OFFICE USE ONLY | Accession #

SALIMARK™ OSCC Salivary Gene Expression Test

PATIENT INFORMATION

NAME: _____
LAST NAME FIRST NAME

DATE OF BIRTH: ____/____/____
MM DD YY

BIOLOGICAL SEX (Please select one): O Female O Male O Other

PHONE NUMBER: _____

SAMPLE INFORMATION

DATE OF COLLECTION: ____/____/____
MM DD YY

MEDICAL RECORD #: _____

SAMPLE TYPE: **Saliva**

TEST CODE: **11271**

INFORMATION FOR FACILITY SENDING SPECIMEN:

ORDERING PHYSICIAN'S NAME: _____

NAME OF FACILITY: _____

CONTACT PERSON: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

PHONE: _____ FAX: _____

INFORMATION FOR LABORATORY PERFORMING TESTING:

NAME OF LABORATORY DIRECTOR: Kip Kuttner, DO

NAME OF LABORATORY: PrimBio Research Institute, LLC

ADDRESS: 665 Stockton Drive, STE 200I

CITY: Exton STATE: PA ZIP CODE: 19341

PHONE: (610) 458-1112 FAX: (610) 458-1114

CLIA #: 39D2085645, CAP #: 9282399

INDICATION FOR TEST

SYMPTOMS (Summarize below):

OTHER (Specify clinical findings below):

CONSENT

For Physician:

❑ By checking this box I am electing the OSCC Salivary Gene Expression Test to be performed on this sample.

Signature: _____ Date: _____

For Patient:

❑ By checking this box I am electing the OSCC Salivary Gene Expression Test to be performed on this sample.
❑ I understand by submitting my saliva sample that after testing it may be de-identified and used by PrimBio Research Institute for further development.
❑ I understand it is my responsibility to pay for the charge ($299) related to OSCC test.

Signature: _____ Date: _____

BILLING INFORMATION

Credit Card Payment

Valid Card # _____

Exp Date (MM/YY): _____ CVC Code: _____

Billing Address: _____

Cardholder Printed Name: _____

Cardholder Signature: _____

Select one: O AMEX O Discover O MasterCard O Visa

I approve a one-time charge of $299 to my credit card prior to the completion of the OSCC testing. _____ (Patient Initial)

PrimBio Research Institute LLC
665 Stockton Dr. STE 200-i
Exton, PA 19341
Phone: 610-458-1112 Fax: 610-458-1114

Background:

The SaliMark™ OSCC biomarkers have been pre-validated in multiple clinical trials involving over 800 subjects and including an independent study by the National Cancer Institute –Early Detection Research Network.[1-3] These markers were subsequently validated in a prospective blinded clinical study (NCT01587573).[4] The test algorithm was derived from this trial.

SaliMark™ OSCC measures the expression of 3 genes (OAZ1, DUSP1 and SAT) associated with oral squamous cell carcinoma (OSCC) relative to 2 salivary internal reference genes (MT-ATP6 and RPL30). The algorithm is applied to these expression levels to generate a sore that relates to the likelihood of the presence of OSCC. The score range is from 0 to 1.00.

References:

1) Brinkman O, et al. Oral Oncol 2011; 41(1): 51-55.
2) Wei F. et al. Clin Cancer Res 2009; 15:4446-4452.
3) Elashoff D. et al. Cancer Epidemiol Biomarkers Prev 2012; 21(4) 664-72.
4) Martin JL. Compend Contin Educ Dent. 2015; 26: 365-373.

Interpretation:

- The test score is in the range of 0 - 1.0.
- The predictive values in any population are dependent on the disease prevalence. Therefore, the result of the test should be used by in conjunction with clinical assessment to aid in individualized patient decision making.

SCORE	RISK LEVEL	INTERPRETATION
≤0.068	Low	The patient should follow up with their dentist or physician to ensure stability.
0.068 - 0.150	Moderate	The patients should be considered for referral to a specialist, with a decision for follow up or biopsy to be based on the quantitative test score along with other clinical features.
≥0.150	High	The patient should be evaluated by a specialist for consideration of tissue biopsy.

Methodology:

Total RNA was isolated from patient's saliva using the MagMax Viral RNA Isolation Kit and cleaned up using the TURBO DNA-free Kit. The expression levels of three target cancer genes (OAZ1, DUSP1 and SAT) and two internal reference genes (MT-ATP6 and RPL30) are analyzed by the two-step real time PCR by subjecting RNA specimen to reverse transcription and pre-amplification using the Fast Virus 1-step Master Mix, followed by amplification using the Fast Advanced Master Mix.

Disclaimer:

This test was performed using Real Time PCR methodology, and is a Laboratory Developed Test (LDT). Its performance determined by PrimBio Research Institute in accordance with CLIA regulations. It has not been cleared or approved by U.S. Food and Drug Administration. Since FDA approval is not required for clinical use of this test, this laboratory has established and validated the test's accuracy and precision, pursuant to the requirement of CLIA '88. This laboratory is licensed and/or accredited under CLIA.

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NEW YORK STATE NON-PERMITTED LABORATORY TEST REQUEST

Under New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Part 58-1.10 (g) of 10NYCRR), laboratories performing testing for any specimens collected in the State of New York must hold a New York State clinical laboratory permit or have test request approval for specific tests.

Because of the rarity of many genetic conditions, testing may not be available through a permit-holding laboratory, or there may be justification for sending to a non-permitted laboratory. New York State approval must be obtained before sending the specimen to a non-permitted laboratory. The ordering provider requesting testing must document that the patient or legal guardian was informed that the laboratory performing the testing does not hold a New York State laboratory permit or that the test is not approved by the Department.

Our laboratory does not yet hold a New York State license. Therefore, you must first submit a completed **Non-Permitted Laboratory Test Request Approval Form** (see the following page) to the New York State Health Department and receive approval for any patient specimen collected in New York that you wish to send to our laboratory for testing. Upon approval, you may send the patient specimen, test requisition form, and a copy of the approval letter for testing to commence.

Notification of approval or rejection will be sent in writing for each request to use a non-permitted laboratory. If rejected, the reason(s) for denial will be explained in the written response. Please contact the Clinical Laboratory Evaluation Program at (518) 485-5378 with any questions.

For Genetic Tests:
Genetic Testing Quality Assurance Program
Wadsworth Center, NYSDOH
Ph: (518) 474-6271
Fax: (518) 486-2693

For All Other Tests:
Clinical Laboratory Evaluation Program
Wadsworth Center, NYSDOH
Ph: (518) 485-5378
Fax: (518) 485-5414