



SCOPE OF ACCREDITATION TO ISO 15189:2012

SPECTRA EAST, INC.
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CLINICAL

Valid To: June 30, 2020

Certificate Number: 3024.01

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
Microbiology				
	Bacteriology	Culture detection and Identification		
		Anaerobic Cultures		SS; W; Aspirates; other body fluids/tissues
		Blood Cultures		WB; Aspirates; other body fluids
		CSF Cultures		C
		Fluid Cultures		PDF
		Genital Cultures		SS
		Respiratory Cultures		SP; SS; Aspirates
		Urine Cultures		U
		Wound Cultures		SS, W, other body fluids/tissues
		Antimicrobial Drug Susceptibility		C; P; SP; SS; U; W; WB; Aspirates; other body fluids/tissues
		Urine Colony Count		U
		Gram Stain	Manual	C; G; SP; SS; ST; U; W; WB; PDF; ST; Aspirates; other body fluids/tissues
		C. difficile Toxin A & B Antigen	ELISA	ST
		Fecal leukocytes	Microscopy	ST
		Occult Blood, Fecal	Manual	ST
		Wet Mount for Yeast	Microscopy	U; Body Fluids; W; SS; C; Aspirates

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Microbiology				
	Mycology			
		Culture detection and Identification		
		Complete ID		C; SS; W; Aspirates; other body fluids/tissues; WB
		<i>Candida albicans</i>		C; SS; W; Aspirates; other body fluids/tissues; WB
		KOH Prep	Microscopy	C, SS, W, Aspirates; other body fluids/tissues
Diagnostic Immunology				
	General Immunology			
		Ferritin	Chemiluminescence	S
		Folic Acid	Chemiluminescence	S
		HBe Ag	EIA	S; P
		HBs Antibody	Chemiluminescence	S; P
		HBs Antigen	Chemiluminescence	S; P
		HIV Antibody (1/2)	Chemiluminescence	S; P
		Homocysteine	Chemiluminescence	S
		Measles IgG	Chemiluminescence	S
		PSA	Chemiluminescence	S
		RBC Folate	Chemiluminescence	WB
		Rubella IgG	Chemiluminescence	S
		Treponema	Chemiluminescence	S
		Vit B12	Chemiluminescence	S
		Vit D 1, 25 (OH) ₂	Chemiluminescence	S
		Vit D, 25 Hydroxy	Chemiluminescence	S
Diagnostic Immunology				
	Therapeutic Drug Monitoring			
		Carbamazepine	Chemiluminescence	S
		Digoxin	Chemiluminescence	S
		Gentamycin	Chemiluminescence	S
		Phenobarbital	Chemiluminescence	S
		Phenytoin	FPIA	S
		Phenytoin, Free	FPIA	S
		Theophylline	Chemiluminescence	S
		Tobramycin	FPIA	S
		Vancomycin	Chemiluminescence	S; P
Diagnostic Immunology				
	Endocrinology			
		HCG, Total	Chemiluminescence	S
		Intact PTH	Chemiluminescence	P
		T Uptake	Chemiluminescence	S
		T3	Chemiluminescence	S
		T4	Chemiluminescence	S
		T4, Free	Chemiluminescence	S
		TSH	Chemiluminescence	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Diagnostic Immunology				
	Viral Markers			
		Anti-HBc (IgM)	Chemiluminescence	S; P
		Anti-HBc (Total)	Chemiluminescence	S; P
		Anti-HBe	EIA	S; P
		HepA Ab (IgM)	Chemiluminescence	S; P
		HepA Ab (Total)	Chemiluminescence	S; P
		Hep C Antibody	Chemiluminescence	S; P
Diagnostic Immunology				
	Syphilis Serology			
		RPR	Charcoal Flocculation	S
Chemistry				
	General Chemistry			
		ALT	Kinetic	S
		AST	Kinetic	S
		Albumin	Colorimetric	S
		Alk Phos	Kinetic	S
		Amylase	Kinetic	S
		Bilirubin, Direct	Colorimetric	S
		Bilirubin, Total	Colorimetric	S
		BUN	Enzymatic	S; P
		CO ₂	Enzymatic	S; PDF; DF
		Calcium, Ionized	ISE	S
		Calcium	Colorimetric	S; PDF; DF
		Chloride	ISE	S; DF
		Cholesterol	Enzymatic	S
		CK	Kinetic	S
		Creatinine	Enzymatic	S; U; PDF; DF
		Glucose	Enzymatic	S; PDF; DF
		GGT	Kinetic	S
		Haptoglobin	Turbimetric	S
		HDL Cholesterol	Enzymatic	S
		Iron	Colorimetric	S
		LD	Kinetic	S
		LDL cholesterol, Direct	Enzymatic	S
		Lipase	Enzymatic	S
		Magnesium	Colorimetric	S; PDF; DF
		Microalbumin, Quant	Turbimetric	U
		Phosphorus	Colorimetric	S; PDF; DF
		Potassium	ISE	S; DF
		Protein, Total	Colorimetric	S; U; PDF; DF
		Sodium	ISE	S; DF; PDF
		Triglycerides	Enzymatic	S
		UIBC	Colorimetric	S
		Urea Nitrogen	Enzymatic	U; PDF; DF
		Uric Acid	Enzymatic	S
Chemistry				
	Special Chemistry			
		Apolipoprotein A-1	Turbidimetric	S
		Apolipoprotein B	Turbidimetric	S

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Chemistry				
	Special Chemistry (cont.)			
		β-2 Microglobulin	Turbidimetric	S
		C-Reactive Protein, Wide Range	Turbidimetric	S; P
		Prealbumin	Turbidimetric	S
		Transferrin	Turbidimetric	S
Chemistry				
	Trace Elements			
		Aluminum	Atomic Absorption	S
		Zinc	Atomic Absorption	S
Chemistry				
	Urinalysis			
		Chemical Dipstick, Automated	Enzymatic Reflectance	U
		Urine Sediment Microscopy	Microscopic	U
Hematology				
	Automated Hematology			
		CHr	Cyto-Chemical Reaction	WB
		Hematocrit	Calculated	WB
		Hemoglobin	Colorimetric	WB
		HgbA1c	Colorimetric	WB
		Platelet Count	Laser Impedance	WB
		RBC indices (MCH, MCHC)	Calculated	WB
		RBC indices (MCV, RDW)	Laser Impedance	
		Red Cell Count	Laser Impedance	WB
		Reticulocyte Count	Cyto-Chemical Reaction	WB
		WBC Differential (Lymph, Baso)	Laser Impedance	WB
		WBC Differential (Neutro, Mono, Eos)	Flow Cytometry	WB
		White Cell Count	Laser Impedance	WB
Hematology				
	Manual Hematology			
		ESR	Modified Westergren	WB
		WBC Differential	Manual	WB
Hematology				
	Coagulation			
		aPTT	Chronometric	P
		PT/INR	Chronometric	P
Hematology				
	Body Fluid Analysis (Peritoneal Dialysis Fluid)			
		Cell Count, Manual	Manual	PDF; Body Fluid
		White cell Differential	Manual	PDF; Body Fluid

Specialty	Sub Specialty	Test/Analyte	Method	Matrix
Immunohematology				
	Hemagglutination			
		ABO Blood Typing	Agglutination	WB; S
		Rh Typing	Agglutination	WB; S

WITHDRAWN





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

A2LA has accredited

SPECTRA EAST, INC.

Rockleigh, NJ

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 6th day of November 2018.



President and CEO
For the Accreditation Council
Certificate Number 3024.01
Valid to June 30, 2020

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



Raising the Bar in Laboratory Quality