



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

Foundation Medicine Inc.
7010 Kit Creek Road, Morrisville, NC 27560

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO 15189:2022

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017)

***Molecular Genetic Testing
Pathology/Histopathology
(As detailed in the supplement)***

Accreditation claims for such testing services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen
President

Initial Accreditation Date:

February 27, 2019

Issue Date:

June 13, 2023

Expiration Date:

September 30, 2025

Revision Date:

August 02, 2024

Accreditation No.:

103138

Certificate No.:

L23-457-2-R1

Perry Johnson Laboratory
Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlab.com



Certificate of Accreditation: Supplement

Foundation Medicine, Inc.

7010 Kit Creek Road, Morrisville, NC 27560

Contact Name: Aryana Treweek Phone: 267-337-4665

Accreditation is granted to the facility to perform the following testing:

FLEX CODE	FIELD	PROCESS OF EXAMINATION	TEST SAMPLE	PROPERTY	PARAMETER / RANGE	MEASUREMENT TECHNIQUES/ INSTRUMENT
F5	Pathology/ Histopathology ^F	Immunohistochemistry (IHC)	IHC, H&E – FFPE	IHC – PD-L1 scoring (22C3, 28-8, SP142, and SP263)	0 to 100 % Tumor Proportion Score or 0 to 100 Combined Positive Score	IHC-Dako Autostainer Link 48 IHC – Ventana Benchmark ULTRA
F5	Molecular Genetics Testing ^F	Next Generation Sequencing (NGS)	FFPE/Blood/ Frozen Tissue/ Bone Marrow Aspirate	Variant Detected	VAF 0-100%	Illumina Platform

- The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.
- Due to a shared quality management system, this location is linked to 150 Second Street, Cambridge, MA 02141
- Flex Code:
 F1-Introduction of the testing of a new item, material, matrix, or product for an accredited test method
 F2-Introduction of a new version of an accredited standard method (with no modifications)
 F3-Introduction of a new parameter/component/analyte to an accredited test method
 F4-Introduction of a new version or modifications of an accredited non-standard method
 F5-Introduction of a new method that is equivalent to an accredited method (using same technology or technique)