

## Immunoscore® Colon is available as a CE-IVD solution

- Immunoscore® Colon is the first standardized immune-based assay for the classification of cancers
- Immunoscore® has been validated by the Immunoscore® worldwide consortium, led by the SITC (ASCO 2016)
  - Immunoscore® is a superior predictor of survival than microsatellite instability

Marseille, France, January 5, 2017 – HalioDx SAS, an independent immuno-oncology diagnostic company, today announced that its Immunoscore® Colon, a unique diagnostic assay for guiding therapeutic decisions in colon cancer, is available as a CE-IVD solution in Europe.

Immunoscore® Colon CE-IVD test is intended as an aid for clinicians to assess prognosis of primary colon cancer at diagnosis, in combination with the TNM classification and other relevant clinical and biological features. By evaluating the immune contexture of a patient's colon tumor, the test can determine the likelihood that the cancer cells will spread and cause the disease to recur after surgery. In particular, Immunoscore® Colon enables healthcare professionals to identify a subgroup of patients with high risk of relapse who could potentially benefit from more intensive adjuvant treatment.

Immunoscore® evaluates the immune contexture of the tumor by quantifying CD3+ and CD8+ T-cells infiltrates both in the core of the tumor and in its invasive margin (Hermitte F, 2016), which has been shown to have a significant prognostic value in several cancers. Immunoscore® Colon was demonstrated to improve prognostic accuracy independently of clinical variables for all patients with Colon Cancer stages I-III and to have superior prognostic power versus the classical TNM staging system (Galon J, 2006; Mlecnik B, 2011). It was also demonstrated to have a superior predictive value than Microsatellite instability with respect to patients' disease-specific recurrence and survival (Mlecnik B, 2016). These results have been confirmed in the Immunoscore® worldwide consortium multicentric study, including more than 3,800 stage I-III colon cancer patients, led by the Society for Immunotherapy of Cancer (SITC) (Galon J, 2016 (A); Galon J, 2016 (B)).

In 2016, HalioDx initiated retro-prospective clinical studies on several hundreds of patients' samples from randomized clinical trials. The results expected in 2017 and 2018 will increase the Immunoscore® Colon level of evidence, support its integration in routine practice and its expanded access thanks to a dedicated reimbursement.

Immunoscore® Colon is available since July 2016 through HalioDx service laboratory. More than 850 tests have already been performed by HalioDx. Immunoscore® Colon CE-IVD test is now available as a full service or through the Immunoscore® Colon CE-IVD kit. The image analysis, critical to the robustness of the results is in all cases provided by HalioDx.

Vincent FERT, CEO of HalioDx comments *"The commercial availability of Immunoscore® for guiding treatment options in colon cancer is indeed an important critical milestone for HalioDx. It is also a landmark event in the era of immuno-oncology, for patients, caregivers and industry as Immunoscore® is the first test enabling a robust and precise assessment of the patient's immune response to cancer. We envision that Immunoscore® is going to be a standard in cancer diagnostic and will expand its utility to many other cancers"*.

He added: “We are in line with our timelines for launching our first CE-IVD test and are pursuing our efforts to develop and make available other breakthrough immune diagnostic solutions for unmet medical needs.”

### About Immunoscore® Colon

The Immunoscore® Colon assay consists of two subsystems:

1. An IHC kit which contains ready-to-use anti-CD3 and CD8 antibodies and controls for performing IHC staining on FFPE tissue sections from primary tumor samples.
2. The Immunoscore® Analyzer which is a dedicated software for automated tissue segmentation and positive cells quantification; based on calculated densities of CD3 and CD8 lymphocytes in the core of the tumor and the invasive margin regions, it reports the Immunoscore®.

The Immunoscore® scoring has been defined in an international retrospective validation study conducted on more than 3,800 colon cancer patients. The Immunoscore® is reported in five scoring values (IS 0 to IS 4) corresponding to 3 risk categories:

- Immunoscore®-Low (low infiltration of the tumor, IS 0-1) indicating a bad prognosis
- Immunoscore®-Intermediate (intermediate infiltration, IS 2) indicating an intermediate risk of relapse
- Immunoscore®-High (for highly infiltrated tumors, IS 3-4) indicating a good prognosis

The Immunoscore® Colon Kit is intended for *in vitro* diagnostic use in Europe (CE-IVD) while a Research Use Only (RUO) solution is available in the Rest of the World.

For more information, please visit: [www.immunoscore-colon.com](http://www.immunoscore-colon.com)

### About HalioDx

#### The Immune Response to Cancer Diagnostics

By precisely measuring the immune reaction in and around the tumor, HalioDx tests allow the clinician to determine the degree of severity of the patient’s disease and predict the response to treatment, regardless of the cancer stage or the molecular class.

HalioDx designs and develops a unique range of immune scoring tests, whose first-in-class product is Immunoscore®. Considered a future diagnostic standard in oncology, this biomarker has already demonstrated strong prognostic value in colon cancer.

HalioDx was founded in 2014 by the former management team of Ipsogen (leader in the molecular diagnosis of leukemia), and a pioneer in integrative immunology and oncology, Dr. Jérôme Galon. HalioDx benefits of worldwide licenses on a broad portfolio of IP rights on immuno-oncology biomarkers (including the Immunoscore® and Immunosign™ technologies) developed by Dr. Jérôme Galon, Research Director at Inserm, and his team (Inserm UMRS1138) at Cordeliers Research Center, Paris, France.

HalioDx has an experienced team of more than 100 employees and compliant facilities to develop, manufacture, deliver and market *in vitro* diagnostic products and services in immuno-oncology. Based, in Marseille, France, HalioDx® is co-founder of the European immunology cluster Marseille Immunopole (MI).

More information: [www.haliidx.com](http://www.haliidx.com)

### Publications

Galon J et al. Type, density, and location of immune cells within human colorectal tumors predict clinical outcome. *Science*. 2006; 29:313

Galon J et al. (A) Validation of the Immunoscore (IM) as a prognostic marker in stage I/II/III colon cancer: Results of a worldwide consortium-based analysis of 1,336 patients. *J Clin Oncol* 2016; 34 Suppl abstr 3500.

Galon J (B) Immunoscore as a prognostic marker in stage I-III colon cancer: Results of a SITC-led global validation study. Abst # 465. SITC 2016

Hermitte F. Biomarkers immune monitoring technology primer: Immunoscore® Colon. *Journal for ImmunoTherapy of Cancer*. 2016 ; 4:57

Mlecnik B et al. Histopathologic-based prognostic factors of colorectal cancers are associated with the state of the local immune reaction. *J Clin Oncol*. 2011; 29:6

Mlecnik B et al. The tumor microenvironment and Immunoscore are critical determinants of dissemination to distant metastasis. *Immunity*. 2016; 44:3

### Contacts

#### **HalioDx SAS**

#### **Vincent Fert**

President and CEO

+ 33 (0)4 91 29 30 90

[vincent.fert@haliodx.com](mailto:vincent.fert@haliodx.com)

#### **ATCG Press**

Marie Puvieux (France)

Mob: +33 (0)6 10 54 36 72

Jean-Mehdi Grangeon (ROW)

Mob: +33 (0)6 62 22 00 24

[haliodx@atcg-partners.com](mailto:haliodx@atcg-partners.com)

[Twitter: twitter.com/haliodx](https://twitter.com/haliodx)