



The *therascreen*<sup>®</sup> KRAS RGQ PCR Kit is a clinically validated in vitro diagnostic test to aid the identification of NSCLC patients who may be eligible for treatment with LUMYKRAS<sup>®</sup> (sotorasib)



## Unlock *KRAS* G12C for lung cancer treatment decisions

Sample to Insight

## Reliable detection of KRAS G12C is the key to a new treatment option

In Europe, lung cancer is the second most common cancer among men and the third most common cancer among women with >477,500 new cases in 2020 (1). Of these cases, non-small cell lung cancer (NSCLC) accounts for between 80 and 90% (2). Although development of NSCLC is associated with many forms of mutation in a large number of genes, activating mutations in the proto-oncogene KRAS are among the most frequent (3), with the specific mutation KRAS G12C present in 13–15% of NSCLC cases (4, 5). Until recently, there has been no targeted treatment for KRAS G12C-positive NSCLC, despite decades of research.

The clinically validated *therascreen* KRAS RGQ PCR Kit is the first tissue in vitro diagnostic (IVD) test to aid patient selection and guide treatment options in KRAS G12C-positive NSCLC.

The *therascreen* KRAS RGQ PCR Kit identifies patients that may be eligible for treatment with the K-Ras G12C-selective inhibitor LUMYKRAS (sotorasib), based on the detection of the clinically actionable KRAS G12C mutation in tumor DNA isolated from FFPE tissue samples. This rapid and sensitive test is part of a simple and reliable workflow with automated result reporting. It has proven analytical and clinical validity, having been evaluated in 124 subjects in a clinical trial (6).

## Response to LUMYKRAS linked to the presence of the KRAS G12C mutation

Clinical trial 20170543 was an open-label, multi-center, phase 1/2 study designed to evaluate the efficacy and safety of LUMYKRAS (sotorasib) in adult subjects with advanced solid tumors that harbor the KRAS G12C mutation (6).

The primary endpoint of the NSCLC phase 2 portion of this study was to evaluate tumor objective response rate (ORR), assessed by RECIST 1.1 criteria, of LUMYKRAS (sotorasib) as monotherapy in subjects with KRAS G12C-mutated advanced tumors.

Of a total of 126 subjects, 124 subjects were included in the full analysis set.

The primary endpoint of ORR (complete response + partial response) assessed per RECIST 1.1 by blinded independent centralized review (BICR) for subjects with KRAS G12C-mutated NSCLC was 37.1% (46 of 124 subjects; 95% CI: 28.7–46.3%); 2.4% (three subjects) achieved complete response and 34.7% (43 subjects) achieved partial response\*.

The *therascreen* KRAS RGQ PCR Kit enables the selection of KRAS G12C-positive patients with advanced NSCLC who may benefit from treatment with LUMYKRAS (sotorasib).

\* Based on data with a cut-off date of December 1, 2020.

## Sample to Insight<sup>®</sup> workflow

The simple testing workflow begins with manual DNA extraction from formalin-fixed, paraffin-embedded (FFPE) NSCLC tumor tissue using the QIAamp<sup>®</sup> DSP DNA FFPE Tissue Kit, followed by sensitive real-time PCR on the Rotor-Gene<sup>®</sup> Q MDx 5plex HRM instrument and automated data analysis with Rotor-Gene Q software (Figure 1).

(G 12A; G 12D; G 12R; G 12C; G 12S; G 12V; G 13D). Qualitative results are displayed in Rotor-Gene Q software, informing the system operator if one or more of the seven mutations detected by the kit are present. The assay can be completed in ~8 hours, providing next-day results.

The *therascreen* KRAS RGQ PCR Kit targets seven mutations in codons 12 and 13 of the KRAS gene



Figure 1. Simple, efficient workflow with the *therascreen* KRAS RGQ PCR System.

## Ordering Information

Product	Contents	Cat. no.
<i>therascreen</i> KRAS RGQ PCR Kit (24)	For 24 reactions: 1 Control Assay, 7 Mutation Assays, Positive Control, Water, Taq DNA Polymerase	874011
<b>Related products</b>		
QIAamp DSP DNA FFPE Tissue Kit (50)	For 50 DNA preps: QIAamp MinElute® columns, Proteinase K, Buffers, and Collection Tubes (2 ml)	60404
Rotor-Gene Q MDx 5plex HRM System	Real-time PCR cyclers and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training	9002033

The *therascreen* KRAS 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](http://www.qiagen.com) or can be requested from QIAGEN Technical Services (or your local distributor).

## References

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2. ESMO. Non-Small Cell Lung Cancer. ESMO Patient Guide Series. [esmo.org](http://esmo.org). Accessed: April 17, 2022
3. Fernandez-Medarde, A., et al. (2011) *Genes Cancer*. **2**, 344.
4. Biernacka, A., et al. (2016) *Cancer Genetics*. **S2210-7762**, 30021.
5. Sebastian, M., et al. (2021) *Lung Cancer*. **154**, 51.
6. *therascreen* KRAS RGQ PCR Kit Instructions for Use (Handbook). July 2022

 Learn more about KRAS G12C in NSCLC at [www.qiagen.com/KRAS-CE](http://www.qiagen.com/KRAS-CE)

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