

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0477913	(X3) Date Survey Completed 11/10/2022
Name of Provider or Supplier Sparks Clinic	Street Address, City, State 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	<p>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 493.1213 Toxicology 493.1403 Laboratories performing moderate complexity testing; laboratory director 493.1409 Laboratories performing moderate complexity testing; technical consultant 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 Dallas Regional Office (RO) 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.</p>
D5022	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS)-116 form, manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to meet the requirements for the subspecialty of toxicology as evidenced by: 1. The laboratory failed to verify the accuracy of non-regulated toxicology analytes at least twice annually for 2 of 2 testing events in 2021 and 2 of 2</p>

testing events in 2022. Refer to D5217. 2. The laboratory failed to follow the manufacturer's instructions for performing confirmatory testing prior to reporting results of MEDTOX PROFILE II urine drugs screens (UDS). Refer to D5401. 3. The laboratory failed establish a procedure for performing urine drug screen testing. Refer to D5403 I. 4. The laboratory failed to perform verification studies for the MEDTOX PROFILE II urine drug screen test prior to reporting patient test results. Refer to D5421. 5. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for drugs of abuse using the MEDTOX PROFILE II urine drug screen test. Refer to D5449.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, CLIA FDA online database, MEDTOX PROFILE II package insert, laboratory proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated toxicology analytes at least twice annually for 2 of 2 testing events in 2021 and 2 of 2 testing events in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed MEDTOX PROFILE II urine drug screens. 2. Review of the CLIA FDA online database revealed the MEDTOX PROFILE II urine drug screen was listed as moderate complexity. 3. Review of the MEDTOX PROFILE II package insert revealed the MEDTOX PROFILE II urine drug screen tested for the following analytes: THC Cannabinoids (11-nor-9-carboxy-9-THC) OPI2 Opiates (Morphine) OPI3 Opiates (Morphine) AMP Amphetamine (d-Amphetamine) COC Cocaine (Benzoylcegonine) PCP (Phencyclidine) TCA Tricyclic Antidepressants (Desipramine) BAR Barbiturates (Butalbital) MTD Methadone (Methadone) BZO Benzodiazepines (Nordiazepam) PPX Propoxyphene (Norpropoxyphene) MAMP Methamphetamine (d-methamphetamine) MDMA 3.4 Methylenedioxymethamphetamine OXY Oxycodone (Oxycodone) 4. Review of the laboratory's proficiency testing records for 2021 and 2022 revealed no documentation of twice annual accuracy assessments for the above non-regulated toxicology analytes for 2 of 2 testing events in 2021 and 2 of 2 testing events in 2022. The surveyor requested documentation of twice annual accuracy assessments for the non-regulated toxicology analytes. None was provided. 5. During an interview on 11/10/2022 at 12:05 p.m., testing person 1 and testing person 2 confirmed the above findings. Key: CLIA: Clinical Laboratory Improvement Amendments FDA: Federal Drug Administration

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 review of the Centers for Medicare and Medicaid Services (CMS)- 116 form, MEDTOX PROFILE II package insert, patient test records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for performing confirmatory testing prior to reporting results of MEDTOX PROFILE II urine drugs screens (UDS) for 7 of 7 patients (random sampling) in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed MEDTOX PROFILE II urine drug screens. 2. Review of the MEDTOX PROFILE II package insert revealed: "THE PROFILE-II/VERDICT-II DRUGS OF ABUSE TEST PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULTS. GAS CHROMATOGRAPHY/ MASS SPECTROPHOTOMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY/TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED." 3. Review of patient records revealed no documentation of confirmatory testing performed on urine drugs screens reported as "positive" for the following 7 of 7 (random sampling) MEDTOX PROFILE II urine drug screens in 2022: Patient DOB: 11/28/56 Results: "Positive AMP" Patient DOB: 07/02/82 Results: "Positive AMP" Patient DOB: 03/10/76 Results: "Positive AMP" Patient DOB: 06/19/81 Results: "Positive AMP" Patient DOB: 04/16/79 Results: "Positive AMP" Patient DOB: 02/06/69 Results: "Positive AMP" Patient DOB: 07/11 /2001 Results: "Positive AMP" 4. Review of laboratory records revealed the laboratory performed 222 MEDTOX PROFILE II urine drug screens in 2022. 5. During an interview on 11/10/2022 at 12:05 p.m., testing person 1 and testing person 2 confirmed the above findings. Key: DOB(s)- Date of Birth(s)

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on review of laboratory policies and confirmed in interview, the laboratory

failed establish a procedure for performing urine drug screen testing in 2021 and 2022. Findings included: 1. Review of the laboratory's policies revealed a manufacturer's package insert for a MEDTOX PROFILE-II Cassette Drug Testing Device for urine drug screens. The policy manual did NOT include a written policy for testing performed on the MEDTOX testing device. The laboratory was asked to provide a copy of their policy for urine drug screens. No policy was provided. The laboratory failed to implement policies for the following components of the services provided by the laboratory for patient toxicology testing: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, referral, and specimen acceptability and rejection criteria. b. Procedures for interpretation of results and instructions for tests were not established. c. Preparation of controls and reagents for testing on the MEDTOX PROFILE-II Cassette Drug Testing Device procedures were not established. d. Control procedures were not established. e. Corrective action or troubleshooting steps to take when QC (quality control) was unacceptable was not established. 2. During an interview on 11:32 am, Testing Person-2 confirmed the laboratory did not establish a policy for testing on MEDTOX PROFILE-II Cassette Drug Testing Device for urine drug screens. II. Based on review of the laboratory's policies and for 2021 and 2022 and staff interview, the laboratory failed to define imminently life-threatening test results, or panic or alert values for hematology. The findings include: 1. A review of the laboratory's policies for 2021 and 2022 revealed there was no policy in place to define panic or alert values. 2. The laboratory was asked to provide documentation of establishing panic or alert values for hematology analytes that may yield life-threatening results. No documentation was provided. 3. During an interview at 10:15 am on 11/10/2022, Testing Person-2 stated that they physicians determined which values may be life-threatening or they would use a hospital's values, but the laboratory had not developed a procedure. This confirmed the findings.

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 Centers for Medicare and Medicaid Services (CMS)- 116 form, laboratory records, patient test records, and confirmed in interview, the laboratory failed to perform verification studies for the MEDTOX PROFILE II urine drug screen test prior to reporting patient test results. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed MEDTOX PROFILE II urine drug screens. 2. Review of laboratory records revealed no documentation of verification studies performed to demonstrate the accuracy, precision, reportable range, and reference range for the MEDTOX PROFILE II urine drug screen test. The laboratory was asked to provide documentation of verification studies for the MEDTOX PROFILE II urine drug screen test. None were provided. 3. Further review

of laboratory records revealed the laboratory performed 222 MEDTOX PROFILE II urine drug screens in 2022. 4. During an interview on 11/10/2022 at 12:05 p.m., testing person 1 and testing person 2 confirmed the above findings.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the package insert, quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for drugs of abuse using the MEDTOX PROFILE II urine drug screen test for 8 of 8 days in 2022 (May through November). The findings include: 1. Review of the MEDTOX PROFILE II urine drug screen test package insert revealed: "11. Quality Control An internal procedural control is included on each device. A line must form at the Control (CTRL) position in the result window to indicate that the proper sample volume was used and that the reagents are migrating properly. If a Control line does not form, the test is considered invalid ...In addition, if the test has been performed correctly and the device is working properly, the background will clear such that result lines are distinct. The cleared background may be considered an internal positive procedural control. The visible Control line (CTRL) should always be present regardless of whether drug is absent or present in the sample. The purpose of quality control in laboratory testing is to ensure accuracy, reliability of results and to detect errors. Because the devices are self-contained, single use tests, traditional quality control programs do not apply. The Quality Control program MEDTOX PROFILE II recommends for these non-instrumented test devices includes a combination of the internal device controls and external controls to ensure accuracy, reliability and to detect possible errors. The on-board reactive device controls may be one aspect of the quality program utilized by a laboratory to satisfy the daily quality control requirement established by the Laboratory Director. Another aspect of a quality control program includes an external negative control containing no drug and a positive drug control challenging to the assay cutoff concentration. These controls may be used to initially test each shipment of product received by the laboratory or to verify appropriate storage conditions and long-term stability of the test reagent. To follow good laboratory practices, we recommend that the user document the receipt of each new lot number of devices, the results of external controls performed initially and periodically thereafter, and the results of the internal controls within each device. It is the responsibility of each Laboratory Director to demonstrate and document the validity of the alternate QC procedure they choose to use in their laboratory. For additional information or forensic and workplace testing requirements, users should contact and follow the appropriate federal, state, and local guidelines ..." 2. Review of QC and patient test records from May to November 2022 revealed the laboratory failed to document negative and positive controls each day of patient testing on the following days: 05/11/2022; Patient DOB: 11/28/56 05/17/2022; Patient DOB: 07/11/2001 05/23/2022; Patient DOBs: 04/16/79, 06/19/81 06/01/2022; Patient DOB: 02/06/69, 07/02/82 06/02/2022; Patient DOB: 11/02/68 06/09/2022; Patient DOB: 03/10/76

06/15/2022; Patient DOB: 07/04/1991 11/01/2022; Patient DOB: 08/21/74 3. During an interview on 11/10/2022 at 12:05 p.m., testing person 1 and testing person 2 confirmed the above findings. Key: DOB(s)- Date of Birth(s)

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid (CMS)- 209 form, laboratory policies, personnel records, and confirmed in staff interview, the laboratory director failed to meet the qualifications requirements and provide overall management and direction as evidenced by: 1. The Laboratory Director failed to meet the qualifications for director of a moderate complexity laboratory. Refer to D6003. 2. The Laboratory Director failed to ensure testing systems provided quality laboratory service for all aspects of test performance for the subspecialty of toxicology. Refer to D6007. 3. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 5 of 5 Testing Persons (TP1 through TP5) performing moderate complexity testing. Refer to D6030.

D6003

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in

a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before

January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed in interview, the Laboratory Director (LD) failed to meet the qualifications for director of a moderate complexity laboratory. The findings include: 1. Review of the Laboratory Director's personnel records revealed a current Texas Medical License and no documentation of either a Certification in Anatomic and/or Clinical Pathology, 1 year directing/supervising non-waived testing, 20 CMEs in laboratory practice or laboratory training during residency. 2. During an interview with the LD on 11/10/2022 at 11:10 a.m., the surveyor asked for documentation of either a Certification in Anatomic and/or Clinical Pathology, 1 year directing/supervising non-waived testing, 20 CMEs in laboratory practice or laboratory training during residency. None was provided. This confirmed the above findings. Key: CME- Continuing Medical Education

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services (CMS)-116 form, manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to ensure testing systems provided quality laboratory service for all aspects of test performance for the subspecialty of toxicology. Refer to D5022.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid (CMS)- 209 form, laboratory policies, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 5 of 5 Testing Persons (TP1 through TP5) performing moderate complexity testing. The findings include: 1. Review of the CMS 209 form revealed 5 Testing Persons (TP1 through TP5) performing moderate complexity testing. 2. Review of the laboratory's policy binder revealed there was no policy for competency assessment for personnel performing moderate complexity testing. The laboratory was asked to provide a copy of the competency assessment policy. None was provided. 3. During an interview on 11/10/2022 at 10:15 a.m., TP1 and TP2 confirmed the above findings.

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, laboratory personnel records, and confirmed in interview, the Technical Consultant failed to meet the qualification requirements and provide technical oversight as evidenced by: 1. The laboratory failed to have documentation of training /experience to qualify the Laboratory Director as the Technical Consultant. Refer to D6035. 2. The Technical Consultant failed to observe and document direct observation of performance of instrument maintenance and function checks for competency assessments of 3 of 5 testing persons (TP1, TP2, and TP3) for the Sysmex XN-330 in 2021. Refer to D6050. 3. The Technical Consultant failed to evaluate and document semi-annual competency for 2 of 5 testing persons (TP4 and TP5) in 2022. Refer to D6053. Note: This was a repeat deficiency from the last survey on 09/21/2021.

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 the Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory personnel records, and confirmed in interview, the laboratory failed to have documentation of training/experience to qualify the Laboratory Director (LD) as the Technical Consultant (TC). The findings include: 1. Review of the laboratory's CMS-209 form revealed the Laboratory Director was also the Technical Consultant. 2. Review of the Laboratory Director's personnel records revealed a current Texas Medical License and no documentation of either a Certification in Anatomic and/or Clinical Pathology or 1 year of laboratory training or experience in the designated specialty of Hematology. 3. During an interview with the LD on 11/10 /2022 at 11:10 a.m., the surveyor asked for documentation of either a Certification in Anatomic and/or Clinical Pathology or 1 year of laboratory training or experience in the designated specialty of Hematology. None was provided. This confirmed the above findings. Note: This was a repeat deficiency from the last survey on 09/21 /2021.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory "Competency Assessment Review" forms, and confirmed in interview, the Technical Consultant (TC) failed to observe and document direct observation of performance of instrument maintenance and function checks for competency assessments of 3 of 5 testing persons (TP1, TP2, and TP3) for the Sysmex XN-330 in 2021. The findings include: 1. Review of the CMS-209 form revealed 5 testing persons (TP1 through TP5) performing moderate complexity testing. 2. Review of "Competency Assessment Review" forms for TP1, TP2, and TP3 revealed the following: "Scoring: 4= Excellent 3=Good 2=Fair 1=Unacceptable N/A=

Not observed" TP1 Date of Assessment: 01/06/2021 Component Assessed: Proper instrument set-up and function checks Score: "N/A" Component Assessed: Able to perform routine, daily, weekly, monthly, and scheduled maintenance as needed Score: "N/A" TP2 Date of Assessment: 01/12/2021 Component Assessed: Proper instrument set-up and function checks Score: "N/A" Component Assessed: Able to perform routine, daily, weekly, monthly, and scheduled maintenance as needed Score: "N/A" TP3 Date of Assessment: 03/15/2021 Component Assessed: Proper instrument set-up and function checks Score: "N/A" Component Assessed: Able to perform routine, daily, weekly, monthly, and scheduled maintenance as needed Score: "N/A" The Technical Consultant failed to observe and document direct observation of performance of instrument maintenance and function checks. 3. During an interview on 11/10/2022 at 10:15 a.m., TP1 and TP2 confirmed the above findings.

D6053

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 at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid (CMS)- 209 form, personnel records, and confirmed in interview, the Technical Consultant failed to evaluate and document semi-annual competency for 2 of 5 testing persons (TP4 and TP5) in 2022. The findings include: 1. Review of the CMS-209 form revealed 5 testing persons (TP1 through TP5) performing moderate complexity testing. 2. Review of personnel records for TP4 and TP5 revealed the following: TP4 Initial training: 11/15/2021 Competency #1 (6-month): 05/06/2022 No elements of competency were assessed and documented by the Technical Consultant TP5 Initial training: 06/14/2021 Competency #1 (6-month): 12/06/2021 No elements of competency were assessed and documented by the Technical Consultant The Technical Consultant failed to assess and document semi-annual competencies. 3. During an interview on 11/10/2022 at 10:15 a.m., TP1 and TP2 confirmed the above findings.