Oncomine Comprehensive Panel FAQs

What is the Oncomine Comprehensive Mutation Panel test?
The Oncomine Comprehensive Mutation Panel assay is a targeted test for the identification of clinically significant somatic mutations including single nucleotide variants (SNVs), insertions and deletions (Indels), gene fusions and copy number alterations (CNAs) from DNA and RNA of 143 cancer-related genes (>2,500 amplicons) in solid tumors, using targeted next generation sequencing (NGS).

The genes interrogated in the assay are categorized by genomic alterations into 73 hot spot genes (with SNVs and Indels), including 49 genes with focal CNAs, such as ERBB2, and 23 genes with known fusions such as ALK and ROS1 in NSCLC. The test also includes four pairs of 5’, 3’ expression imbalance assays for ALK, ROS1, RET and NTRK1. In addition, the test provides full coverage of 26 tumor suppressor genes. The assay is performed on the Ion Torrent S5 XL NGS system.

What is the test utilization for Oncomine Comprehensive Mutation Panel?
Currently the Clinical Genomics Laboratory can only accept cancers of the Lung and Thyroid.
1. Non-Small Cell Lung Cancer
2. Thyroid- Malignant Neoplasm

What kind of specimens can be used for testing?
1. **Formalin-fixed paraffin embedded (FFPE) specimens**
   a. One H&E Slide and 15-20 Unstained sections are required
   b. The minimum amount of neoplastic cellularity acceptable is 20%

2. **Fixed Fine Needle Aspiration (FNA) specimens**
   a. One H&E Slide and 15-20 Unstained sections from cell block are required
   b. The minimum amount of neoplastic cellularity acceptable is 20%

3. **CytoLyt Solution**
   a. Cells suspended in CytoLyt or PreservCyt solution
   b. Preserved at room temperature no longer than 8 days.

Note: A surgical pathology and/or cytology report and completed Molecular Requisition form must accompany all specimens.
Where is the test performed?
The test is performed in the Clinical Genomics Laboratory located in room LC-904.

How is the test ordered?
The Oncomine Comprehensive Mutation Panel is available in Epic and can be ordered by an Oncologist. A Pathologist or Cytopathologist may also order the test directly through CoPath.

Can the test be performed on tissue specimens from outside hospitals?
Yes, however it is required that all material be reviewed in Surgical Pathology. If you are requesting the Oncomine Comprehensive Panel on a patient who has material at an outside hospital, please request 15-20 unstained slides (or block) and 1 re-cut H&E slide. Once your office receives the material it can be submitted to Pathology Department with both a Surgical Pathology Consult order AND an Oncomine order.

Can we order the test again on new tissue from the same patient (a later biopsy)?
Yes, the test can be ordered again if clinically indicated.

Is there a requirement for a consent form?
We do not test for constitutional/inherited mutations at this point. Therefore, no consent form is needed.

How long will it take for results (turn-around time)?
Our estimated turn-around-time is 7-10 business days.

Will results be in EPIC?
Yes, the results for the Oncomine test will be available in both Copath and EPIC.

Is a Pre-Authorization Form required?
Pre-Authorization is currently required for all Oncomine orders placed in the Doctor’s Office (PVT AMB) setting. The physician should begin the process by providing the necessary form to the billing department. The form will be used to communicate with the insurance company to authorize the test.
How much will the test cost patients?
Oncomine is a billable clinical test and will be billed based on specific CPT codes. For the gross billing charges please contact the billing office directly. Health plans/insurance companies will be billed the cost of both the test and the professional interpretation. The patient will be responsible for any deductible and co-payment required by the respective insurance company.

Contact information for billing office:
NGSBilling@med.cornell.edu
T: 212-746-6445  F: 646-962-0477

Who do we contact with questions about the test and results?
For further information on the assay or for questions on the results of the Oncomine test please contact:

**CONTACT INFORMATION**

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<tr>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
<th>Email</th>
</tr>
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<tbody>
<tr>
<td>Dr. Wei Song</td>
<td>Director, Clinical Genomics Laboratory</td>
<td>212-746-6419</td>
<td><a href="mailto:SOW2005@med.cornell.edu">SOW2005@med.cornell.edu</a></td>
</tr>
<tr>
<td>Jeffrey Catalano</td>
<td>Manager, Clinical Genomics Laboratory</td>
<td>212-746-9117</td>
<td><a href="mailto:JPC2004@med.cornell.edu">JPC2004@med.cornell.edu</a></td>
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