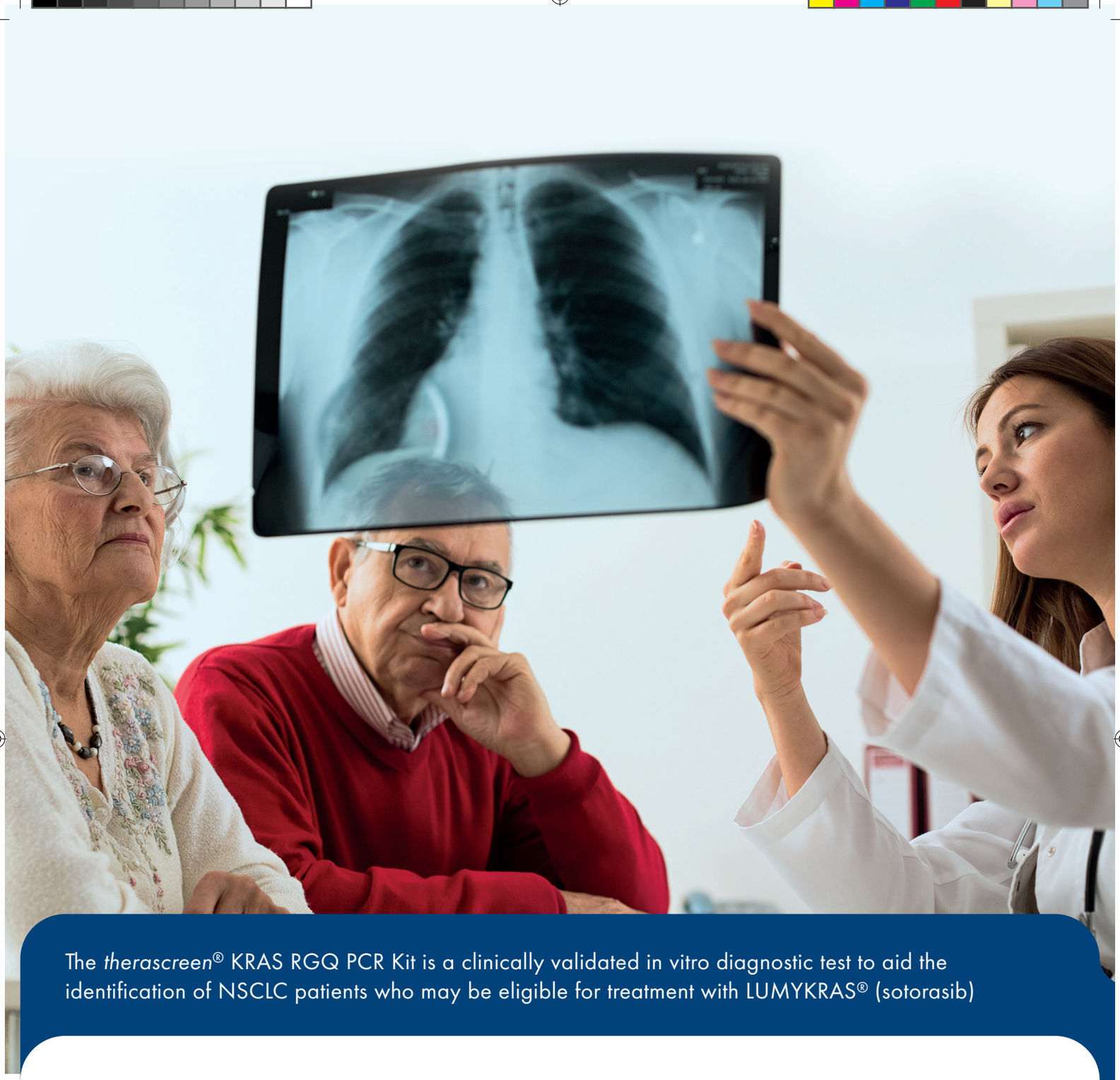

The *therascreen*® KRAS RGQ PCR Kit is a clinically validated in vitro diagnostic test to aid the identification of NSCLC patients who may be eligible for treatment with LUMYKRAS® (sotorasib)

QIAGEN

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® workflow

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

The *therascreen* KRAS RGQ PCR Kit targets seven mutations in codons 12 and 13 of the *KRAS* gene (G12A; G12D; G12R; G12C; G12S; G12V; G13D). 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.

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

Ordering Information

Product	Contents	Cat. no.
therascreen KRAS RGQ PCR Kit (24)	For 24 reactions: 1 Control Assay, 7 Mutation Assays, Positive Control, Water, *Taq* DNA Polymerase	874011
Related products		
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 cycler 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** or can be requested from QIAGEN Technical Services (or your local distributor).

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Learn more about *KRAS* G12C in NSCLC at **www.qiagen.com/KRAS-CE**

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