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Title: Noninvasive detection of EGFR T790M mutation in gefitinib resistant non-small cell lung cancer using mutant-enriched PCR

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Body: Epidermal growth factor receptor (EGFR) T790M mutation has been reported in non-small cell lung cancer (NSCLC) patients with acquired resistance to the tyrosine kinase inhibitors (TKIs). However, the tissue availability and technical feasibility limits the pre-therapeutic genotyping of EGFR T790M mutation in a clinical setting. The current study is, therefore, designed to develop a blood-based approach to detect the EGFR T790M mutation in advanced NSCLC patients. Plasma samples from 33 NSCLC patients treated with gefitinib were subjected to mutant-enriched PCR and direct sequencing. The results showed the mutant-enriched PCR could successfully detect the T790M mutation in patient samples with drug resistance. The mutant-enriched PCR were able to detect one mutant in the presence of 1×10^3 wild-type genes. Furthermore, the detection rate was higher using mutant-enriched PCR (36.4%) than that using direct sequencing (6.1%). Mutations were more frequent in post-treatment samples (36.4%) than that in pre-treatment samples (6.1%). Those with EGFR T790M mutation have a better prior gefitinib response compared to those without EGFR T790M mutation. These results suggest that the blood-based mutant-enriched PCR is an ideal noninvasive monitoring system for detecting EGFR T790M mutation for clinical application.