



SCOPE OF ACCREDITATION TO ISO 15189:2012

MYRIAD GENETIC LABORATORIES  
 320 Wakara Way  
 Salt Lake City, UT 84108  
 Dr. Benjamin B. Roa Phone: 801-584-3049

CLINICAL

Valid To: March 31, 2025

Certificate Number: 5165.01

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 **Saliva (S), Whole Blood (WB), Formalin Fixed Paraffin Embedded (FFPE) Samples, and Extracted RNA:**

<u>Specialty</u>	<u>Sub Specialty</u>	<u>Test/Analyte</u>	<u>Method</u>	<u>Matrix(ces)</u>
<b>Pathology</b>				
	<b>Molecular Pathology</b>			
		BRACAnalysis® 診断システム HBOC Syndrome Mutation Detection Targeting <i>BRCA1/BRCA2</i> , Approved by Japan's MHLW for CDx Use	Sanger Sequencing, PCR	WB
		BRACAnalysis CDx™ Genetic Mutation Detection Targeting <i>BRCA1/BRCA2</i> , FDA-Approved for Companion Diagnostic Use	Sanger Sequencing, PCR	WB
		BRACAnalysis® Hereditary Breast and Ovarian Mutation Detection Targeting <i>BRCA1/BRCA2</i>	Next Generation Sequencing	WB, S
		Colaris® Hereditary Mutation Detection Targeting <i>MLH1, MSH2, MSH6, PMS2</i>	Next Generation Sequencing	WB, S
		Colaris AP® Hereditary Mutation Detection Targeting <i>APC, MYH</i>	Next Generation Sequencing	WB, S
		EndoPredict® Breast Cancer Recurrence Score	Quantitative Reverse Transcription-PCR	FFPE Sample, Extracted RNA
		Melaris® Hereditary Mutation Detection Targeting <i>CDKN2A, INK4A</i>	Next Generation Sequencing	WB, S
		Panexia™ Hereditary Mutation Detection Targeting <i>PALB2, BRCA2</i>	Next Generation Sequencing	WB, S
		Prolaris® Prostate Cancer Prognosis Score	Quantitative Reverse Transcription-PCR	FFPE Sample, Extracted RNA
		myRisk™ Hereditary Cancer	Next Generation Sequencing	WB, S
		myPath® Melanoma Diagnostic Score	Quantitative Reverse Transcription-PCR	FFPE Sample, Extracted RNA

<u>Specialty</u>	<u>Sub Specialty</u>	<u>Test/Analyte</u>	<u>Method</u>	<u>Matrix(ces)</u>
<b>Pathology</b>				
	<b>Molecular Pathology (cont.)</b>			
		myChoice® Homologous Recombination Deficiency (HRD) and Mutation Detection Test Offerings include: <ul style="list-style-type: none"> <li>• myChoice® CDx – GIS + B1/B2, FDA Approved for CDx use</li> <li>• myChoice® 診断システム – GIS + B1/B2, Approved by Japan’s MHLW for CDx Use</li> <li>• myChoice® CDx PLUS – GIS + B1/B2 <i>or</i> GIS + 15 Gene Panel, CE Marked for CDx Use</li> <li>• myChoice® HRD – GIS + B1/B2 (<i>no CDx claims</i>)</li> </ul>	Next Generation Sequencing	FFPE Sample, Extracted DNA

<sup>1</sup>This accreditation covers testing performed at the main laboratory listed above, and the following satellite laboratory listed below:

MYRIAD GENETIC LABORATORIES, INC.  
 322 North 2200 West  
 Salt Lake City, UT 84108

<u>Specialty</u>	<u>Sub Specialty</u>	<u>Test/Analyte</u>	<u>Method</u>	<u>Matrix(ces)</u>
<b>Pathology</b>				
	<b>Molecular Pathology</b>			
		EndoPredict® Breast Cancer Recurrence Score	Quantitative Reverse Transcription-PCR	FFPE Sample, Extracted RNA





## Accredited Laboratory

A2LA has accredited

# MYRIAD GENETIC LABORATORIES

*Salt Lake City, UT*

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 IAF-ILAC-ISO Communiqué dated November 2021).



Presented this 2<sup>nd</sup> day of March 2023.

A blue ink signature of Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 5165.01  
Valid to March 31, 2025

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