Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0858508	10/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
John D Sprandio Md Laboratory	30 Lawrence Road, Suite 201, Broomall, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Sysmex XNL-430 analyzer validation records, lack of documentation, and interview with testing personnel #1 (TP), the laboratory failed to establish criteria for acceptable performance specifications for 12 of 12 analytes performed on the Sysmex XNL-430 analyzer from 08/15/2022 to the date of survey. Findings include: 1. On the day of survey, 10/12/2022 at 11:10 am, review of the Sysmex XNL-430 analyzer validation records revealed that the validation performed on 08/15/2022 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy, reportable ranges, and reference intervals/range (normal values) for the following analytes: - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) -Mean Platelet Volume (MPV) -Red Blood Cell Distribution Weight (RDW) - Neutrophils (NEU) - Lymphocytes (LYM) 2. The laboratory could not provide documentation verifying that the manufacturer's reference intervals are appropriate for the laboratory's patient population. 3. The laboratory could not provide a procedure for new method/test validation. 4. The laboratory director did not review and approve all validation studies performed on the Sysmex XNL-430 before reporting patient results. 5. The laboratory performed 6666

	hematology examinations from 9/19/2022 to 10/12/2022. 6. TP #1 confirmed the findings above on 10/12/2022 around 12:00 pm.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's manual differential quality control (QC) log, procedure manual, and interview with testing personnel #1 (TP), the laboratory failed to establish criteria for intended reactivity to ensure acceptable staining characteristics for manual differentials stained using Quik Diff Stain from 08/20/2020 to the date of survey. Findings: 1. On the day of survey, 10/12/2022 at 11:35 am, review of manual differential QC logs and the laboratory's Reportable Phrasing for Smears procedure revealed that the laboratory did not establish or document criteria for intended reactivity for acceptable staining characteristics of manual differentials stained using Quik Diff Stain from 08/20/2020 to 10/12/2022. 2. TP #1 confirmed the findings above on 10/12/2022 around 12:00 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel qualification records and interview with Testing Personnel #1 (TP), the laboratory failed to have a technical consultant who meets the qualification requirements (493.1411) for moderate complexity hematology testing from 08/20/2020 to the date of survey. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or

	subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel qualification records, competency assessment (CA) records and interview with testing personnel #1 (TP), the laboratory failed to ensure that 1 of 1 laboratory staff who performed the responsibilities of a technical consultant (TC) from 8/20/2020 to the date of survey met the required TC qualifications under C. F.R 493.1411. Findings include: 1. Review of the CMS 209 personnel form, signed by the laboratory director (LD) on 10/12/2022, lists the LD as the only TC. 2. Further review of CA records and interview with TP#1 on 10/12/2022 at 09:30 am, revealed that TP#1 performed the duties of a TC listed under C.F.R. 493.1413 from 08/20/2020 to 10/12/2022. 3. Review of personnel credentials provided on the date of suvey, 10/12 /2022 at 11:00 am, revealed TP #1 has a high school diploma, which does not meet the minimal educational qualifications (493.1411) to perform technical consultant responsibilities for moderate complexity testing in hematology . 4. TP#1 confirmed the findings above on 10/12/2022 around 12:00 pm.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment (CA) records and interview with testing personnel #1 (TP), the Technical Consultant (TC) failed to reevaluate and document the performance of 13 of 13 TP responsible for moderate complexity hematology testing performed on new instrumentation (Sysmex XNL-430) prior to reporting patient test results from 09/19/2022 to the date of survey.

	Findings include: 1. At the time of survey, 10/12/2022 at 11:00 am, the laboratory could not provide documentation of the reevaluation of performance for 13 of 13 testing personnel performing complete blood counts (CBC) on new instrumentation (Sysmex XNL-430) implemented by the laboratory prior to reporting patient test results from 09/19/2022 to 10/12/2022. 2. TP #1 confirmed the above findings on 10 /12/2022 around 12:00 pm.