

## **TEST CHANGE - UPDATE**

Notification Date: September 17, 2025 Effective Date: September 17, 2025

# NTRK Gene Fusion Panel, Tumor

Test ID: NTRK

**Explanation:** Correction — Specimen Requirements

Cytology slides have been removed from the Specimen Required section. They were inadvertently listed in the September 9, 2025 Test Change update.

#### **Current Specimen Required**

## This assay requires at least 10% tumor nuclei.

- -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm(2)
- -Minimum amount of tumor area: tissue 36 mm(2).
- -These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei.
- -Tissue fixation: 10% neutral buffered formalin, not decalcified
- -For specimen preparation guidance, see <u>Tissue</u> Requirement for Solid Tumor Next-Generation

  Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides: approximate/equivalent to 36 mm(2).

**Preferred:** Submit 3, if available, or 2 of the following specimens.

**Acceptable:** Submit at least one of the following specimens.

Specimen Type: Tissue block

**Collection Instructions:** Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue.

Specimen Type: Tissue slide

Slides: 1 Hematoxylin and eosin-stained and 10

unstained

**Collection Instructions:** 

Submit the following slides:

1 slide stained with hematoxylin and eosin

AND

#### **New Specimen Required**

## This assay requires at least 10% tumor nuclei.

- -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm(2)
- -Minimum amount of tumor area: tissue 36 mm(2).
- -These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei.
- -Tissue fixation: 10% neutral buffered formalin, not decalcified
- -For specimen preparation guidance, see <u>Tissue</u>
  Requirements for Solid Tumor Next-Generation
  Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred:
  approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides:
  approximate/equivalent to 36 mm(2).

**Preferred:** Submit 2, if available, of the following specimens.

**Acceptable:** Submit at least one of the following specimens.

Specimen Type: Tissue block

**Collection Instructions:** Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue.

Specimen Type: Tissue slide

Slides: 1 Hematoxylin and eosin-stained and 10

unstained

**Collection Instructions:** 

Submit the followings slides:

1 Slide stained with hematoxylin and eosin AND

10 unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.

**Note:** The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block.

**Additional Information:** Unused unstained slides will not be returned.

**Specimen Type: Cytology slide** (direct smears or ThinPrep)

Slides: 1 to 3 Slides

Collection Instructions: Submit 1 to 3 slides stained and coverslipped with a total of 5000 nucleated cells (preferred), or a minimum of 3000 nucleated cells.

Note: Glass coverslips are preferred; plastic coverslips are acceptable but will result in longer turnaround times.

**Additional Information:** Cytology slides will not be returned. An image of the slides will be stored per regulatory requirements.

10 Unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.

**Note:** The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block.

**Additional Information:** Unused unstained slides will not be returned.

#### Questions