tissue. *L858R*, *del19* and *T790M* mutations were determined in corresponding blood plasma samples. Sanger sequencing and real-time PCR revealed sensitivity in plasma samples less than 20%. Comparison of the *EGFR* mutations status in plasma by LNA-clamp real-time PCR and dPCR and tumor revealed concordance 88.7% [95% CI: 85–92%], sensitivity – 83.3% [95% CI: 76–90%], specificity-100%. Comparison of these two PCR approaches revealed 100% concordance of results in plasma samples, despite the higher analytical capabilities of dPCR, that was received with artificial plasmid positive controls application. It had shown a potential of reliable detection of cDNA with mutation amount less than 1% (5-10 copies mutant gene per reaction) with excess background of wild type DNA (ratio DNA mutation to wild-type DNA 1: 10000).

### Biography

Brovkina O I has completed her PhD from State Research Center GosNIIgenetika. At present, she is a Postdoctoral fellow in the Genetic Laboratory of Government Scientific Clinical Center of Federal Medical and Biological Agency of Russia. She has published 4 papers in reputed journals in Russian language.

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