# Detailed Instructions for OncoPrism®-HNSCC Testing

For questions regarding data entry, specimen preparation and/or shipping, after reading this document, please contact:

Cofactor Genomics Support - 240-534-1241 - support@cofactorgenomics.com

## Instructions for completing OncoPrism-HNSCC Requisition Form

OncoPrism-HNSCC is intended to help guide the treatment decisions for patients diagnosed with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). Treatment decisions for an individual patient should be based on the patient's medical condition and a comprehensive review of available health information including other pathological tests.

1. **Physician Information**
   On the requisition form, provide your institution's information, where applicable, to enable communication and verification of subsequent data and results. Testing results will be faxed or emailed to the fax number or secure email you provide in this section.
2. **Physician Authorization and Signature**
   The ordering physician should describe the testing procedure and resulting process to the patient, answer all questions, and acknowledge appropriateness of testing by signing the form.
3. **Clinical Information**
   a. Enter information, where applicable, from the patient's medical record.
   b. For ICD-10 HNSCC Diagnosis Code(s), only codes related to a diagnosis of HNSCC should be provided. Please provide all relevant codes that are listed in the patient's medical record. A list of potential ICD-10 codes is included on pages 3-4. Note: This list is not exhaustive as codes are continually updated.
   c. For disease status and previous treatment, check all boxes that apply.
   d. For PD-L1 status, please check the box for unknown if the patient has never been tested for PD-L1 status.
4. **Specimen Information**
   a. Provide the institution's laboratory contact information for specimen collection from the specific FFPE block required for testing
   b. For accession number and biopsy date, please provide the specific ID information for the FFPE block/ medical case that should be used for OncoPrism testing
   c. For the FAX/EMAIL section, please provide a number or secure email to be used for receipt of patient testing results
   d. At a minimum, ONE of the following specimen sets (comprising a total of 30 microns of tissue) must be labeled and sent to Cofactor Genomics for processing:
      i. Six (6) charged slides of 5µm thickness OR

ii. Two (2) charged slides of 5µm thickness and two (2) tissue curls of 10µm thickness, OR
iii. Other acceptable format such as, the entire FFPE block (with at least 30µm of material remaining) or an agreed upon distribution of curls and slides totaling at least 30µm of specimen (must be pre-discussed and accepted by Cofactor Genomics)

b. Specimens sent for processing must be from patients with a documented clinical diagnosis of recurrent or metastatic HNSCC
c. Specimens sent for processing will be rejected if they fulfill any of the criteria below:
   i. Specimens from unacceptable pathology sites (i.e bone, decalcified or not, and liver).
   ii. Specimens not meeting minimum of 4-6 adjacent sections of tumor (two 5µm slides and two 10µm slides or curls, or six 5µm slides)
   iii. Specimens that are greater than 2 years old
   iv. Specimens that are not from either recurrent or metastatic HNSCC tumors
   v. Other specimens that are not within the scope of the intended use and/or have not been validated
   vi. Specimens that are damaged, incomplete, or not clearly labeled with the required information
   vii. Specimens not accompanied by a complete physical or electronic requisition form and pathology report
   viii. Specimens that do not contain a minimum tumor content of 10% tumor cellularity (when measured as tumor cell nuclei/ non-tumor cell nuclei)
d. Small size tissue samples, small biopsy specimens, hypocellular, fibrotic, fatty samples, or samples with extensive necrosis may require additional unstained slides or tissue curls. If necessary, the entire FFPE block can be shipped to Cofactor Genomics, however, we may exhaust the block during on-site tissue processing.

5. **Patient Identification Information**
   a. Enter information, where applicable, from the patient's medical chart.
   b. Patient’s address should be last known verified residence of domicile if multiple addresses exist
6. **Patient Billing Information**
   a. Enter information, where applicable, from the patient's medical chart or have the patient complete this section.
   b. Please provide both front and back copies of the patient’s insurance card(s).

**After completion of the requisition form please collect front and back copies of the patient’s insurance card(s) and a copy of the patient's face sheet from their medical record. Fax all documents to Cofactor Genomics at 1 (844) 328-5841 or send by secure email to oncoprism@cofactorgenomics.com. Please also send the requisition form to your appropriate location specific pathology contact, if applicable, to avoid processing delays.**

Below is a non-exhaustive list of potential ICD-10 Diagnosis Codes for OncoPrism-HNSCC testing:

| ICD-10 Category with Specific Code and Descriptor |
|---|
| C00 Malignant Neoplasm of the Lip |
| C00.0 Malignant neoplasm of external upper lip |
| C00.1 Malignant neoplasm of external lower lip |
| C00.2 Malignant neoplasm of external lip, unspecified |
| C00.3 Malignant neoplasm of upper lip, inner aspect |
| C00.4 Malignant neoplasm of lower lip, inner aspect |
| C00.5 Malignant neoplasm of lip, unspecified, inner aspect |
| C00.6 Malignant neoplasm of commissure of lip, unspecified |
| C00.8 Malignant neoplasm of overlapping sites of lip |
| C00.9 Malignant neoplasm of lip, unspecified |
| C01 Malignant Neoplasm of Base of Tongue |
| C01 Malignant neoplasm of base of tongue |
| C02 Malignant Neoplasm of Other and Unspecified Parts of Tongue |
| C02.0 Malignant neoplasm of dorsal surface of tongue |
| C02.1 Malignant neoplasm of border of tongue |
| C02.2 Malignant neoplasm of ventral surface of tongue |
| C02.3 Malignant neoplasm of anterior two-thirds of tongue, part unspecified |
| C02.4 Malignant neoplasm of lingual tonsil |
| C02.8 Malignant neoplasm of overlapping sites of tongue |
| C02.9 Malignant neoplasm of tongue, unspecified |
| C03 Malignant Neoplasm of Gum |
| C03.0 Malignant neoplasm of upper gum |
| C03.1 Malignant neoplasm of lower gum |
| C03.9 Malignant neoplasm of gum, unspecified |
| C04 Malignant Neoplasm of Floor of Mouth |
| C04.0 Malignant neoplasm of anterior floor of mouth |
| C04.1 Malignant neoplasm of lateral floor of mouth |
| C04.8 Malignant neoplasm of overlapping sites of floor of mouth |
| C04.9 Malignant neoplasm of floor of mouth, unspecified |

| ICD-10 Category with Specific Code and Descriptor |
|---|
| C05 Malignant Neoplasm of Palate |
| C05.0 Malignant neoplasm of hard palate |
| C05.1 Malignant neoplasm of soft palate |
| C05.2 Malignant neoplasm of uvula |
| C05.8 Malignant neoplasm of overlapping sites of palate |
| C05.9 Malignant neoplasm of palate, unspecified |
| C06 Malignant Neoplasm of Other and Unspecified Parts of Mouth |
| C06.0 Malignant neoplasm of cheek mucosa |
| C06.1 Malignant neoplasm of vestibule of mouth |
| C06.2 Malignant neoplasm of retromolar area |
| C06.80 Malignant neoplasm of overlapping sites of unspecified parts of mouth |
| C06.89 Malignant neoplasm of overlapping sites of other parts of mouth |
| C06.9 Malignant neoplasm of mouth, unspecified |
| C09 Malignant Neoplasm of Tonsil |
| C09.0 Malignant neoplasm of tonsillar fossa |
| C09.1 Malignant neoplasm of tonsillar pillar (anterior) (posterior) |
| C09.8 Malignant neoplasm of overlapping sites of tonsil |
| C09.9 Malignant neoplasm of tonsil, unspecified |
| C10 Malignant Neoplasm of Oropharynx |
| C10.0 Malignant neoplasm of vallecula |
| C10.1 Malignant neoplasm of anterior surface of epiglottis |
| C10.2 Malignant neoplasm of lateral wall of oropharynx |
| C10.3 Malignant neoplasm of posterior wall of oropharynx |
| C10.4 Malignant neoplasm of branchial cleft |
| C10.8 Malignant neoplasm of overlapping sites of oropharynx |
| C10.9 Malignant neoplasm of oropharynx, unspecified |

(continued on next page)

| ICD-10 Category with Specific Code and Descriptor |
|---|
| C12 Malignant neoplasm of pyriform sinus |
| C12 Malignant neoplasm of pyriform sinus |
| C13 Malignant Neoplasm of Hypopharynx |
| C13.0 Malignant neoplasm of postcricoid region |
| C13.1 Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect |
| C13.2 Malignant neoplasm of posterior wall of hypopharynx |
| C13.8 Malignant neoplasm of overlapping sites of hypopharynx |
| C13.9 Malignant neoplasm of hypopharynx, unspecified |
| C14 Malignant Neoplasm of Other and Ill-Defined Sites in the Lip, Oral Cavity, and Pharynx |
| C14.0 Malignant neoplasm of pharynx, unspecified |
| C14.2 Malignant neoplasm of Waldeyer's ring |
| C14.8 Malignant neoplasm of overlapping sites of lip, oral cavity, and pharynx |
| C30 Malignant Neoplasm of Nasal Cavity and Middle Ear |
| C30.0 Malignant neoplasm of nasal cavity |
| C30.1 Malignant neoplasm of middle ear |
| C31 Malignant Neoplasm of Accessory Sinuses |
| C31.0 Malignant neoplasm of maxillary sinus |
| C31.1 Malignant neoplasm of ethmoidal sinus |
| C31.2 Malignant neoplasm of frontal sinus |
| C31.3 Malignant neoplasm of sphenoid sinus |
| C31.8 Malignant neoplasm of overlapping sites of accessory sinuses |
| C31.9 Malignant neoplasm of accessory sinus, unspecified |

| ICD-10 Category with Specific Code and Descriptor |
|---|
| C32 Malignant Neoplasm of Larynx |
| C32.0 Malignant neoplasm of glottis |
| C32.1 Malignant neoplasm of supraglottis |
| C32.2 Malignant neoplasm of subglottis |
| C32.3 Malignant neoplasm of laryngeal cartilage |
| C32.8 Malignant neoplasm of overlapping sites of larynx |
| C32.9 Malignant neoplasm of larynx, unspecified |
| C76 Malignant Neoplasm of Head, Face, and Neck (other and ill-defined sites) |
| C76.0 Malignant neoplasm of head, face, and neck |

# Pathology: Instructions For specimen preparation and shipment

**Please verify section 4 of the OncoPrism-HNSCC Requisition form entitled Specimen Information**

For questions regarding data entry, specimen preparation and/or shipping, after reading all documents, please contact: Cofactor Genomics Lab - 240-534-1241 - support@cofactorgenomics.com

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## Tumor Specimen Preparation

Please prepare specimens in ONE of the following ways for a **minimum total of 30 microns of tissue** (additional curls/slides can be prepared if needed to encompass 30 microns of tissue):

- **Six (6) charged slides of 5µm thickness**
  **OR**
- **Two (2) charged slides of 5µm thickness and two (2) tissue curls of 10µm thickness**
  **OR**
- **Other acceptable format such as, the entire FFPE block (with at least 30µm of material remaining) or an agreed upon distribution of curls and slides totaling at least 30µm of specimen (must be pre-discussed and accepted by Cofactor Genomics)**

Please ensure the following requirements are also met when choosing tissue specimens:

- Specimens sent for processing must be from patients with a documented clinical diagnosis of recurrent or metastatic HNSCC.

- Specimens from pathology sites bone, decalcified or not, and liver are NOT accepted. All other tissue types are acceptable.

- Specimens must have been collected and prepared within the last 2 years.

- Minimum Tumor Content: Specimens will be evaluated for tumor cellularity. A minimum of 10% tumor cellularity (tumor cell nuclei/non-tumor cell nuclei) is required. If you do

not believe the specimen contains at least 10% tumor cellularity, please provide an alternative specimen if available, or contact support.

- Tumor block from resection/excision specimen is preferred over core biopsy or endoscopic biopsy. Please choose the tumor block with largest tumor focus or highest tumor cellularity.

- Small size tissue samples, core biopsy specimens, hypocellular, fibrotic, fatty samples, or samples with extensive necrosis may require additional unstained slides, permission to exhaust the block or alternate tumor tissue block to obtain sufficient RNA for testing.

- Total tissue volume provided should be no less than 30 microns. Sending more than the minimum required slides will reduce the chances of a Quantity Not Sufficient (QNS) result.

## Tumor Specimen Packaging and Shipment

The OncoPrism-HNSCC kits contain shipping materials and prepaid labels for use. Please follow the guidelines below for tissue shipment packaging:

- Place prepared slides in the provided slide holders and tape shut
- Place 1.5 ml Eppendorf tubes containing unmounted sections in the provided gray tube holder. Each unmounted section must always be placed in its own individual tube. Tube holder can ship a maximum of five 1.5 ml tubes.
- **Three Documents to include in shipment:**
    - **A printed copy of the OncoPrism-HNSCC Requisition form**
    - **A printed copy of the pathology report for the specimen provided**
    - **A completed Specimen Shipment Checklist (included in kit document package)**
- Place all materials, including any unused materials, in the provided packaging and seal.
- Place FedEx shipment label on outer package and ship to Cofactor Genomics via FedEx.

**Cofactor Genomics Support** **240-534-1241** **support@cofactorgenomics.com**

# Specimen Shipment Checklist

**Please check the box for the type(s) of specimens included in the shipment:**

☐ Six (6) charged slides of 5-micron thickness
OR

☐ Two (2) charged slides of 5-micron thickness and two (2) tissue curls of 10-micron thickness
OR

☐ Other, please specify:_____

**Please ensure these documents are included in the shipment:**

- A printed copy of the OncoPrism-HNSCC Requisition form
- A printed copy of the pathology report for the specimen provided
- A completed specimen shipment checklist document

**Please provide the date that this package is completed for shipment below:**

Date _____