



## OncoEGFR-GeneSGKit<sup>®</sup>

Sistemas Genómicos, which belongs to the ASCIRES biomedical group, has designed the **OncoEGFR-GeneSGKit<sup>®</sup>**, the most sensitive test on the market for the detection of *EGFR* gene mutations, most commonly associated with **somatic lung cancer**, from tumour DNA for **Digital Droplet PCR** platforms.

cDNA	Protein
c.2235_2249del15	p.Glu746_Ala750del
c.2235_2252delinsAAT	p.Glu746_Thr751delinsIle
c.2236_2250del15	p.Glu746_Ala750del
c.2237_2255delinsT	p.Glu746_Ser752delinsVal
c.2238_2248delinsGC	p.Leu747_Ala750delinsPro
c.2238_2252delinsGCA	p.Leu747_Thr751delinsGln
c.2238_2255del18	p.Glu746_Ser752delinsAsp
c.2239_2248delinsC	p.Leu747_Ala750delinsPro
c.2239_2251delinsC	p.Leu747_Thr751delinsPro
c.2239_2253del15	p.Leu747_Thr751del
c.2239_2256del18	p.Leu747_Ser752del
c.2239_2258delinsCA	p.Leu747_Pro753delinsGln
c.2240_2254del18	p.Leu747_Thr751del
c.2240_2257del18	p.Leu747_Pro753delinsSer
c.2573T>G	p.Leu858Arg
c.2582T>A	p.Leu861Gln

OncoEGFR-GeneSGKit<sup>®</sup> enables the detection and quantitation of the percentage of tumour DNA in a sample carrying the variants to be tested in the *EGFR* gene. The kit provides the most sensitive and specific data available on the market for the established assay conditions, with only **25 ng of tumour DNA** obtained from **fresh frozen tissue samples or samples embedded in paraffin blocks (FFPE)**, with minimal handling time.

### HIGHLIGHTS

#### Quick and easy:

The workflow only requires final preparation of the mix for amplification by PCR, according to the number of samples to be tested, and the subsequent generation of the procedure's respective droplets. Subsequently, all that needs to be done is to perform the PCR process in the thermal cycler and to read and analyse the results obtained. Optimisation of the procedure means that results are obtained on the same working day.

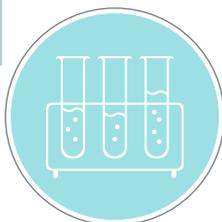
#### Quality:

It generates reproducible and consistent results.

#### Optimal integration in the laboratory:

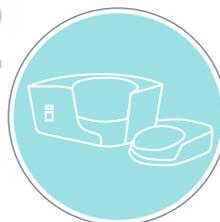
The test may be quickly incorporated into routine practice at the user's facility and readily scaled, with no need to obtain additional resources to increase the number of samples processed.

1



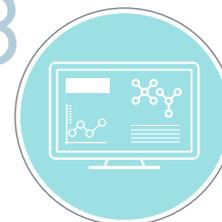
Sample preparation

2



Processing in ddPCR\*

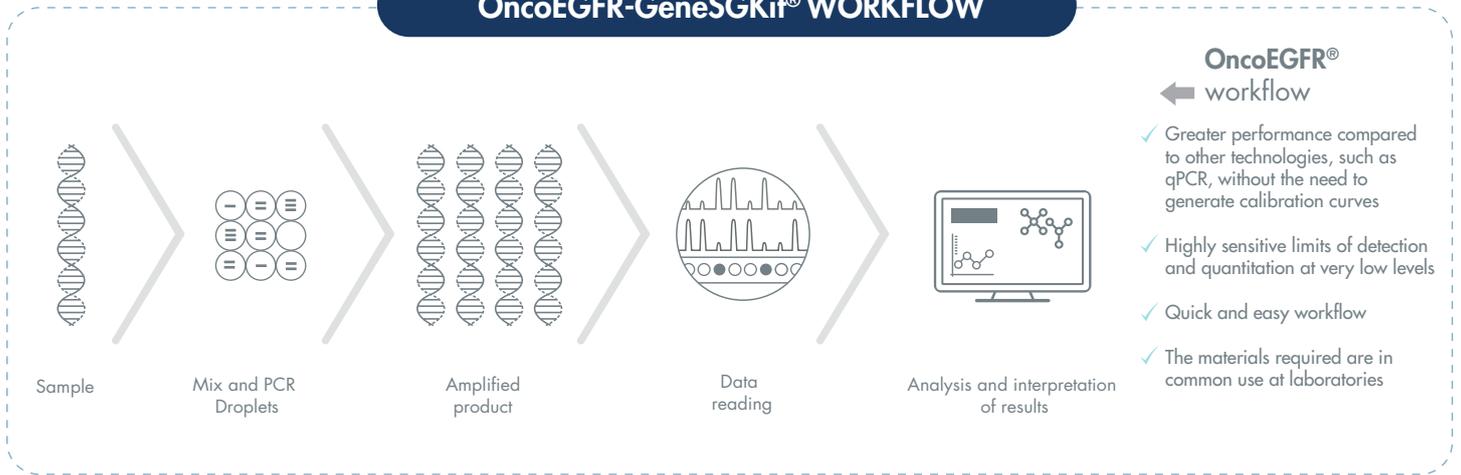
3



Analysis of results

\*BioRad and Life Technologies

## OncoEGFR-GeneSGKit® WORKFLOW



### ABOUT US

Sistemas Genómicos (ASCIREs Group) is a leader in the use of next-generation sequencing (NGS) for genetic diagnosis. Accredited and certified under the most stringent quality standards (**ISO9001, ISO17025, ISO15189, ISO13485 and CLIA**), Sistemas Genómicos (ASCIREs Group) offers solutions for implementing and standardising NGS-based genetic diagnosis. We give professionals the **tools they need to complete the diagnostic process quickly and efficiently.**

### OUR GOAL

Sistemas Genómicos (ASCIREs Group) provides **optimised diagnostic solutions**, based on state-of-the-art technology, in order to provide our customers with the necessary experience and know-how for the benefit of patients. **OncoEGFR-GeneSGKit®** enables the detection of specific treatment-related mutations in the *EGFR* gene, and the implementation of this service in laboratories, without the need to outsource the process. The results are highly reliable and the results report is generated more quickly.



### DESIGN AND WORKFLOW

The OncoEGFR-GeneSGKit® working protocol is optimised for processing tumour samples, whether fresh tissue or paraffin-embedded material. The kit also contains a positive control to establish and confirm the validity of the results obtained. The technique's characteristics provide the most sensitive limits of detection and quantitation on the market.



### EGFR PERFORMANCE

OncoEGFR-GeneSGKit® enables the detection and quantitation of **90% of the most significant mutations** to facilitate the **selection of the most appropriate therapy for patients with somatic lung cancer.**



### CUSTOMER SUPPORT

For Sistemas Genómicos (ASCIREs Group), high-quality customer service, support and follow-up are absolutely essential. Through our adapted training programmes, we provide a **personalised service** enabling efficient implementation of NGS-based diagnosis. These programmes provide fast and simple training in the skills required to successfully and efficiently use the latest advances in sequencing technology, and to facilitate the **rapid inclusion of GeneSGKits® in routine at any laboratory.**

 GeneSGKit®

## Sensitivity and specificity

cDNA	PROTEIN	FALSE POSITIVE RATE (%)	LIMIT OF DETECTION (%)	LIMIT OF QUANTITATION (%)
c.2235_2249del15	p.Glu746_Ala750del E746_A750del	<0.00001	0.0188	0.0188
c.2235_2252delinsAAT	p.Glu746_Thr751delinsIle E746_T751>I	<0.00001	0.0182	>0.0812
c.2236_2250del15	p.Glu746_Ala750del E746_A750del	<0.00001	0.00571	0.063
c.2237_2255delinsT	p.Glu746_Ser752delinsVal E746_S752>V	<0.00001	0.029	0.0942
c.2238_2248delinsGC	p.Leu747_Ala750delinsPro L747_A750>P	<0.00001	0.00587	0.124
c.2238_2252delinsGCA	p.Leu747_Thr751delinsGln L747_T751>Q	<0.00001	0.00733	0.138
c.2238_2255del18	p.Glu746_Ser752delinsAsp E746_S752>D	<0.00001	0.0116	0.102
c.2239_2248delinsC	p.Leu747_Ala750delinsPro L747_A750>P	<0.00001	0.0844	0.0844
c.2239_2251delinsC	p.Leu747_Thr751delinsPro L747_T751>P	0.501	>1.91	>1.91
c.2239_2253del15	p.Leu747_Thr751del L747_T751>N	<0.00001	0.0148	0.192
c.2239_2256del18	p.Leu747_Ser752del L747_S752del	<0.00001	0.103	0.103
c.2239_2258delinsCA	p.Leu747_Pro753delinsGln L747_P753>Q	<0.00001	0.09260	0.336
c.2240_2254del18	p.Leu747_Thr751del L747_T751del	<0.00001	0.01500	0.105
c.2240_2257del18	p.Leu747_Pro753delinsSer L747_P753>S	<0.00001	0.01610	0.107
c.2573T>G	p.Leu858Arg L858R	0.0045	0.118	0.118
c.2582T>A	p.Leu861Gln L861Q	0.122	0.255	0.452

### References

OncoEGFR-GeneSGKit<sup>®</sup>: LV3803 (30 reactions) LV3804 (120 reactions)

