



Accredited Laboratory

A2LA has accredited

GENOMIC HEALTH, INC.

Redwood City, CA

for technical competence in the field of

Clinical

This laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012 *Medical laboratories - Requirements for quality and competence*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint IAF-ILAC-ISO Communiqué dated November 2021).



Presented this 25th day of March 2022.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3922.01
Valid to March 31, 2024
Revised April 14, 2022

For the tests to which this accreditation applies, please refer to the laboratory's Clinical Scope of Accreditation.



SCOPE OF ACCREDITATION TO ISO 15189:2012

GENOMIC HEALTH, INC.
301 Penobscot Drive
Redwood City, CA 94063
Dr. Patrick Joseph Phone: 650-569-5684

CLINICAL

Valid To: March 31, 2024

Certificate Number: 3922.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of testing on human samples, including: **formalin fixed paraffin embedded (FFPE) samples.**

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Molecular Pathology			
		Oncotype DX [®] Breast Recurrence Score	RT-PCR	FFPE samples
		Oncotype DX [®] Colon Recurrence Score	RT-PCR	FFPE samples
		Oncotype DX [®] Genomic Prostate Score	RT-PCR	FFPE samples
		Oncotype DX [®] Breast DCIS Score	RT-PCR	FFPE samples



*Joint IAF-ILAC-ISO Communiqué
on the
Management system requirements of ISO 15189 - Medical laboratories -
Particular requirements for quality and competence*

A medical laboratory's fulfilment of the requirements of ISO 15189 means the laboratory meets both the technical competence requirements and the **management system requirements** necessary for it to consistently deliver technically valid test results. The **management system requirements** in ISO 15189 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001.

A handwritten signature in black ink, appearing to read 'E. Riva'.

**IAF Chair
Emanuele Riva**

A handwritten signature in blue ink, appearing to read 'Etty Feller'.

**ILAC Chair
Etty Feller**

A handwritten signature in blue ink, appearing to read 'J. F. ...'.

ISO Secretary General