

With just one
slide, measure
ALK plus:

ROS1*
RET*
NTRK1*
HER2*
cMET*



Product Overview

HTG's new sequencing-based assay for detecting ALK status plus more.

The HTG EdgeSeq ALKPlus Assay EU is an *in vitro* diagnostic, next-generation sequencing (NGS)-based assay intended to measure and analyze mRNA ALK gene fusion events in formalin-fixed, paraffin-embedded (FFPE) lung tumor specimens from patients previously diagnosed with non-small cell lung cancer (NSCLC). The HTG EdgeSeq ALKPlus Assay EU is indicated as an aid in identifying patients eligible for treatment with XALKORI (crizotinib).

Data are available in research use only (RUO) mode for ROS1, RET, NTRK1, HER2, and cMET. This all-in-one test is available for use on the Illumina MiSeqDx and Illumina MiSeq sequencers.

Features and Benefits

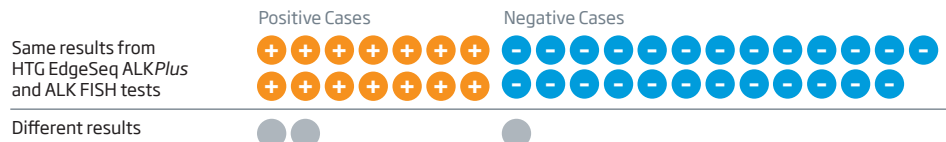
- Obtain ALK status using an NGS-based test:
results are available in as little as 36 hours
- Consolidates molecular testing into a single platform solution:
automated on the HTG EdgeSeq system
- Enables additional research on potential therapeutic agents:
data on ROS1, RET, NTRK1, HER2, and cMET biomarkers

Agreement with FISH

HTG EdgeSeq ALKPlus Assay EU shows a 93% agreement with the Vysis ALK FISH test.

In a total of 42 cases, HTG EdgeSeq ALKPlus Assay EU tests produced the same results as Vysis ALK FISH 39 times. This illustrates a 93% agreement between the results of these two methods.

HTG EdgeSeq ALKPlus Assay EU vs. ALK FISH



For *In Vitro* Diagnostic Use.

*Data available in RUO mode – ROS1, RET, NTRK1, HER2, cMET.
HTG EdgeSeq ALKPlus Assay EU is not for sale in North America.



Ordering Information

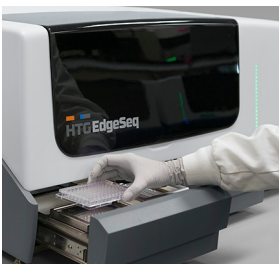
Analyze 8 or 24 samples per run on Illumina MiSeqDx and Illumina MiSeq next-generation sequencing systems.

Catalog Number	Samples per Run	Product Description
CE-006-208	8	1 plate, 8 samples per plate
CE-006-008	8	4 plates, 8 samples per plate
CE-006-024	24	4 plates, 24 samples per plate

Sample Requirements

FFPE Tissue	6.5 mm ² from a 5 µm section
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- Obtain ALK status using an NGS-based test
- Consolidate molecular testing to a single platform solution
- Enable additional research on potential therapeutic agents



Partner with HTG

HTG EdgeSeq System

HTG offers automated workflow solutions for molecular profiling that can be deployed in your laboratory to help address the unique needs and challenges through every step of your project.

VERI/O Laboratory Services

VERI/O Laboratory Services support biomarker research and companion diagnostic development using HTG's extraction-free technology and growing portfolio of profiling assays. ALK rearrangement status and gene expression data for ROS1, RET, NTRK1, HER2, and cMET results are provided for retrospective samples and are not for use in diagnostic procedures.

HTG Preferred Service Providers

HTG has partnered with several preferred service provider laboratories that can process your samples using HTG EdgeSeq systems and assays.

Learn More

The HTG EdgeSeq system has a number of key advantages, including multiplexing from tens to thousands of biomarkers in a single sample; very low sample input requirements; simple, extraction-free sample preparation; automated workflow; and simplified data output.

The HTG EdgeSeq system is a powerful solution providing gene expression profiling results for researchers, laboratory staff, and clinicians pursuing discovery, translational medicine, and diagnostic oncology applications.

For more information contact HTG Molecular Diagnostics at 1-877-289-2615, info@htgmolecular.com or contact your local HTG Molecular Diagnostics representative. Visit www.htgmolecular.com.