

# ISO 15189:2012 Internationally-Recognized Accredited Laboratory

A2LA has accredited

## GENOMIC HEALTH, INC.

Redwood City, CA

for technical competence in the field of

### Clinical Testing

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 ISO-ILAC-IAF Communiqué dated January 2015).

Presented this 22<sup>nd</sup> day of March 2016.

t- (. Buil



Senior Director of Quality and Communications For the Accreditation Council Certificate Number 3922.01 Valid to March 31, 2018

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 Ph.: 650-569-5684

#### **CLINICAL**

Valid To: March 31, 2018 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				
		Onco <i>type</i> DX ® Breast Recurrence Score	RT-PCR	FFPE samples	
		Onco <i>type</i> DX ® Colon Recurrence Score	RT-PCR	FFPE samples	
		Onco <i>type</i> DX ® Genomic Prostate Score	RT-PCR	FFPE samples	
		Onco <i>type</i> DX ® Breast DCIS Score	RT-PCR	FFPE samples	
Histopatholo	gy				
	Anatomic Patho	Anatomic Pathology			
		Mismatch Repair (MMR) MLH1 and MSH2	IHC	FFPE samples	



# ISO 15189:2012 Internationally-Recognized Accredited Laboratory

A2LA has accredited

## GENOMIC HEALTH, INC.

Redwood City, CA

for technical competence in the field of

### Clinical Testing

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 ISO-ILAC-IAF Communiqué dated January 2015*).

Presented this 22nd day of March 2016.



President and CEO
For the Accreditation Council
Certificate Number 3922.01
Valid to March 31, 2018

Revised: January 27, 2017



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

Raising the Bar in Laboratory Quality