Deliver the full genomic story

through optimized testing and tissue processing

Methods for an efficient tumor sampling process to ensure personalized treatment guidance for each patient

oncoExTra™

by EXACT SCIENCES

You have the power to optimize tissue samples for personalized care

Today's targeted treatments demand biomarker testing. There are approximately[1]*†:

80 FDA-approved treatments linked to biomarker indications

51 actionable genomic variations

32 cancer types treatable by biomarker targeting

Over 1/3 of US patients with cancer miss out on precision oncology treatment because of suboptimal testing practices specifically related to quality or sample management issues[8]

Personalized attention can make all the difference—not only for the patient's journey, but for the journey of the tumor sample as well.

*OncoKB Therapeutic data.[2] †As of August 2023.

Stay ahead of testing process barriers with these solutions

1 Communicate early and often across your patient's care team

Molecular testing is ideally planned by clinicians before the biopsy procedure, although pathologic evaluation may expand or change the necessary panel of tests. Planning ahead supports the quality of tissue with steps such as[3]:

- Assessing crucial factors such as tumor viability, necrosis, and percentage of tumor cellularity[3]
- Mitigating the need for resampling[3]

An informed pathologist can serve as the centerpiece of communication to help ensure that personalized testing starts at the tissue.

2 Be part of the initial tumor sampling

Pathologists can effectively identify and supervise challenging situations where the physician performing the sampling procedure may not adequately determine sample quality.[3]

- Identifying the best lesion initially may decrease time to result and subsequent treatment[3]
- Testing performed on the best sample can help increase diagnostic accuracy[3]

Communication with the surgeon during or prior to resection can help ensure that the specimen is of sufficient quantity and quality.[3]

3 Prioritize the most appropriate and comprehensive tests first

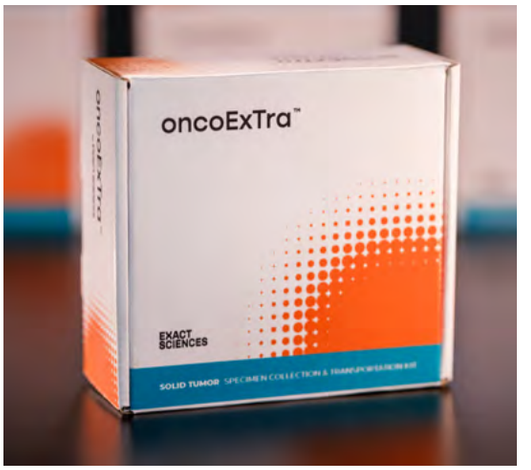
Upfront tissue processing and sequential single-gene testing may exhaust tissue prior to comprehensive genomic testing.[4,5]

- Separating samples into individual blocks may increase tissue availability[5]
- Refer to clinical guidelines for specific use cases for IHC, FISH, or other techniques[6]

Consider comprehensive tests that enable simultaneous testing for multiple approved therapeutic targets.[6]

FISH=fluorescence in situ hybridization; IHC=immunohistochemistry.

Performing ultra-comprehensive genomic profiling early provides numerous benefits



For eligible patients,* ordering a more comprehensive testing option early may help to:

- **Allow** for efficient use of tumor biopsy tissue[6]
- **Avoid** degradation of tumor sample quality[3,4]
- **Summarize** comprehensive results in a single report
- **Reduce** delays in treatment initiation[6]

*The OncoExTra test may be right for patients with advanced solid tumor cancer that is rare, aggressive, or unresponsive to treatment.

SIMPLE AND EASY-TO-FOLLOW SPECIMEN REQUIREMENTS

The solid tumor specimen guidelines for the OncoExTra™ test enable a seamless preparation experience.

	Specimen type	Requirements
Tumor samples	Paraffin block	Fixed tissue with surface area ≥25 mm^2
	Core needle biopsy	3-5 cores from a single tumor
	Scrolls	6-10 freshly cut scrolls at 10 µm each
	Unstained slides (USS)	10 (charged, unbaked) from a single tumor, ≥50 µm total + H&E
	Fresh frozen tissue	5 mm^3
	Minimum tumor content is 20% Send H&E slide or attestation of tumor content for tumor samples, along with corresponding pathology report If sending decalcified bone samples in FFPE, use EDTA-based methods—do NOT use strong acids	
IHC testing	Paraffin block	5-10 µm of tissue used per USS
	USS	2 (charged, unbaked) slides at 4-5 µm per IHC stain 8 (charged, unbaked) slides at 4-5 µm per IHC panel

EDTA=ethylenediaminetetraacetic acid; FFPE=formalin-fixed, paraffin-embedded; H&E=hematoxylin and eosin.

View the full specimen and shipping guidelines

Make the most of every tissue sample with the OncoExTra test

The OncoExTra test uncovers the full genomic story by looking at DNA+RNA

- Interrogates nearly 20,000 genes[7]
- Covers all DNA protein-coding sequences and all RNA transcripts[7]
- Delivers high accuracy with 98.8% sensitivity and >99.9% specificity[7]
- Highlights results in an easy-to-interpret report featuring mutations associated with FDA-approved treatments and clinical trial options*

The OncoExTra report simplifies test interpretation

The organized and clear report helps streamline communication between you, oncology, and other team members to help enable personalized treatment decisions.

*The OncoExTra test is not an FDA-cleared or -approved IVD device or companion diagnostic for the referenced biomarkers and FDA-approved therapies.

By looking at DNA as well as RNA, the OncoExTra test provides a detailed view of more variants—giving patients with advanced cancers more personalized treatment selection right from the start.

Learn more about the benefits of using OncoExTra early

References:

1. Memorial Sloan Kettering Cancer Center. OncoKB Therapeutic. Accessed August 30, 2023. https://www.oncokb.org/actionableGenes#levels=1&sections=Tx,Tx **2.** Chakravarty D, Gao J, Phillips SM, et al. OncoKB: a precision oncology knowledge base. *JCO Precis Oncol.* 2017;2017:PO.17.00011. **3.** De Las Casas LE, Hicks DG. Pathologists at the leading edge of optimizing the tumor tissue journey for diagnostic accuracy and molecular testing. *Am J Clin Pathol.* 2021;155(6):781-792. **4.** Yu TM, Morrison C, Gold EJ, Tradonsky A, Layton AJ. Multiple biomarker testing tissue consumption and completion rates with single-gene tests and investigational use of Oncomine Dx Target Test for advanced non-small-cell lung cancer: a single-center analysis. *Clin Lung Cancer.* 2019;20(1):20-29.e8. **5.** Aisner DL, Rumery MD, Merrick DT, et al. Do more with less: tips and techniques for maximizing small biopsy and cytology specimens for molecular and ancillary testing: the University of Colorado experience. *Arch Pathol Lab Med.* 2016;140(11):1206-1220. **6.** Chakravarty D, Johnson A, Sklar J, et al. Somatic genomic testing in patients with metastatic or advanced cancer: ASCO provisional clinical opinion. *J Clin Oncol.* 2022;40(11):1231-1258. **7.** White T, Szelinger S, LoBello J, et al. Analytic validation and clinical utilization of the comprehensive genomic profiling test, GEM ExTra®. *Oncotarget.* 2021;12(8):726-739.

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