

**QUESTIONS?**

**Call:** 1-833-5-PROTEO (1-833-577-6836)

**Email:** [clientservices@proteocyte.com](mailto:clientservices@proteocyte.com)

Fax all completed forms and patient chart notes to **1-855-566-0488**

To successfully order a STRATICYTE test for your patient, please ensure that all checklist items for each step have been completed:

<p><b>STEP 1</b> Complete the following documents</p>	<p><b>STEP 2</b> Fax the following completed documents to <b>1-855-566-0488</b></p>
<ul style="list-style-type: none"> <li>○ Consent form signed by patient/caregiver (pg. 3)</li> <li>○ Test Request Form (pg. 2) <ul style="list-style-type: none"> <li>○ <i>Important: payment information</i></li> <li>○ <i>Important: biopsy type and site(s)</i></li> </ul> </li> <li>○ Patient demographics sheet</li> </ul> <p><b>For insurance coverage, the following may be necessary:</b></p> <ul style="list-style-type: none"> <li>○ Documentation of the patient’s diagnosis of OPMD/oral pre-cancer</li> <li>○ Documentation indicating that STRATICYTE is a medically necessary test for the patient</li> <li>○ Other documentation required by specific insurance providers</li> </ul>	<p><b>Forms completed in STEP 1:</b></p> <ul style="list-style-type: none"> <li>○ Patient/caregiver consent form</li> <li>○ Test Request Form</li> <li>○ Patient demographics sheet</li> <li>○ Insurance documents (e.g. copy of insurance card)</li> </ul> <p><b>Clinical documentation from patient chart:</b></p> <ul style="list-style-type: none"> <li>○ Chart notes documenting OPMD</li> <li>○ Diagnosis documentation (ICD-10) code: K13.21, K13.29, K13.79, or other</li> <li>○ Images of lesion(s) (if available)</li> <li>○ Pathology report of biopsy specimen(s)</li> <li>○ History of any other types of cancer(s), risk for cancer, or relevant clinical information</li> <li>○ Documentation indicating that STRATICYTE is a medically necessary test for the patient</li> </ul>

**Support information to provide the patient and/or caregiver:**

- The additional information provided by the STRATICYTE test is an adjunct to routine histopathology (H&E) testing
- The STRATICYTE test supports assessment of the 5-year probability of a precancerous oral lesion/OPMD transforming into oral cancer (*Patient Brochure*)
- Medicare/Private Insurance claims may be processed after the test is completed. If Proteocyte is contacted by the insurer for additional documentation, Proteocyte will provide the documents that were faxed to them by the healthcare provider (See STEP 2)

PATIENT INFORMATION			
<i>COMPLETE the following or attach copy of face sheet/demographic sheet</i>			
Last Name		First Name	
Date of Birth (mm/dd/yyyy)		Sex at Birth <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Decline to Answer	
Address		Middle Initial	
		Last 4 digits of SSN	
		City	
		State	
		Zip Code	
Preferred Phone #		Preferred Email	
Caregiver Name		Relationship to Patient	
Caregiver Phone #		Caregiver Email	

PRIMARY BILLING / PAYMENT INFORMATION	
<i>COMPLETE the following or attach a copy of front and back of insurance cards (if applicable)</i>	
PAYOR TYPE	<input type="checkbox"/> Patient <input type="checkbox"/> Commercial <input type="checkbox"/> Medicare FFS <input type="checkbox"/> Medicare Adv <input type="checkbox"/> Medicaid FFS <input type="checkbox"/> Managed Medicaid
Plan Name	Plan Phone
Plan Type <input type="checkbox"/> HMO <input type="checkbox"/> PPO <input type="checkbox"/> POS <input type="checkbox"/> HDHP <input type="checkbox"/> Other	Plan Fax
Policy Holder Name	Date of Birth (mm/dd/yyyy)
Member ID	Group ID
Dental Insurance Plan	Dental Phone

SECONDARY PATIENT INSURANCE INFORMATION (IF APPLICABLE)	
<i>COMPLETE the following or attach a copy of front and back of insurance cards (if applicable)</i>	
PAYOR TYPE	<input type="checkbox"/> Patient <input type="checkbox"/> Commercial <input type="checkbox"/> Medicare FFS <input type="checkbox"/> Medicare Adv <input type="checkbox"/> Medicaid FFS <input type="checkbox"/> Managed Medicaid
Plan Name	Plan Phone
Plan Type <input type="checkbox"/> HMO <input type="checkbox"/> PPO <input type="checkbox"/> POS <input type="checkbox"/> HDHP <input type="checkbox"/> Other	Plan Fax
Policy Holder Name	Date of Birth (mm/dd/yyyy)
Member ID	Group ID
Coordination of Benefits (if known)	

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CLINICAL INFORMATION		
<b>ICD-10</b> <input type="checkbox"/> K13.21 Leukoplakia of oral mucosa, including tongue <input type="checkbox"/> K13.29 Other disturbances of oral epithelium, including tongue <input type="checkbox"/> K13.79 Other lesions of oral mucosa <input type="checkbox"/> Other: _____	<b>Biopsy Date (mm/dd/yyyy)</b>  	<b>Biopsy Site</b> <input type="checkbox"/> Lip <input type="checkbox"/> Buccal Mucosa <input type="checkbox"/> Floor of Mouth <input type="checkbox"/> Tongue <input type="checkbox"/> Other _____
	<b>Biopsy Type</b> <input type="checkbox"/> Excision <input type="checkbox"/> Incision	
<b>Final Diagnosis of Biopsy</b>		
<b>3-tier</b> <input type="checkbox"/> No dysplasia <input type="checkbox"/> Mild dysplasia <input type="checkbox"/> Moderate dysplasia <input type="checkbox"/> Severe dysplasia	<b>2-tier</b> <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia	<b>Notes &amp; Concerns</b>  
SPECIMEN INFORMATION & RETRIEVAL		
Surgical Specimen/Accession #	<input type="checkbox"/> Corresponding Pathology Report Attached	
ORDERING CLINICIAN		
Site Name	Site Phone	
	Site Fax	
Address	City	
	State	Zip Code
Site Contact Name	Role	
Site Contact Phone	Site Contact Fax	
Site Type <input type="checkbox"/> MDO <input type="checkbox"/> HOPD <input type="checkbox"/> ASC <input type="checkbox"/> Dentist <input type="checkbox"/> Lab <input type="checkbox"/> Other _____	Health System	
Provider Name	NPI	
Provider Specialty	State License #	TIN#
Medicaid Provider ID #	Medicare PTAN	

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**LAB TEST ORDERED: STRATICYTE™**

STRATICYTE – uses a probability algorithm developed from an annotated cohort of reference cases to assess the 5-year probability of an oral potentially malignant lesion transforming to oral squamous cell carcinoma. It provides supplemental information for the corresponding pathology report. This test is not appropriate for lesions diagnosed as carcinoma.

**ORDERING CLINICIAN SIGNATURE**

I hereby authorize testing and confirm that informed consent has been obtained from the patient for relevant information to be sent to Proteocyte AI for testing. I hereby attest as the ordering clinician that I am authorized by law in the relevant jurisdiction to order the test requested herein. By signing this form, I attest that the patient meets the inclusion criteria stated in the test ordered section, and the clinical information described on this form is correct and belongs to the patient named. I have had a discussion prior to testing regarding how the results of the test may be used to guide patient management.

Ordering Clinician Signature	Date (mm/dd/yyyy)
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**PATIENT CONSENT AND/OR AUTHORIZED SIGNATORY**

I understand that my tissue sample provided to the pathologist from my biopsy will be collected, transported, and delivered to Proteocyte AI to assess my probability of an oral potentially malignant lesion transforming to oral squamous cell carcinoma, providing supplemental information for my corresponding pathology report. I have been informed by my treating clinician about the purpose, scope, and limitations of the test ordered. I understand that the results of the test will be sent or made available to my treating clinician, and when the results are ready, I will collect the information from my treating clinician. I am informed of who may have access to my sample and test results, which includes confidential protected health information (PHI). I understand that my PHI will be securely handled by Proteocyte AI for data processing, billing, reimbursement, and administration of services. I hereby give consent to such processing and storage of my PHI, and may revoke this consent at anytime. I have read this form, and I agree to undergo the test. I confirm I have had the opportunity to ask any questions that I might have had regarding this test and process, and have received satisfactory answers from my treating clinician.

Patient Signature	Date (mm/dd/yyyy)
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