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## Instructions for Submitting Order of TruSight Oncology 500 (TSO500) Testing to the Laboratory of Pathology, NCI, NIH

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**Purpose:** To provide detailed instructions for entering CRIS orders and tissue specimen submission for TruSight Oncology 500 (TSO500) testing.

**Principle:** Currently three NGS panel tests are available in NCI-COMPASS program. These are Oncomine Comprehensive Assay v3, Primary CNS Tumor Panel, and TSO500. Please **order one NGS test only** based on cancer type and your clinical need. All molecular pathology requests require concurrent surgical pathology review and both laboratories must be contacted.

### 1. Molecular Pathology – TSO500

- Enter the Molecular CRIS order as follows
  - Anatomic Pathology
    - Molecular Pathology
      - Collection Date- surgery date
      - Specimen for Block Only -
      - Brief Clinical History- NSCLC (for example)
      - Specimen Source- tissue
      - **Test(s) Requested - Check off “TruSight Oncology 500 Gene Panel”** (see screenshot below)
      - Special Instructions - Indicate the outside tissue block accession number and/or number of slides being submitted
- Submit a concurrent Surgical Pathology CRIS if the tissue has not been reviewed by the Laboratory of Pathology (LP), NCI, NIH (see below for detailed instructions)

### 2. Specimen and Handling Requirements

- 1) **A new tissue specimen is being submitted from a procedure performed at the NIH CRC.** In this case, two separate CRIS orders are required - one for surgical pathology or cytopathology to request routine pathology services, and a second CRIS order for the molecular pathology test needed. Please also indicate in the special instructions box on the surgical pathology or cytopathology CRIS order that TSP500 testing is being requested on the sample and, if appropriate, that tissue should be prioritized for molecular testing.
- 2) **For cases that have been already been signed out by LP, the tissue specimens are retained in LP.** A single molecular pathology CRIS order is required to trigger the TSO500 testing. Please indicate the LP surgical case number in the Special Instructions, if known (this number can be obtained from the LP pathology report).

- 3) **All specimens from in-house surgery and outside materials** (surgical specimens, tissue blocks, stained and unstained slides, and outside reports) are to be brought directly to General Surgical Pathology office - 10/Room 2S262 (open 7:30 AM to 4:00 PM). The molecular diagnostics laboratory cannot accession cases.
- 4) Paraffin-embedded tissue specimens from outside must be formalin fixed. You may submit **either a tissue block containing >20% tumor, or a minimum of 10 unstained slides** for molecular pathology testing and surgical pathology review. Keep in mind that copy number alteration assessment will be compromised below 50% tumor content.

### 3. Surgical Pathology and Molecular Pathology Reports:

Surgical pathology reports are automatically linked to the CRIS system if an appropriate CRIS order has been entered and are also available through the Surgical Pathology Office. TSO500 testing is batched and run every week. Preliminary molecular test results will be sent out through email per request. The final molecular pathology report will be uploaded to the CRIS and available in about two weeks.

**For questions regarding ordering or patient result, contact: Ms. Kayla O'Donnell, 301-480-7422, kayla.o'donnell@nih.gov**

**For general questions regarding the TSO500 assay, contact: Dr. Liqiang Xi 301-480-8933, xil2@mail.nih.gov**

Molecular Pathology Order ID: 002GSR00H

By: D Souza, Precilla Template Name:

Instruction for submitting blood and bone marrow: BLOOD - 3 ml whole blood collected in light blue citrate tube (one tube only) and must put a second CRIS order (Research Blood) to Outpatient Phlebotomy. BONE MARROW ASPIRATE - draw 2 ml in plain syringe with NO anticoagulant and immediate to Room 3S247.

Allocate Order to Protocol: 1S-HG-0101E

Conditional Order  Max # of activations:

Priority: Routine Clear

Collection Date: 09/17/2019

Specimen for Block Only:

Brief Clinical History:

Specimen Source:

Tests Required: **NOTICE: At least one test must be selected to process this request. Identify the Test(s) requested using the checkboxes provided below. Select all that apply.**

Hematopathology	Sarcoma Translocations
<input type="checkbox"/> B Cell Clonality <span style="float: right;">Clear</span>	<input type="checkbox"/> Desmoplastic Small Round Cell Tumor <span style="float: right;">Clear</span>
<input type="checkbox"/> T Cell Clonality	<input type="checkbox"/> Ewing's
<input type="checkbox"/> (Virus) EBV/EBNA-2	<input type="checkbox"/> Rhabdomyosarcoma
<input type="checkbox"/> (Virus) HHV-8	<input type="checkbox"/> Synovial
<input type="checkbox"/> (Virus) HTLV-1/2 and III	
Oncology - Solid Tumor	COMPASS
<input type="checkbox"/> OncoPrint Comprehensive Assay <span style="float: right;">Clear</span>	<input type="checkbox"/> TruSight Oncology 500 Gene Panel <span style="float: right;">Clear</span>
<input type="checkbox"/> Primary CNS Tumor Panel	
<input type="checkbox"/> BRCA1/2	
<input type="checkbox"/> EGFR Gains Mutation	
<input type="checkbox"/> MGMT Methylation	
<input type="checkbox"/> MYD88 Mutation	

Provider to notify (select button):

Additional Notification:

Provider's email: