CDx Announcement

FoundationOne®CDx is now FDA-approved as a companion diagnostic (CDx) for a new indication of **KEYTRUDA®** (pembrolizumab)

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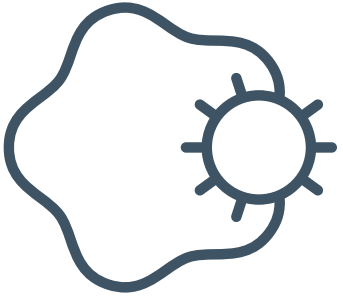

Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) received label expansion approval for adult and pediatric patients with unresectable or metastatic **solid tumors with TMB-H** (≥10 mutations/megabase) that have progressed following prior treatment and who have **no satisfactory alternative treatment options.**[1]

This **pan-tumor approval** is especially critical for those patients with common tumor types that may be **PD-L1 negative or microsatellite stable (MSS)** OR patients with certain rare tumor types that have **limited therapy options** and were not part of the previous FDA-approved indications:

- Anal cancer
- Mesothelioma cancer
- Neuroendocrine cancer
- Salivary cancer
- Thyroid cancer
- Vulvar cancer

FoundationOne®CDx has been **FDA-approved as a companion diagnostic test** for KEYTRUDA® (pembrolizumab)

Including TMB in your biomarker testing could identify more patients who may now benefit from pembrolizumab. FoundationOne®CDx is a comprehensive genomic profiling test that analyzes 324 genes and reports TMB and MSI, with the option to add PD-L1, for all of your advanced-stage patients.

FOUNDATIONONE®CDx

Order FoundationOne®CDx

Web: **foundationmedicine.com**
Email: **client.services@foundationmedicine.com**
Call: **888.988.3639**

1. FDA approves pembrolizumab for adults and children with TMB-H solid tumors. https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-adults-and-children-tmb-h-solid-tumors. Accessed June 17, 2020.

FoundationOne®CDx is a next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit *www.F1CDxLabel.com*

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