

Immunoscore® Colon test available

- Immunoscore® has confirmed its potential to become a major component of the colon cancer classification at ASCO 2016.
- Immunoscore® Colon is available as a laboratory service in July 2016 and on track to be commercialized as a CE-IVD solution by end of the year.

Marseille, Paris, France, July 7, 2016 – HaliDx SAS, an immuno-oncology diagnostic company, the French National Institute of Health and Medical Research (Inserm) and Inserm Transfert, its subsidiary, today announced the commercialization of Immunoscore® Colon, a unique diagnostic assay for guiding therapeutic decisions in colon cancer.

Based on Immunoscore® an Inserm technology protected and licensed by Inserm Transfert, HaliDx development team worked on the reagents components of the assay, to guarantee a robust and reliable staining, but also on the image analysis software to render Immunoscore® a straightforward, standardized and quantitative assay.

The very first test, Immunoscore® Colon, will be available in July 2016 through HaliDx service laboratory*. By the end of the year, pathologists will have access to a CE-IVD assay in Europe, while a RUO (Research Use Only) solution will also be available in the rest of the World.

The CE-IVD test will be intended as an aid for clinicians to assess prognosis of colon cancer at diagnosis, in combination with the TNM classification and other relevant clinical and biological patient and tumor features. Immunoscore® Colon has demonstrated its robustness and accuracy in several retrospective studies, including in the recent Immunoscore® Validation Project led by the Society for Immunotherapy of Cancer (SITC) involving 23 pathology centers from 17 countries, where more than 3,800 patient samples were evaluated. Positive results were presented at ASCO 2016 by Dr Jérôme GALON, Research Director at Inserm, Head of the laboratory of Integrative Cancer Immunology, Paris, France and principal investigator of the study. ([Press Release & video presentation](#))

Vincent FERT, CEO of HaliDx comments *“This an important milestone achieved by our teams, demonstrating that the quantitative analysis of immune cells can be performed in a routine setting and the information delivered can be integrated in the routine practice of pathologists and oncologists. Associating the simplicity of immunohistochemistry methodology with advanced image analysis is a powerful concept for providing standardized, objective and quantitative information in the immuno-oncology diagnostics. We are in line with our plan for the commercial launch of Immunoscore® Colon with a first version available in July, as a service performed in our laboratory* and with a CE-IVD solution, available by the end of the year.”*

“Inserm Transfert rapidly realized that the technology Immunoscore® developed by Dr. J. GALON and his team had an outstanding potential in helping physicians to stratify cancer patients and support anti-cancer therapeutic approaches. We were very pleased to sign a licensing agreement with HaliDx on this unique technology in late 2014. 18 month later, we are delighted to see Immunoscore® will be available for the oncologists community by the end of the year.” added Pascale AUGÉ, CEO of Inserm Transfert.

About Immunoscore® Colon

Immunoscore® Colon measures the density of two T lymphocyte populations in the center and at the periphery of the tumor: CD8+ and CD3+ T cells. The technology used is immuno-histochemistry coupled to advanced image analysis for a standardized tissue segmentation and immune cells quantification. Cell densities are then computed to calculate the sample's Immunoscore®.

Dr. Jérôme GALON, Research Director at Inserm and Head of the Laboratory of Integrative Cancer Immunology, developed the concept of immune contexture consisting on analyzing the immune variables associating the type, density, location and functional orientation of immune cells within and around the tumor from which Immunoscore® was derived. The assay was developed to predict the ability of a person's immune system to fight tumor cells and its performance has been documented in a number of studies for its ability to predict recurrence in colon cancer. Additionally, a prospective trial headed by Franck Pagès at the European George Pompidou Hospital (HEGP, Paris, France) is ongoing.

Immunoscore® Colon is one of the first diagnostic test that will be used in routine by pathology labs leveraging advanced image analysis. The accuracy and robustness of the test relies on precise counting of positive immune cells in predefined regions and automatic calculation of Immunoscore® for each sample based on specific algorithm.

The Immunoscore® Colon assay is available as a laboratory service* in July 2016.

For more information, please visit: www.halioldx.com or www.immunoscore-colon.com

* This test is intended for Research Use Only. Not for use in diagnostic procedures.

About HalioDx SAS

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 colorectal 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® technology) 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 87 employees and compliant facilities to develop, manufacture, deliver and market in vitro diagnostic products and services in immuno-oncology.

For more information, please visit: www.halioldx.com

HalioDx and Immunoscore are registered trademarks.

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About Inserm

Inserm is the French National Institute of Health and Medical Research. Ranked as the number one academic research institution for biomedical research in the European Union, Inserm operates under the dual auspices of the Ministry of Health and the Ministry of Research. It was created in 1964 as a successor to the French National Institute of Health.

About Inserm Transfert

Founded in 2000, Inserm Transfert SA is the private subsidiary of the French National Institute of Health and Medical Research (Inserm), dedicated to technology transfer (from scouting of invention disclosure to industrial partnership). Inserm Transfert also manages European and International research projects, and assists large-scale projects in epidemiology, cohorts, and public health. Inserm Transfert runs an internal proof of concept fund. The company also supports entrepreneurs in the biotech sector. www.inserm-transfert.fr

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