OncoPrism-HNSCC Ordering via Web Portal

For direct assistance please contact Cofactor Genomics at:

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

Follow the instructions below:

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. **Login to the portal (https://cofactor.labsvc.net/labgen/)** by entering the provided user name and password.
2. **Select** the **Order Labwork** button and then the **New Patient** button.
   Alternatively, if the patient has been entered already, search by name.
3. **Patient Identification Information**
   Enter information, where applicable, from the patient's medical chart. Required fields include first and last name, date of birth, sex, full address, phone number, race, ethnicity and patient client. Click the **Save** button.
4. **Clinic Information**
   Enter **Pathology Lab** for patient specimen retrieval and provide the appropriate pathology lab information. Type the first few letters and choose the correct lab. If the pathology lab is NOT pre-populated, please enter the pathology lab name, then click the **Path Lab Information** drop down menu and type the full name and all contact information in the Path Lab information sheet. Testing results will be faxed or emailed to pathology via the fax number or secure email you provide in this section.
5. **Billing and Insurance**
   Select the **Billing Detail** button. Check **Same as Patient** box to pre-populate patient demographic information. In the **Type Insurance Name** box, search for the patient's health insurance and choose the appropriate one. Enter specific policy and group information. If applicable, add **Secondary Insurance** by selecting the **Plus (+)** button and repeating the process. Click the **Back** button to return to the main order page (changes are automatically saved).
6. **Add a comment** if necessary by selecting the **Comments** box and entering the information.
7. **Adding the OncoPrism Test**
   Select the **Test List** button. Click the **Plus (+)** button next to ONCOPRISM-HNSCC. **Check** the box to add the test to the order. Click the **dark blue X** at the top right of the window

(circle) to return to the main order page. The test should now be added for this patient request.

8. **Diagnosis Codes**
   Scroll down and click the **Diagnosis List** button. Select the **Plus (+)** button next to HNSCC DIAGNOSIS CODES. **Check** boxes for ALL relevant patient assigned codes. A list of potential ICD-10 codes is included on pages 3-4. Select the **dark blue X** at the top right of the window (circle) to return to the main order page. The diagnosis codes should now be added for this patient request.
   a. If no codes match, check the lower box and notify Cofactor Genomics by email (support@cofactorgenomics.com) for followup before testing can be ordered.
9. **EHR**
   Click the **dark blue paperclip** at the top right of the screen (circle) to attach the patient's EHR face sheet and insurance card(s). Click the **Choose** button and navigate to the appropriate files on your computer to be uploaded. Once all files have been selected, click the **dark blue X** to return to the main order page. Click the **Submit** button.
10. **Input information** for all of the AOE Questions on ONCOPRISM-HNSCC. These answers will be used to contact pathology and retrieve the correct specimen for testing. Click the **Save** button.
    a. 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.
       i. Specimens sent for processing must be from patients with a clinical diagnosis of recurrent or metastatic HNSCC.
       ii. Specimens from pathology site bone (decalcified or not) or liver are NOT accepted. All other sites are acceptable.
       iii. Specimens must have been collected and prepared within the last two years.
    b. For PD-L1 status, please select unknown if the patient has never been tested.
    c. For disease status and previous treatment, check all boxes that apply.
11. **Physician Authorization and Signature**
    Enter your initials and click the **Save** button. Follow your clinic protocol to sign the order (if you are a medical provider) or use the signature on file from the medical provider at your clinic. The ordering physician should describe the testing procedure and resulting process to the patient, answer all questions, and acknowledge appropriateness of testing.
12. **A completed** two-page OncoPrism order form will pop up in a new tab on your browser for your records. Note: You may need to adjust your browser settings if you do not receive an OncoPrism report in a new browser tab. Please look through the form to verify it is complete and correct. If correct, you are done and can view the order under the left Toolbar Menu's **Order Log.**
    a. If changes need to be made, select the **Edit Order** choice from the Main Menu's Order toolbar. Enter the patient name and click the **Search** button. Verify the patient listed needs an order update and **click on the row** with their information. A new set of choices will appear at the bottom right of the order and you will have the ability to edit the information. Edit as needed and click the **Submit** button.

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 the Specimen Information from the OncoPrism-HNSCC Requisition form

For questions regarding specimen preparation and/or shipping, after reading all documents, please contact: Cofactor Genomics Support - 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**:

- **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.

- 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 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. Each 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.

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

☐ FFPE block with at least 30µm of material remaining
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 _____