



The *therascreen*® EGFR Plus RGQ PCR Kit – a clinically validated in vitro diagnostic test to help guide your NSCLC treatment

Empowering treatment decisions in NSCLC



Mutation analysis in non-small cell lung cancer (NSCLC) is the gold-standard method of determining presence of a driver mutation in *EGFR* and enabling oncologists to make *EGFR* TKI treatment decisions for patients with advanced NSCLC (1, 2). Our new *therascreen* EGFR Plus RGQ PCR Kit gives you:

- Sensitive detection of all currently known activating and resistance *EGFR* mutations – including T790M and C797S
- Manual or automated sample preparation options
- The ability to test FFPE and liquid biopsy samples in the same PCR run
- Next-day results with a simple, ready-to-use system
- Automated data analysis using Rotor-Gene AssayManager® Software

Sample to Insight

Detection of *EGFR* mutations is key in NSCLC

Lung cancer is the second (men) or third (women) most common cancer in Europe with >477,500 new cases in 2020 (3) 80–90% of which were NSCLC (2). Mutations in the *EGFR* gene are observed in ~15% of NSCLC adenocarcinomas; higher in Asian populations, up to 63% (4).

In NSCLC, the presence of certain *EGFR* mutations (exon 19 deletions, exon 20 insertions and exon 21 L858R) strongly predicts for sensitivity to *EGFR* tyrosine kinase inhibitors (TKIs) (4).

Test for activating and resistance mutations



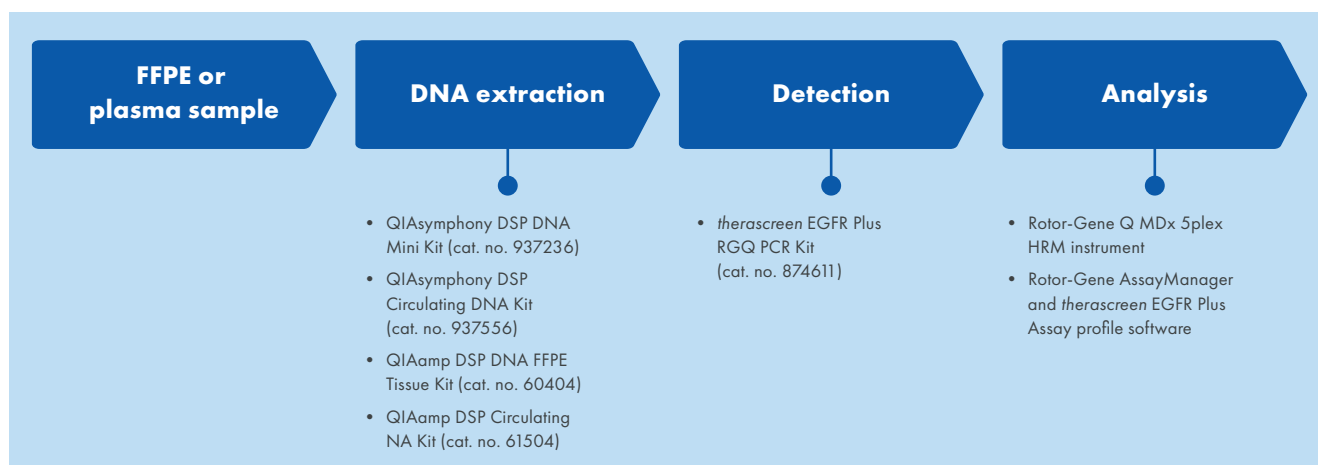
Mutation analysis in NSCLC is the gold-standard test for driver mutations in *EGFR*, the results of which empower oncologists to tailor patients' treatment.

The *therascreen EGFR Plus* RGQ PCR Kit enables sensitive detection of all currently known activating and resistance *EGFR* mutations – including T790M and C797S. The flexible assay tests both FFPE tissue and plasma samples and provides next-day results with automated data analysis (5).

Less invasive patient sampling

Ongoing mutation testing enables oncologists to tailor patients' treatment over time – but repeated tissue biopsies are invasive and painful. Clinical guidelines recommend that liquid biopsy samples can be used where repeated biopsies are not feasible (1, 2, 6). Liquid biopsies may also test DNA from the whole tumor, including metastases. With the *therascreen EGFR Plus* RGQ PCR test, you can test FFPE and liquid biopsy samples in the same PCR run, allowing for matched testing of FFPE and plasma and removing the need to batch samples before a run (5).

- Extraction of DNA from FFPE tissue or plasma samples can be performed manually or automated on the QIAasymphony® SP.
- Sensitive real-time PCR is performed on the Rotor-Gene® Q MDx 5plex HRM instrument with automated data analysis using Rotor-Gene AssayManager® software.
- Qualitative results are displayed in the software.
- The 8-hour workflow provides next-day results, informing earlier treatment decisions.



Clinical performance

When compared to the analytical reference method, there was a high level of concordance between *therascreen* EGFR Plus RGQ PCR Kit and the analytical accuracy method(s) (5).

Results were analyzed to assess the positive percent agreement (PPA), negative percent agreement (NPA) and overall percent agreement (OPA) regarding EGFR mutation status (mutant [MT] or wild-type [WT]) and *EGFR* target (mutation identification) for FFPE and plasma samples between *therascreen* EGFR Plus RGQ PCR Kit and respective reference method and subsequent discrepancy resolution method.

FFPE samples

In the study, 170 FFPE samples were tested, of which 148 gave valid interpretable results. Results of the *therascreen* EGFR Plus RGQ PCR Kit were

compared to results of the respective reference method and four *EGFR* samples status (MT or WT) showed discordance. Following discrepancy resolution, the number of discordant samples decreased to one (false-negative). PPA, NPA and OPA with corresponding two-sided 95% confidence intervals (CI) are summarized in Table 1.

Table 1. Agreement of overall mutation status after discordance investigation (FFPE samples)

		Lower limit 95% CI	Upper limit 95% CI
OPA	99.32%	96.29%	99.98%
PPA (sensitivity)	98.33%	91.06%	99.96 %
NPA (specificity)	100.00%	95.89%	100.00%

NPA: Negative percent agreement OPA: Overall percent agreement; PPA: Positive percent agreement.

Table 2. Agreement of overall mutation status after discordance investigation (plasma samples)

		Lower limit 95% CI	Upper limit 95% CI
OPA	99.32%	96.29%	99.98%
PPA (sensitivity)	98.33%	91.06%	99.96 %
NPA (specificity)	100.00%	95.89%	100.00%

NPA: Negative percent agreement OPA: Overall percent agreement; PPA: Positive percent agreement.

Plasma samples

In the study, 106 plasma samples were tested and 106 gave valid interpretable results.

Results of the *therascreen* EGFR Plus RGQ PCR Kit were compared to results of the respective reference method and nine *EGFR* samples status (MT or WT) showed discordance. Following discrepancy resolution, the number of discordant samples decreased to three (one false-negative and two false-positive). PPA, NPA and OPA with corresponding two-sided 95% confidence intervals (CI) are summarized in Table 2.

Ordering Information

Product	Contents	Cat. no.
<i>therascreen</i> EGFR Plus RGQ PCR Kit (24)	For 24 reactions: T790M & L861Q Mix, Insertions & G719X Mix, L858R & C797S Mix, Deletions & S768I Mix, PCR Master Mix, EGFR Positive Control, RNase/DNase-free Water	874611
Related products		
QIAamp DSP DNA FFPE Tissue Kit (50)	For 50 DNA preps: 50 QIAamp MinElute® Columns, Proteinase K, Buffers and Collection Tubes (2 ml)	60404
QIAamp DSP Circulating NA Kit (50)	For 50 preps: QIAamp Mini columns, Buffers, Carrier DNA, QIAGEN Proteinase K and tubes	61504
QIAasymphony DSP DNA Mini Kit (192)	For 192 preps of 200 µl each: Includes 2 reagent cartridges and enzyme racks and accessories	937236
QIAasymphony DSP Circulating DNA Kit (192)	Reagent cartridges, accessories and proteinase K vials for 192 preps of 2000 µl or 4000 µl each	937556
Rotor-Gene Q MDx 5plex HRM System	Real-time PCR cyclers and High Resolution Melt analyzer with 5 channels plus HRM channel, laptop computer, software, accessories, 1-year warranty on parts and labor, installation and training included	9002033
Rotor-Gene AssayManager v2.1	Software for routine testing in combination with Rotor-Gene Q instruments. License key not included.	9024203

Note: Rotor-Gene AssayManager v2.1 Gamma Plug-In and the specific *therascreen* EGFR Plus run templates for FFPE and plasma samples must be downloaded from www.qiagen.com

The *therascreen* EGFR Plus RGQ PCR Kit is intended for in vitro diagnostic use.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit instructions for use or user operator manual. QIAGEN instructions for use and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services (or your local distributor).

References

1. ESMO. Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Available at: <https://www.esmo.org/guidelines/lung-and-chest-tumours/clinical-practice-living-guidelines-metastatic-non-small-cell-lung-cancer>. Accessed: March 15, 2022.
2. Lindeman, N.I., et al. (2018) Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment With Targeted Tyrosine Kinase Inhibitors Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. Arch. Pathol. Lab. Med. **142**, 321-346.
3. GLOBOCAN 2020. <http://gco.iarc.fr/today>. Accessed: March 10, 2022.
4. Pakkala, S. and Ramalingam, S.S. (2018). JCI insight, **3**, e120858.
5. EGFR Plus RGQ PCR Kit Instructions for Use. (March 2022).
6. Pérez-Callejo, D., et al. (2016) Liquid biopsy-based biomarkers in non-small cell lung cancer for diagnosis and treatment monitoring. Transl. Lung Cancer Res. **5**, 455-465.

➔ Learn more about EGFR mutation testing in NSCLC at www.qiagen.com/EGFR-Plus

➔ Watch the latest webinars on our solid tumor webinar hub, visit <https://www.qiagen.com/applications/oncology/solid-tumor/webinars>

Trademarks: QIAGEN®, Sample to Insight®, QIAamp®, QIAasymphony®, MinElute®, Rotor-Gene®, Rotor-Gene AssayManager®, *therascreen*® (QIAGEN Group).

Registered names, trademarks, etc. used in this document, even when not specifically marked as such, may still be protected by law.

PROM-15974-001 1126602 05/2022 © 2022 QIAGEN, all rights reserved.

Ordering www.qiagen.com/shop | Technical Support www.support.qiagen.com | Website www.qiagen.com