FAQ for the CANCER GENE MUTATION PANEL-50 (CGMP-50) NGS TEST

- What is the Cancer Gene Mutation Panel- 50 test?
The Cancer Gene Mutation Panel- 50 (CGMP-50) test is a Targeted Next Generation Sequencing (NGS) assay that is used to interrogate the variant status of 50 cancer-related genes in solid tumors including but not limited to Colorectal, Lung, Brain, Ovarian, Thyroid, Breast cancers and Melanomas. The assay is performed on the Ion Torrent Personal Genome Machine (PGM) platform.

- Where is the test performed?
The test is performed in the Molecular Pathology Laboratory (New York Presbyterian Hospital), of the Molecular & Genomic Pathology division (http://cornellpathology.com/clinical-services/molecular-and-genomic-pathology)

- How can one order the test?
As per the current procedure for all oncology tests, oncologists can request this test through Surgical Pathology at the time the specimen is sent for diagnosis. Surgical Pathology then orders the test through Molecular Pathology. For now the order should specify testing for either, KRAS, BRAF or EGFR. (A test order for all 50 genes will be available shortly). All tests where KRAS, BRAF or EGFR mutation analysis is requested will be sequenced on the CGMP_50 NGS assay.

  Variants with COSMIC ID's (Catalog of Somatic Mutations in Cancer) present in the 50 genes interrogated will be reported. The genes in the panel are listed in the table below:

<table>
<thead>
<tr>
<th>ABL1</th>
<th>AKT1</th>
<th>ALK</th>
<th>APC</th>
<th>ATM</th>
<th>BRAF</th>
<th>CDH1</th>
<th>CDKN2A</th>
<th>CSF1R</th>
<th>CTNNB1</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR</td>
<td>ERBB2</td>
<td>ERBB4</td>
<td>E2H2</td>
<td>FBXW7</td>
<td>FGFR1</td>
<td>FGFR2</td>
<td>FGFR3</td>
<td>FLT3</td>
<td>GNA11</td>
</tr>
<tr>
<td>GNAS</td>
<td>GNAQ</td>
<td>HNF1A</td>
<td>HRAS</td>
<td>IDH1</td>
<td>IDH2</td>
<td>JAK2</td>
<td>JAK3</td>
<td>KDR</td>
<td>KIT</td>
</tr>
<tr>
<td>KDR</td>
<td>MET</td>
<td>MLH1</td>
<td>MPL</td>
<td>NPM1</td>
<td>NOTCH1</td>
<td>NRAS</td>
<td>PDGFRA</td>
<td>PIK3CA</td>
<td>PTEN</td>
</tr>
<tr>
<td>PTPN11</td>
<td>RB1</td>
<td>RET</td>
<td>SMAD4</td>
<td>SMARCB1</td>
<td>SMO</td>
<td>SRC</td>
<td>STK11</td>
<td>TP53</td>
<td>VHL</td>
</tr>
</tbody>
</table>

- Will all tests sent for KRAS, BRAF and EGFR be run and reported with the CGMP_50 gene NGS assay?
The NGS assay can accommodate most specimens sent for KRAS, BRAF and EGFR testing. However, in cases where the DNA concentration or quality is a limiting factor, which occurs in about 20% of the specimens, we will use the single gene assays that are currently available. In these cases a report for individual genes (KRAS, BRAF or/and EGFR) will be issued.

- What kind of specimens can be used for testing?
Formalin Fixed Paraffin Embedded (FFPE) tissue biopsies fixed and embedded appropriately are acceptable for testing. The test can also be performed on additional sample types such as Fine Needle Aspirates (FNAs) and FFPE core biopsies.
• Can the test be performed on tissue specimens from outside hospitals?
Specimens from outside hospitals should be routed through surgical pathology. As per the protocol with surgical pathology Formalin Fixed Paraffin Embedded tissue or cell blocks are preferred as these are necessary for estimating the neoplastic content using a stained section. Alternatively, 10 unstained 5µ sections along with a H&E stained slide from the same block can be used for testing.

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

• Where is the tissue sent?
Oncologists can request this test through Surgical Pathology at the time the specimen is sent for diagnosis. Tissue specimens that need to be tested should be sent to Surgical Pathology Starr 10

• 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 CGMP_50 NGS test will be reported in Cerner and populated into EPIC.

• Can we give results to a patient?
Results from this test should be treated as any other clinical test result.

• Who do we contact with questions about the results?
For further information on the assay or for questions on the results of the CGMP_50 NGS test please contact the directors of the Molecular Pathology Laboratory:

  ➢ Helen Fernandes PhD,  Tel: 212-746-3503;  email: hef9020@med.cornell.edu
  ➢ Hanna Rennert PhD,  Tel: 212-746-6412;  email: har2006@med.cornell.edu

For information pertaining to the laboratory:
  ➢ Phyllis Ruggeiro, Supervisor, Molecular Pathology;  email: pcr9004@nyp.org
  ➢ John Sipley, Technical Specialist, Molecular Pathology  email: jos9015@nyp.org

• Can we make clinical decisions on the results?
Results from this test should be treated as any other clinical test result.

• How much will the test cost patients?
Currently, the specific test requested is what will be billed. For example, if the request for lung adenocarcinoma specifies testing for EGFR and KRAS, then the patient will be billed for the 2 mutations only. The reasonable charge for the 50 Gene panel is still to be determined, pending the availability of additional CMS and market information.

• 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. The test does not interrogate germline variants.