PRODUCT SHEET

Seraseq™ FFPE Tumor KRAS Reference Material Kit v1

RELIABLE, CONSISTENT KRAS TUMOR MUTATION REFERENCE MATERIAL

HIGHLIGHTS

SEVEN CLINICALLY ACTIONABLE KRAS MUTATIONS AT LOW ALLELE FREQUENCY; ASSURES PRECISE DETECTION OF THERAPEUTICALLY RELEVANT TARGETS.

FFPE FORMAT MIMICS A TRUE PATIENT SAMPLE; TESTS YOUR ENTIRE PROCESS, FROM PRE-ANALYTICS THROUGH GENERATION OF FINAL CALLS.

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; SAVES TIME AND PROCUREMENT COST PRODUCING HOME-BREW MATERIALS.

INTRODUCTION

KRAS mutation testing is important for predicting response to anti-EGFR therapy for both lung cancer and colorectal cancer patients.[1,2] Therefore, companion diagnostic developers and clinical labs targeting KRAS need a reliable source of reference materials to ensure tests can accurately and robustly detect therapeutically relevant mutations. However, use of residual patient samples and cell lines pose significant challenges due to limited availability, poor characterization, and significant time and effort to maintain materials.

Seraseq FFPE Tumor KRAS Reference Material Kit v1 solves the challenges of limited availability and poor characterization of residual samples by offering a reliable and consistent source of standards for KRAS mutation detection tests. This formalin-fixed, paraffin-embedded (FFPE) reference material contains 7 prevalent, clinically actionable KRAS mutations in a convenient single-product format. Each mutation is present in a separate FFPE section at 4-5% variant allele frequency relative to a well-characterized genomic background.

PRODUCT FEATURES

- 7 prevalent, actionable KRAS mutations across codons 12 & 13
- 4-5% variant allele frequency challenges the limit of detection (LoD)
- FFPE format (single 10 µm section for each mutation) mimics a true patient sample
- Mutation targets quantitated with highly sensitive digital PCR establish “ground truth”
- Well-characterized GM24385 human genomic DNA background “wild-type” material reduces mutation artifacts
- Manufactured in cGMP compliant, ISO 9001 and ISO 13485 certified facilities

KRAS MUTATIONS COVERED BY THE SERASEQ FFPE TUMOR KRAS REFERENCE MATERIAL KIT V1

KRAS Mutation	HGVS Name	COSMIC Identifier
G12C	c.34G>T	516
G12S	c.34G>A	517
G12R	c.34G>C	518
G12V	c.35G>T	520
G12D	c.35G>A	521
G12A	c.35G>C	522
G13D	c.38G>A	532

ABOUT SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS.

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS.

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS.

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: **WWW.SERACARE.COM.**

PRECISELY QUANTITATED PATIENT-LIKE REFERENCE MATERIAL

KRAS VARIANT ALLELE FREQUENCIES BY DIGITAL PCR

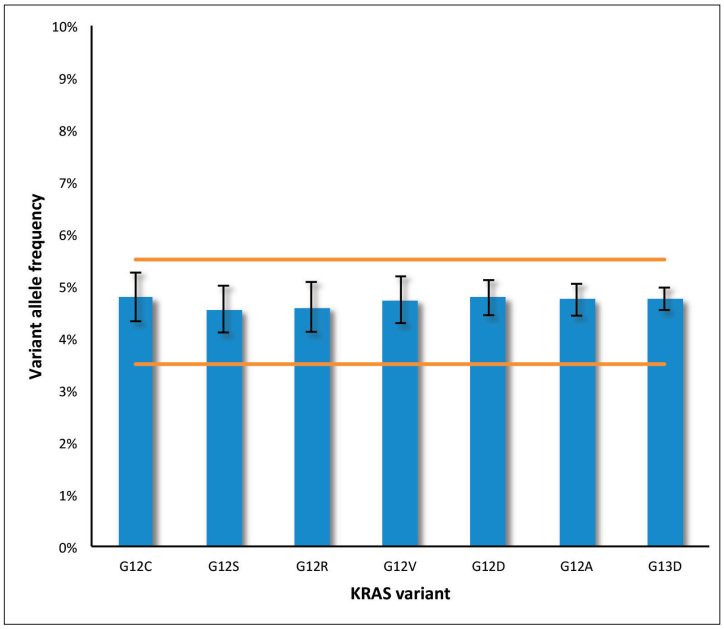

FIGURE 1: Digital PCR data for individual mutations. Error bars represent 95% confidence interval for variant allele frequency, and orange lines indicate lower 3.5% and upper 5.5% acceptable limits for variant allele frequency.

Seven cell lines, each carrying a single KRAS mutation, are separately blended with wild-type GM24385 cells to achieve 4-5% variant allele frequency for each KRAS mutation. After FFPE treatment, 10-micron sections are cut from different areas across each block to ensure thorough QC testing, and mutation frequencies are assessed using digital PCR (Figure 1). All 7 FFPE sections, each carrying a different KRAS mutation, are then packaged into a single kit with 7 individual vials.

This highly commutable full-process reference material can be used to establish and monitor the performance of a wide range of molecular KRAS assays, as well as the pre-analytic portions of your laboratory workflow.

ORDERING INFORMATION		
Material #	**Product**	**Fill Size**
0710-0098	Seraseq Tumor KRAS Reference Material Kit v1	7 vials, 1 FFPE section / vial

LEARN MORE

To learn more about Seraseq FFPE Tumor KRAS Reference Material Kit v1 and SeraCare's products for precision oncology diagnostics, visit **www.seracare.com/oncology**.

Contact us at +1.508.244.6400 and 800.676.1881 or email us at info@seracare.com.

REFERENCES

1. Markman B et al. EGFR and KRAS in colorectal cancer. Adv Clin Chem. 2010 51:71-119. PubMed PMID:20857619
2. Pao W et al. KRAS mutations and primary resistance of lung adenocarcinomas to gefitinib or erlotinib. PLoS Med. 2005 2(1):e17. doi:10.1371/journal.pmed.0020017

seracare™

MKT-00322-01