



SCOPE OF ACCREDITATION TO ISO 15189:2012

CLINICAL REFERENCE LABORATORY, INC.
MDxE LABORATORY
8433 Quivira Rd.
Lenexa, KS 66215-2802
Dr. Heather L. Fehling, Ph.D. 913-696-5408

CLINICAL

Valid To: September 30, 2019

Certificate Number: 4065.02

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: **plasma(P), serum(S), Sterile Swabs(SS), urine(U), whole blood (WB), and other bodily fluids/tissues.**

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Chemistry				
	Special Chemistry			
		Bone Specific Alk Phos	ELISA	S
		FGMP	ELISA	U
		CKMB	ELISA	S
		Clara Cell (Cytokeratin 19)	ELISA	S
		Copeptin	Kryptor Trace	P
		FGF19	ELISA	S
		Galectin 3	ELISA	S
		HSV antibody	ELISA	S
		IFN gamma	Luminex Immunofluorescence	S
		IGF-1/ Somatomedin C	ELISA	S
		IL 13 (Luminex)	Luminex Immunofluorescence	S
		IL 1b (Luminex)	Luminex Immunofluorescence	S
		IL 2 (Luminex)	Luminex Immunofluorescence	S
		IL10 (Luminex)	Luminex Immunofluorescence	S
		IL12 (Luminex)	Luminex Immunofluorescence	S
		IL4	ELISA	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
		IL5 (Luminex)	Luminex Immunofluorescence	S
		IL6	ELISA	S
		IL6 (Luminex)	Luminex Immunofluorescence	S
		IL8	ELISA	S
		IL8 (Luminex)	Luminex Immunofluorescence	S
		Iso Insulin	ELISA	P
		Leptin	ELISA	S
		MMP2(Total)	ELISA	S
		Multimeric Adiponectin	ELISA	S
		NGAL Lipcalin-2	ELISA	S
		PAI-1 Ag	ELISA	P
		Pentraxin III	ELISA	P
		PIIINP	RIA	S
		PINP	RIA	S
		Renin III (CisBio)	RIA	P
		Rubeola antibody	ELISA	S
		ST II	ELISA	S
		Surfactant Protein D	ELISA	S
		TIMP-2	ELISA	S
		TNF alpha	ELISA	S, P
		TNF alpha (Luminex)	Luminex Immunofluorescence	S
		Varicella-zoster antibody	ELISA	S
Pathology				
	Molecular Pathology			
		SureGene Pharmacogenomic Single Nucleotide Polymorphisms (substitutions of one nucleotide base for another occurring in > 1% of the general population.)	Nucleic Acid Amplification (PCR Testing) and Allelic Discrimination	SS, WB



Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Pathology				
	Molecular Pathology			
		ApoE Pharma-cogenomic Single Nucleotide Polymorphisms (substitutions of one nucleotide base for another occurring in > 1% of the general population.)	Nucleic Acid Amplification (PCR Testing) and Allelic Discrimination	SS, WB
		SureGene (rs25531 & rs63749047) Pharma-cogenomic Single Nucleotide Polymorphisms	Nucleic Acid Amplification (PCR Testing) and Gel Electrophoresis	SS
		Gene CYP2D6 Gene Copy Number Assay (The copies of the Cytochrome p450 gene responsible for the CYP2D6 enzyme subst)	Nucleic Acid Amplification (PCR Testing)	SS
		Nucleic acid amplification		SS, Tissue, WB
		PCR Testing		DNA/RNA

Withdrawn





ISO 15189:2012
Internationally-Recognized
Accredited Laboratory

A2LA has accredited

**CLINICAL REFERENCE
LABORATORY, INC.**

MDxL LABORATORY

Leavenworth, KS

Withdrawn

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 21st day of September 2017.

A handwritten signature in blue ink, likely of the President and CEO, is shown above a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 4065.02
Valid to September 30, 2019



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

