



***ISO 15189:2012
Internationally-Recognized
Accredited Laboratory***

A2LA has accredited

SPECTRA LABORATORIES, INC.
Milpitas, 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 ISO-ILAC-IAF Communiqué dated January 2015*).

Presented this 7th day of August 2018.



A handwritten signature in black ink, appearing to read "L. J. ...".

President and CEO
For the Accreditation Council
Certificate Number 3219.01
Valid to December 31, 2019

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



Raising the Bar in Laboratory Quality



SCOPE OF ACCREDITATION ISO 15189:2012

SPECTRA LABORATORY, INC.
 525 Sycamore Drive
 Milpitas, CA 95035
 Claude O. Burdick, M.D.

CLINICAL

Valid To: December 31, 2019

Certificate Number: 3219.01

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: **CSF (C), Gastric Contents (G), Plasma (P), Serum (S), Sputum (SP), Sterile Swabs (SS), Stool (ST), Urine (U), Wounds (W), Whole Blood (WB), and other bodily fluids/tissues including PD Dialysate Fluids (PDF) and Dialysis Fluid (DF).**

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Chemistry				
	General Chemistry			
		ALT	Kinetic	S; P
		AST	Kinetic	S; P
		Albumin	BCG	S; P
		Alk Phos	PNPP/AMP	S; P
		Amylase	Chromogenic Blocked p-nitrophenyl substrate	S; P
		β-2 Microglobulin	Turbimetric	S; P
		Bilirubin, Direct	DPD Diazonium Salt	S; P
		Bilirubin, Total	DPD Diazonium Salt	S; P
		CO ₂	Enzymatic	S; DF; PDF; P
		Calcium	Arsenazo	S; DF; PDF; P
		Calcium, ionized	ISE	S
		Chloride	ISE	S; DF; PDF; P
		Cholesterol	Colorimetric/Enzymatic	S; P
		cLDL	Calculation	S; P
		CK	Creatinine phosphate/NADP	S; P
		Creatinine	Alkaline Picrate - Jaffe Kinetic Rate	S; U; PDF; DF; P
		WR C-reactive protein, quantitative (incl. hsCRP and CRP)	Immunoturbidimetric	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Chemistry				
	General Chemistry cont.			
		GGT	L-g-glutanyl-3-carboxy-4-nitroanalyte/ glycoglycine	S; P
		Glomerular Filtration Rate	EPI	S; P
		Glucose	Hexokinase	S; PDF; DF; P
		HDL Cholesterol	Enzymatic/Homogenous-Immuno Inhibition	S; P
		Iron	Colorimetric/Tripyridyltriazine w/o PPR	S; P
		Iron Sat	Calculation	S; P
		LDH	Lactate to Pyruvate	S
		LDL Cholesterol	Enzymatic/Homogenous-Immuno Inhibition	S; P
		Lipase	Enzymatic/Colorimetric	S; P
		Magnesium	Colorimetric/Xylidyl Blue/Mago	S; DF; P
		Microalbumin, Quantitative	Immunoturbidimetric	U
		Phosphorus	Colorimetric/Phosphomolybdate-no reduction	S; P
		Potassium	ISE	S; DF; P
		Prealbumin	Immunoturbidimetric	S; P
		Protein	Pyrogallol Red	U; PDF
		Protein, Total	Biuret	S; P
		Sodium	ISE	S; DF; PDF; P
		Transferrin	Spectrophotometry/Immunoturbidimetric	S; P
		Triglycerides	Enzymatic	S; P
		UIBC	Colorimetric	S; P
		Urea	Enzymatic	S; PDF; U; P
		Uric Acid	Colorimetric	S; P
		Urine Albumin/ Creatine Ratio	Calculation	U
Chemistry				
	Special Chemistry			
		Aluminum	ICP-MS	S
		Cyclosporine	Enzyme Immunoassay	WB
		Fructosamine	Colorimetric	P; S
		Glomerular Filtration Rate	EPI	S; P
		Hemoglobin A1C	Colorimetry/Turbidimetry/IFCC	WB
		Zinc	ICP-MS	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Chemistry				
Therapeutic Drug Monitoring				
		Carbamazepine	FPIA	S
		Digoxin	Chemiluminescence	S; P
		Gentamicin	FPIA	S
		Phenobarbital	FPIA	S
		Phenytoin	FPIA	S
		Phenytoin, Free	FPIA	S
		Valproic Acid	Chemiluminescence	S
		Vancomycin	Chemiluminescence	S
Hematology				
Urinalysis				
		Specific Gravity	Colorimetric	U
		Urinalysis Dipstick, Automated	Colorimetric	U
		Urinalysis Dipstick, Manual	Colorimetric	U
		Urinalysis Automated Imaging Systems	Colorimetric	U
		Urine Microscopy Automated	Colorimetric	U
		Urine Sediment Microscopy (including crystal ID)	Colorimetric	U
		Urobilinogen	Colorimetric	U
Hematology				
Automated Hematology				
		Eosinophil Count		WB
		Hematocrit		WB
		Hemoglobin		WB
		Platelet Count (PLT)		WB
		RBC Count		WB
		RBC Indices (e.g. MCV, RDW)		WB
		Reticulocytes - Automated		WB
		WBC Count		WB
		WBC Differential		WB
		ESR		WB
		CHR		WB
Hematology				
Manual Hematology				
		Blood film (WBC Differential, RBC Morphology)	Manual	WB
Hematology				
Body Fluid Analysis				
		Body Fluid Cell Count, Manual		Body Fluids
		Body Fluid Differential		Body Fluids
		Body Fluid Cell Count, Automated		Body Fluids



Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Hematology				
	Coagulation			
		INR	Electromechanical	P
		PT	Electromechanical	P
		PTT	Electromechanical	P
Immunology				
	General Immunology			
		BNP	Chemiluminescence	P
		Ferritin	Chemiluminescence	S; P
		Folate	Chemiluminescence	S
		HAV Antibody, IgM	Chemiluminescence	S; P
		HAV Antibody, total	Chemiluminescence	S; P
		HBc Antibody, IgM, EIA	Chemiluminescence	S; P
		HBc Antibody, total,	Chemiluminescence	S; P
		HBs Antibody,	Chemiluminescence	S; P
		HBsAg	Chemiluminescence	S; P
		hCG, with Qualitative Interpretation	Chemiluminescence	S; P
		HCV Antibody	Chemiluminescence	S; P
		HIV-1/2 Antibody, Immunoassay	Chemiluminescence	S
		Homocysteine	Chemiluminescence	S; P
		Parathyroid Hormone (PTH), Intact	Chemiluminescence	P
		Prostate Specific Antigen (PSA)	Chemiluminescence	S; P
		RPR	Cardiolipin-Flocculation	S; P
		Rubella Antibody, Quantitative	Chemiluminescence	S; P
		Treponema Pallidum (Syphilis antibodies)	Chemiluminescence	S
		T3, Free	Chemiluminescence	S; P
		T3, Total	Chemiluminescence	S; P
		T3, Uptake	Chemiluminescence	S; P
		T4, Free	Chemiluminescence	S; P
		T4, Total	Chemiluminescence	S; P
		TSH Ultra	Chemiluminescence	S; P
		Vitamin B12	Chemiluminescence	S; P
		Vitamin D, 25-Hydroxy	Chemiluminescence	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
		Vitamin D, 1, 25-Dihydroxy	Chemiluminescence	S
Microbiology				
	Bacteriology			
		Antimicrobial Susceptibility, Urine	Turbidimetric/Disk Diffusion	U
		Antimicrobial Susceptibility, Other	Turbidimetric/Disk Diffusion	SP; SS; ST; W; WB; PDF
		Bacterial Identification, Throat	Colorimetric	SS
		Bacterial Identification, Urine	Colorimetric	U
		Genital Cultures	Culture ID	SS
		Occult blood, Fecal	Hemoccult cards	ST
		Urine Colony Count	Manual	U
Microbiology				
	Culture detection and Identification			
		Anaerobic Cultures	Colorimetric	SS; W; WB; PDF; Aspirates; other body fluids
		Bacterial Culture, Complete ID	Colorimetric	SP; U; SS; ST; W; WB; PDF; Aspirates; other body fluids
		Bacterial Culture, Partial ID	Colorimetric	SP; U; SS; ST; W; WB; PDF; Aspirates; other body fluids
		Blood Cultures	Colorimetric	WB
		Genital Cultures	Colorimetric	SS
		Respiratory Cultures	Colorimetric	SP; SS
		Stool Culture	Colorimetric	ST
		Urine Cultures	Colorimetric	U
		Wound Cultures	Colorimetric	SS; W
		PDF Cultures	Colorimetric	PDF
		Fluid, Other Cultures	Colorimetric	Aspirates; Other body fluids



Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Microbiology				
	Molecular Microbiology			
		Hepatitis C Viral Load	PCR	P
		Hepatitis B Viral Load	PCR	P

