

HalioDx receives CLIA Compliance for Immunoscore® Colon

- HalioDx received CMS¹ CLIA Compliance for its laboratory based in Marseille
- Immunoscore® Colon, is now available to US patients in selected states with a turnaround time of 10 days

Marseille, June 21, 2017 - HalioDx announced today that the company is compliant under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for its Marseille-based full service Reference Laboratory. This compliance allows the company to receive US patient samples for Immunoscore® Colon testing.

As a CLIA compliant laboratory, the Immunoscore® Colon assay is performed on FFPE samples with a turnaround time of 10 days and is offered to oncologists and pathologists taking care of colon cancer patients in selected states in America ([see Immunoscore® website](#)). Immunoscore® Colon is available also as RUO and CE-IVD test in other countries.

Vincent FERT, CEO of HalioDx comments *“The availability of Immunoscore® Colon under CLIA compliance is indeed an important step for serving US patients and oncologists. We envision that Immunoscore® will set a new prognostic standard in guiding the treatment of colon cancer as the test value is now supported by strong clinical data presented at ASCO 2017. HalioDx plans to further reinforce clinical utility of Immunoscore® in colon cancer and also to expand to other types of cancer”.*

About Immunoscore®

Immunoscore® is an immunohistochemistry (IHC) assay enhanced by image analysis intended to quantify the immune infiltration in patient’s tumors that guides treatment at the time of diagnosis. The Immunoscore® assay for colon cancer (Immunoscore® Colon) is standardized and has been extensively validated in a number of clinical studies worldwide. 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 the United-States, samples can be tested in our full service CLIA Reference Laboratory.

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

About HalioDx

The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists with first-in-class Immune-based diagnostic products and services to guide therapeutic decision for existing agents or new immuno-therapeutics. HalioDx Immunoscore® technology integrates immunohistochemistry (IHC) combined with advanced imaging analysis solution enabling extraction of spatially-organized tissue information with strong clinical relevance in

¹ Centers for Medicare & Medicaid Services.

colon cancer but also in other cancer types. In addition to Immunoscore[®], HalioDx has a pipeline of unique and proprietary assays such as Halioseek[™] PD-L1/CD8 (IHC assays) and Immunosign[®] (molecular assay) dedicated to guide immuno-oncology drug development and stratify responder patients as Companion Diagnostics.

HalioDx has an experienced team of more than 110 employees, a CLIA compliant laboratory and cGMP facilities to develop, manufacture, register and market in vitro diagnostic (IVD) products in Europe, Asia and USA. The company co-founded the European immunology cluster Marseille Immunopole (MI).

For more information, please visit our website www.halioldx.com and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx).

Contacts

HalioDx SAS

Vincent Fert

President and CEO

+ 33 (0)4 91 29 30 90

vincent.fert@halioldx.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

halioldx@atcg-partners.com