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CUSTOMER INFORMATION (To be completed by the ordering physician)

I. SUBMISSION TYPE

SUBMISSION: FIRST RESUBMISSION – Associated Requisition _____

II. ORDERING PHYSICIAN

ORDERING PHYSICIAN NAME: Last, First _____
 ORDERING PHYSICIAN E-MAIL _____
 INSTITUTION / DEPARTMENT / DISTRIBUTOR _____
 STREET ADDRESS _____
 CITY _____ POSTAL CODE _____ COUNTRY _____
 PHONE / MOBILE _____ FAX _____
 OFFICE CONTACT NAME & E-MAIL _____

III. PATIENT INFORMATION

PATIENT NAME: Last, First _____
 DATE OF BIRTH _____ Female Male
 MEDICAL RECORD NUMBER _____ PATIENT ID _____
 STREET ADDRESS _____
 CITY _____ POSTAL CODE _____ COUNTRY _____
 PRIMARY PHONE _____ ALTERNATE PHONE _____
 DATE OF SURGERY (MM / DD / YYYY) _____

IV. CLINICAL FACTORS

STAGE	<input type="checkbox"/> II	<input type="checkbox"/> III
T	<input type="checkbox"/> T1 <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4	
N	<input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2	

STAGE II HIGH RISK FEATURES	<input type="checkbox"/> Yes <input type="checkbox"/> No
MMR STATUS (If performed)	<input type="checkbox"/> dMMR <input type="checkbox"/> pMMR
MSI STATUS (If performed)	<input type="checkbox"/> MSI-L <input type="checkbox"/> MSI-H <input type="checkbox"/> MSS

Comment

V. SPECIMEN RETRIEVAL FROM PATHOLOGY LAB

SAMPLE PROVIDER NAME (Pathologist)	PHONE / MOBILE
SAMPLE PROVIDER FACILITY NAME	FAX
SAMPLE PROVIDER FACILITY ADDRESS	CITY _____ POSTAL CODE _____ COUNTRY _____

VI. PHYSICIAN SIGNATURE

Your signature constitutes a Certification of Medical Necessity and a certification that the patient has consented for this test to be performed and has been informed that her/his personal data could be transferred to Veracyte, that she/he has a right to access, rectification, erasure and a right to portability, a right of opposition and limitation to the processing of her/his data. For the exercise of her/his rights, any request from the patient can be addressed to privacy@haliodx.com. By signing this Request Form, you attest that the patient meets the criteria to be tested with Immunescore®.

PHYSICIAN SIGNATURE (required) _____ DATE (MM / DD / YYYY) _____
X
 PRINT NAME _____

Any additional documents containing personal data will be destroyed

SAMPLE INFORMATION (To be completed by the pathologist)

VII. PATHOLOGY LABORATORY

SUBMITTING PATHOLOGIST NAME _____

SUBMITTING PATHOLOGIST E-MAIL _____

INSTITUTION / DEPARTMENT _____

PHONE / MOBILE _____

FAX _____

VIII. BLOCK RETURN YES NO

Complete if different from pathology lab
Leave blank if submitting slides

CONTACT NAME _____

INSTITUTION / DEPARTMENT / DISTRIBUTOR _____

STREET ADDRESS _____

CITY _____

POSTAL CODE _____

COUNTRY _____

PHONE / MOBILE _____

FAX _____

The Test Request Form must be filled in and sent back to Veracyte along with samples. Please send either one formalin fixed paraffin embedded (FFPE) tumor block (neutral buffered formalin ONLY) OR six 4µm serial unstained sections per test/specimen mounted on separate slides. For specimen criteria and specimen preparation instructions, see material requirements document attached.

FFPE BLOCK ID

SLIDE 1 ID _____

SLIDE 2 ID _____

SLIDE 3 ID _____

SLIDE 4 ID _____

SLIDE 5 ID _____

SLIDE 6 ID _____

**SPECIMEN
COLLECTION DATE:** _____

All remaining unstained slides will be destroyed after 6 months of storage

The Immunoscore® is a tissue-based immune assay performed on formalin-fixed paraffin-embedded (FFPE) tumor tissue samples of primary colon cancer intended to measure the host immune response at the tumor site. In combination with standard clinicopathologic features, this digital diagnostic test informs adjuvant chemotherapy decision-making for patients with early-stage colon cancer. Immunoscore® values are reported based on pre-defined cut-offs in 5 categorical scores (IS 0 to 4) and in 2 categories of recurrence risk: Immunoscore® Low (IS 0 & 1) and Immunoscore® High (IS 2 to 4), with a higher Immunoscore® associated with a lower risk of recurrence (ref. 1/2/3). In validation studies of stage III colon cancers, only Immunoscore® High patients experienced a significant therapy benefit (ref. 3/4).

The Immunoscore and its performance characteristics were determined by Veracyte. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research. The Veracyte laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

[1] Sinicrope F et al., JNCI Cancer Spectrum 2020

[2] Pagès F et al., Lancet 2018

[3] Pagès F et al., Ann Oncol. 2020

[4] Mlecnick B et al., JCO 2020

Any additional documents containing personal data will be destroyed



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