Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0477913	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sparks Clinic	103 N First Street, Rockwall, TX	

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
D0000	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1409 Technical Consultant 493.1421 Testing Personnel (moderate complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS)-209 form,

	American Proficiency Institute (API) Proficiency Testing (PT) records, and staff interview, the laboratory failed to test Hematology samples in the same manner as it tests patient specimens for 5 of 5 testing events in 2020 (1st, 2nd, and 3rd events) and 2021 (1st and 2nd events). Findings included: 1. Review of the CMS 209 form revealed 5 Testing Persons (TP-1, TP-2, TP-3, TP-4, and TP-5) performing moderate complexity hematology testing for complete blood count analytes. 2. Review of the API proficiency testing records from 2020 (1st, 2nd, and 3rd events) and 2021 (1st and 2nd events) revealed TP-2 performed the proficiency testing for complete blood count analytes for 5 of 5 testing events. 3. In an interview on 09/21/202 at 11:38 am in the conference room, Testing Person -1 was asked if all testing persons listed on the CMS-209 performed complete blood count patient testing. She stated that all testing persons listed performed these tests. TP-1 was asked if the API proficiency testing events were rotated among all testing persons. She confirmed that TP-2 was the only testing person that performed the API proficiency testing for 2020 and 2021. This confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 1 of 1 Technical Consultants (TC-1). Findings included: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy of when and how a competency assessment was to be performed on the Technical Consultant (TC). 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed one Technical Consultant for moderate complexity testing. 3. Review of laboratory personnel records revealed there was no documented competency assessment for the duties performed as a technical consultant. 4. During an interview on 09/21/2021 at 11: 22 am in the conference room, Testing Person-1 was asked to provide a policy to assess technical consultant competency and documentation of that assessment. TP-1 stated that the laboratory did not have a TC competency assessment policy and did not have documentation of any TC competency assessment. This confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, review of manufacturer's

	instructions, patient results (07/16/2021-09/20/2021), and confirmed in staff interview, the laboratory failed to follow its own policy to resolve 9 of 28 abnormal CBC (complete blood count) results with flags. Findings included: 1. During a tour of the laboratory area on 09/21/2021 at 10:05 am, a Sysmex XN-330 hematology analyzer (Serial Number 12076) was observed. 2. The laboratory policy titled, "Flags on CBC Policy" (approved by the laboratory director 04/21/2021) stated, "When an in-house CBC test does not meet standards set by the Sysmex manufacturer, then further testing will be sent out to our contracted lab. This will also be subject to the provider's clinical assessment of each individual patient." 3. The manufacturer's instructions for the Sysmex XN-330 hematology analyzer (Revised June 2017) stated the following: "5.1 Overview of IP messages .... Results without an analysis error are classified as Positive or Negative based on preset criteria. The system judges flags for analysis data based on comprehensive surveys of numerical data, distributions and scattergrams, and provides easily-to-understand messages indicating the results. These messages are referred to as 'IP (Interpretive Program) messages' ...A Positive or Error judgement indicates the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgement occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory ...IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data." 4. A random review of patient test results from 07/16/2021 through 09/20/2021 revealed the following 9 patient reports flagged as "positive" by the instrument and with IP messages indicated on the patient results: a. Patient MARMAR0008; Date of test 07/16/2021; PLT IP Message=PLT Clumps? b. Patient HARDES0001; Date of test 09/15/2021; WBC IP Message=Monocytosis c. Patient RUSKAD0001; Date of test 09/15/2021; PLT IP Message=Thrombocytopenia d. Patient BREANN0001; Date of test 09/16/2021; PLT IP Message=PLT Clumps? e. Patient BRAERI0002; Date of test 09/16/2021; WBC IP Message=WBC Abn Scattergram f. Patient KINGIL0001; Date of test 09/16/2021; WBC IP Message=Monocytosis g. Patient LOFZZZ0001; Date of test 09/17/2021; RBC IP Message=Anisocytosis/Hypochromia h. Patient COLMEL0002; Date of test 09/20 /2021; WBC IP Message=Lymphopenia; PLT IP Message=Thrombocytopenia i. Patient MITSHA0001; Date of test 09/20/2021; RBC IP Message=Anisocytosis /Hypochromia 5. In an interview on 09/21/2021 at 02:34pm in the conference room, Testing Person-1 was asked to provide documentation that the flagged patient specimens listed above were sent out to a contracted laboratory per facility policy. She stated that none of the patient specimens were sent out to a contracted laboratory. She further stated that she did not know if the laboratory had approved protocol for flagged specimens programmed into the Sysmex XN-330 analyzer. This confirmed the above findings. Word Key: WBC=White Blood Cell Count RBC= Red Blood Cell Count PLT=Platelet Abn=Abnormal
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory environmental records (01/2021, 02/2021, 03/2021, 05/2021 and 06/2021), and staff interview, the laboratory failed to ensure room temperatures were within manufacturer's specifications for blood collection tubes for 5 of 5 months. Findings included: 1. During a tour of the testing area on 09/21/2021 at 01:55 pm, the following blood collection tubes were observed: a. 1 package of 50 Greiner Bio-One EDTA blood collection tubes; Lot number B21013P; Expiration date 05/14/2022 b. 2 packages of 100 Becton Dickinson EDTA blood collection tubes; Lot number 1040935; Expiration date 06/30/2022 c. 1 package of 100 Becton Dickinson SST blood collection tubes; Lot number 0267019; Expiration date 09/30/2021 2. The manufacturer's instructions for blood collection storage temperature ranges were stated on the package label: a. Greiner Bio-One EDTA blood collection tubes; Temperature storage range 4-25 C b. Becton Dickinson EDTA blood collection tubes; Temperature storage range 4-25 C c. Becton Dickinson SST blood collection tubes; Temperature storage range 4-25 C 3. A random review of the laboratory environmental records (01/2021, 02/2021, 03/2021, 05/2021 and 06/2021), revealed an acceptable room temperature range of 15-30 C. The laboratory failed to ensure room temperatures were within manufacturer's specifications for the laboratory's blood collection tubes. 4. During an interview on 09/21 /2021 at 02:30 pm in the conference room, Testing Person-1, after review of the records, confirmed the above findings. Word Key: EDTA=Ethylenediaminetetraacetic acid SST= Serum Separator Tube
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) -209 form, personnel records and confirmed in staff interview, it was revealed the laboratory director failed to ensure all personnel had appropriate education, as evidenced by: 1. The laboratory failed to ensure the technical consultant met the educational requirements to perform moderate complexity testing. Refer to D6035. 2. The laboratory failed to have documentation that 1 of 5 testing persons met the educational qualifications required to perform moderate complexity testing. Refer to D6065
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 the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. The laboratory failed to ensure the individual employed met the minimum educational requirements to qualify as a technical consultant. 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 laboratory personnel records, the Centers for Medicare and Medicaid Services (CMS) -209 form and staff interview, the laboratory failed to provide documentation that individuals met the educational requirements to qualify as a technical consultant. Findings included: 1. Review of laboratory personnel competency records for 2020-2021 revealed annual competency was evaluated for TP-1 and TP-2 by an individual not listed on the submitted CMS-209 form. 2. During an interview on 09/21/2021 at 10:38 am in the conference room, Testing Person-1 was

	asked to describe this individual's duties. She stated that the individual was contracted by the laboratory as a laboratory consultant after the last survey conducted 4/10/2019. Testing Person-1 added this individual to the submitted CMS-209 form as the technical consultant. Testing Person-1 was asked to provide educational documents to qualify the individual as the technical consultant. No documentation was provided. This confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records, and staff interview, it was revealed the laboratory failed to have documentation that 1 of 5 testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel records, and confirmed in staff interview, the laboratory failed to have documentation that 1 of 5 testing persons met the educational qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person-1 through Testing Person-5 listed to perform moderate complexity testing on the Sysmex XN-330 hematology analyzer. 2. A review of testing persons' personnel records revealed the laboratory failed to have documentation to ensure the following 1 of 5 testing persons were qualified to perform moderate complexity testing: a. Testing person 3; No education documents provided; Date of Hire: 08/19/2021 3. During an interview on 09/21/2021 at 10:38 am in the conference room, Testing Person-1 was asked to provide documentation of education for the testing persons listed above. No documentation was provided. This confirmed the above findings.