

Immune response is now part of the Essential and Desirable Diagnostic Criteria for Colorectal Cancers in the 5th edition of the WHO Classification of Tumours

Marseille, France, March 5, 2020, 1:45 PM CET - The World Health Organization (WHO), in its latest edition of the [Digestive System Tumours \(5th edition\)](#), introduced immune response as an essential and desirable diagnostic criteria for colorectal cancer, in addition to traditional histological parameters.

Commercialised by HalioDx in more than 20 countries for patients with localized colon cancer, Immunoscore® is an *in vitro* diagnostic test quantifying the immune response for predicting cancer recurrence and personalizing patterns of care¹. The standardized method used in the SITC validation effort (i.e. Immunoscore®) is referenced in the WHO Classification of Tumours, 5th edition, as the most recent evidence of the immune response prognostic power in colon cancer ([Pagès et al. Lancet 2018](#)). Immune response assessment is now an essential complement to the traditional TNM² staging system in colon cancer, Immunoscore® being the reference assay for its evaluation.

Dr Jérôme Galon, the inventor of Immunoscore® says: *“The introduction of the Immune response assessment for colon cancer patients in the WHO classification rewards 15 years of translational research efforts on Immunoscore® with a significant impact on standard of care. This effort is a collective success including numerous French and international collaborators. We are now investing significant efforts in demonstrating Immunoscore® clinical utility, beyond colon cancer, in a broad range of indications”.*

Vincent FERT, CEO of HalioDx, comments: *“The recognition by the WHO panel of the importance of the immune response assessment in colorectal cancer is a key landmark for Immunoscore® and HalioDx. It supports our efforts to make this outstanding technology available to improve cancer care worldwide.”*

The work on Immunoscore was initiated at the French National Institute of Health and Medical Research (INSERM) ([Galon et al Science 2006](#)), and it's international validation supported by the Society for ImmunoTherapy of Cancer (SITC) ([Pagès et al. Lancet 2018](#)).

¹ Disclaimer: The World Health Organization is not endorsing the Immunoscore® commercial assay.

² T describes the size of the tumor and any spread of cancer into nearby tissue; N describes spread of cancer to nearby lymph nodes; and M describes metastasis (spread of cancer to other parts of the body).

About Immunoscore®

Immunity Assessed, Personalized Treatment

Evaluated as an essential and desirable diagnostic criteria by the WHO, immune response assessment is becoming now the necessary complement to the traditional cancer staging system and Immunoscore® is the diagnostic standard to perform this evaluation.

Today, Immunoscore® includes a unique family of immune-based assays, ranging from diagnostic tests such as Immunoscore® Colon (CE-marked In Vitro Diagnostic and CLIA compliant) and Immunoscore® family assays for clinical research. At the forefront of Multiplex Spatial Tissue Analysis, these assays combine proprietary multiplexed immunohistochemistry, advanced image analysis and computerized algorithms.

By precisely quantifying immune cell infiltration in and around the tumor, Immunoscore® has already proven its superior prognostic value than the usual tumor risk parameters, notably in localized colon cancer. Today, Immunoscore® is investigated in a broad number of clinical studies and cancer indications for establishing its performances as a prognostic factor as well as a predictive factor for response to drugs, notably chemotherapies and immunotherapies.

Immunoscore® is commercially available in more than 20 countries.

About HalioDx

The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists and Biopharma with first-in-class immune-based diagnostic products and services to guide cancer care and contribute to precision medicine in the era of immunotherapy and combination therapies.

Thanks to the pioneering work of Dr Jérôme Galon, HalioDx provides a unique range of immune scoring solutions – notably with the flagship Immunoscore® assay - allowing the assessment of the immune contexture of tumor, a key determinant of patients' outcomes and response to cancer treatments (from preclinical stage to approved therapies).

To address the needs of Biopharmas, HalioDx has developed the Immunogram, a platform integrating Immunoscore® assays, innovative technologies such as Multiplex Spatial Tissue Analysis (Brightplex®) and molecular testing (NGS, Immunosign® Gene Expression Signatures).

HalioDx has an experienced team of more than 170 employees, CLIA-certified laboratories and compliant facilities in Europe and in the US to develop, manufacture, register and market *in vitro* diagnostic (IVD) products. The company co-founded the European immunology cluster Marseille Immunopôle (MI).

For more information, please visit our websites www.halioldx.com and www.immunoscore-colon.com and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx) and LinkedIn <https://www.linkedin.com/company/halioldx/>.

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