



## 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 25<sup>th</sup> 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
<b>Pathology</b>				
	<b>Molecular Pathology</b>			
		Oncotype DX <sup>®</sup> Breast Recurrence Score	RT-PCR	FFPE samples
		Oncotype DX <sup>®</sup> Colon Recurrence Score	RT-PCR	FFPE samples
		Oncotype DX <sup>®</sup> Genomic Prostate Score	RT-PCR	FFPE samples
		Oncotype DX <sup>®</sup> 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**



March 22, 2024

Genomic Health, Inc.  
301 Penabscot Drive  
Clinical Laboratory QA Department  
Redwood City, CA 94063

To Whom it May Concern,

This letter serves as confirmation that Genomic Health, Inc. has been continuously working on their renewal of accreditation. The renewal assessment occurred on March 19<sup>th</sup> and 20<sup>th</sup>, 2024. The laboratory did not receive any deficiencies during their assessment of ISO 15189:2022.

The assessment package will be sent to an impartial committee for review, and the assessment will be finalized. Please note that this Accreditation Council has 15 days to vote upon the package.

If there are any questions, please contact me directly.

Sincerely,

*Anastasia M. Miller*

Anastasia Miller  
Accreditation Officer II  
301-644-1931

Master Code: 138418  
Certificates: 3922.01