Patient survival fate is dependent on preexisting immunity

Dr Jérôme Galon, Head of the Integrative Cancer Immunology at the Cordeliers Research Center in Paris, France
WHY IMMUNOSCORE® COLON*

Immunoscore® Colon* is an in vitro diagnostic assay to assess the risk of relapse in colon cancer patients.

By measuring the density of CD3+ and CD8+ T lymphocytes in the center and at the periphery of the tumor, Immunoscore® Colon is a key risk factor to guide treatment strategies for stage II and stage III colon cancer (CC) patients.

Immunoscore® Colon key risk factor

Immunoscore® Colon as key risk factor

The Immunoscore® scoring has been defined in a large international SITC-led retrospective validation study conducted on more than 3800 St I-III CC patients (J Galon et al. J Clin Oncol 2016;34 (Suppl abstr 3500)).

IMMUNOSCORE® COLON SERVICE

Immunoscore® Colon is available as a full service solution (performed in HalioDx laboratories).

ORDERING INFORMATION & CONTACT

Interested in ordering Immunoscore® Colon?
Please contact us at infos@haliodx.com

Interested in including Immunoscore® Colon in your R&D project?
Please fill out our contact form at www.immunoscore-colon.com
CLINICAL UTILITY

Immunoscore® Colon is a test predicting the risk of relapse of patients with localized CC to help guiding treatment strategies. By evaluating the immune reaction at the tumor site, it provides independent and superior prognostic value to usual risk factors. This information supports decision about adjuvant chemotherapy need (stage II) and duration of treatment (stage III).

IMMUNOSCORE® FOR STAGE II CC PATIENTS

In the large Immunoscore® SITC study (more than 3,000 stage I-III patients), Immunoscore® was strongly predictive of the patient outcome and surpassed the TNM classification prognostic performance.

Focusing on stage II (n = 1,433 patients), Immunoscore® identified a subgroup of high-risk stage II patients (25%) who may benefit from chemotherapy.

IMMUNOSCORE® FOR STAGE III CC PATIENTS

Following international IDEA collaboration results, it has been suggested that the duration of adjuvant FOLFOX or CAPOX chemotherapy should be guided by a risk-based approach, based on T and N risk groups (T1-T3 N1 versus T4 or N2).

Immunoscore® has been tested on 600 resected tumors of stage III CC patients from the FOLFOX arm of the prospective NCCTG N0147 clinical trial. This retro-prospective study demonstrated that Immunoscore-Low was associated with a higher risk of recurrence including among the low risk T1-3 N1 subgroup with significantly worse 3-years RFS (78% vs 92%, see figure below). These data underscore the limitations of T and N staging and provide validation for Immunoscore® Colon to identify high risks T1-3 N1 patients for whom a 3 months chemotherapy course might be detrimental.

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### TTR in Stage II patients (n=1433)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Events/Total</th>
<th>5 Year KM Est (95% CI)</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunoscore High</td>
<td>28/364</td>
<td>91.2 (87.9-94.5%)</td>
<td>0.36 (0.23-0.56)</td>
</tr>
<tr>
<td>Immunoscore Intermediate</td>
<td>88/694</td>
<td>85.9 (83.1-88.8%)</td>
<td>0.59 (0.43-0.81)</td>
</tr>
<tr>
<td>Immunoscore Low</td>
<td>83/375</td>
<td>76.8 (72.3-81.5%)</td>
<td>Reference</td>
</tr>
</tbody>
</table>

### DFS in Stage III T1-3N1 Subsets (n=287)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Events/Total</th>
<th>3 Year KM Est (95% CI)</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunoscore High</td>
<td>23/134</td>
<td>91.8 (87.3-96.6%)</td>
<td>0.55 (0.33-0.92)</td>
</tr>
<tr>
<td>Immunoscore Low</td>
<td>43/153</td>
<td>77.5 (71.2-84.9%)</td>
<td>Reference</td>
</tr>
</tbody>
</table>
REFERENCE PUBLICATIONS
IMMUNOSCORE® & IMMUNOSCORE® COLON

Immunoscore® surpasses TNM for prediction of tumor recurrence and survival in CRC patients.
Galon J. et al. ASCO Annual Meeting J Clin Oncol 34:2016 (suppl; abstr 3500)

Stage II CC patients with Immunoscore-Low have a higher risk of recurrence.
Galon J. et al. ASCO Annual Meeting Oral presentation J Clin Oncol 34, 2016 (suppl; abstr 3500)
(manuscript submitted)

Immunoscore® is a stronger predictor of survival than MSI in CC.
Galon J. et al. SITC 2016 Oral presentation of the SITC Immunoscore Study (manuscript submitted)

Stage III CC patients with Immunoscore-High have a lower risk of recurrence regardless of the MSI status.
Sinicrope, F. A et al. ASCO Annual Meeting J. Clin. Oncol. 35, 2017 (suppl; abstr 3579) (manuscript in preparation)

Immunoscore® provides prognostic information in low and high T/N risk subsets of Stage III CC.
Sinicrope, F. A et al. ASCO GI J Clin Oncol 36, 2018 (suppl 4S; abstr 614) (manuscript in preparation)

HalioDx is conducting multiple studies to further support the Immunoscore®-based risk assessment for CC patients management.

Immunoscore® Colon, IS2C402
Dispositif médical de Diagnostic in Vitro pour aider au pronostic des patients atteints de cancer localisé du colon
HalioDx SAS (France)
Lire attentivement les instructions fournies dans le document « Préparation de l'échantillon et Instructions d'envoi » disponible en ligne (http://www.immunoscore-colon.com)

www.immunoscore-colon.com

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