

PLEASE NOTE:

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

The Seraseq® FFPE Tumor KRAS Reference Material Kit v1 contains seven 5-micron sections of FFPE material. Each section is made using cells that carry one of seven different mutations in codon 12 or codon 13 of the KRAS oncogene, blended with GM24385 cells that are known to be wild-type at these positions. The final variant allele frequency for each KRAS mutation is between 4% and 5%. Seraseq FFPE Tumor KRAS Reference Material Kit v1 is intended for use with molecular assays that detect somatic mutations in codon 12 and/or codon 13 of the KRAS oncogene. This product may be used to monitor laboratory processes and bioinformatics pipelines used for detection of somatic KRAS mutations. *For Research Use only. Not for use in diagnostic procedures.*

PRODUCT DESCRIPTION

Seraseq FFPE Tumor KRAS Reference Material Kit v1 is a kit of seven vials, each of which contains a single 5-micron thick section of formalin-fixed, paraffin-embedded cells.

REAGENTS

Item No. 0710-0117. 7 vials, 1 FFPE-treated curl per vial.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle Seraseq FFPE Tumor KRAS Reference Material Kit v1 as though it is capable of transmitting infectious agents. This product contains seven commercially available human cell lines, each carrying a different KRAS mutation. One additional human cell line that is derived from GM24385, a B-lymphocytic, male cell line from the Personal Genome Project offered by the NIGMS Human Genetic Cell Repository (<https://catalog.coriell.org/1/NIGMS>), is also contained in the product. The FFPE-treated curls are lightly fixed with HistoGel then fixed with 10% Formalin and washed prior to embedding.

Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens¹. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use Seraseq FFPE Tumor KRAS Reference Material Kit v1 beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store Seraseq FFPE Tumor KRAS Reference Material Kit v1 at 2-8°C. Shelf life when stored under these conditions is one year from date of manufacture.

PROCEDURE

Materials Provided

7 vials, 1 curl per vial, of Seraseq FFPE Tumor KRAS Reference Material v1.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used, including extraction of nucleic acid from FFPE-treated material.

Instructions for Use

Allow the product vials to come to room temperature before use. Seraseq FFPE Tumor KRAS Reference Material Kit v1 must go through an extraction process. Each FFPE section or curl has been observed to yield at least 2 µg of nucleic acid using the Roche cobas® DNA Sample Preparation Kit and quantitated via UV-Vis (Nanodrop), however yield may vary based on the extraction and quantitation methods used. Refer to your usual test procedures in order to determine the amount of extracted material to use for input into the assay.

EXPECTED RESULTS AND INTERPRETATION

Detection of KRAS mutations may vary across different types of molecular assays. While the expected allele frequency for each mutation is 4-5%, observed allele frequencies may differ due to assay characteristics. Each manufactured batch is tested using a functional digital PCR-based somatic mutation detection assay to ensure all 7 KRAS mutations are present.

Table 1 indicates the KRAS mutations included in the product.

LIMITATIONS OF THE PROCEDURE

Seraseq FFPE Tumor KRAS Reference Material Kit v1 is offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

SPECIFIC PERFORMANCE CHARACTERISTICS

Seraseq FFPE Tumor KRAS Reference Material Kit v1 has been designed for use with KRAS somatic mutation detection assays for the purpose of assessing assay characteristics including lower Limit of Detection. The product is manufactured from human cell lines. Although the product is manufactured to contain each mutation listed in Table 1, Seraseq FFPE Tumor KRAS Reference Material Kit v1 does not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

Table 1: KRAS mutations in the Seraseq[®] FFPE Tumor KRAS Reference Material Kit v1

	KRAS Mutation	HGVS Name	COSMIC ID
1	G12C	c.34G>T	516
2	G12S	c.34G>A	517
3	G12R	c.34G>C	518
4	G12V	c.35G>T	520
5	G12D	c.35G>A	521
6	G12A	c.35G>C	522
7	G13D	c.38G>A	532