

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2126116	(X3) Date Survey Completed 12/17/2018
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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 initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on December 17, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of event 3 of 2018 proficiency testing (PT) records and staff interview, the laboratory failed to have a statement signed by the laboratory director attesting that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the PT attestation statement for event 3 of 2018 revealed it is not signed by the laboratory director. 2. Interview with the testing personnel and office manager on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor confirmed the attestation statement is not signed by the laboratory director.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory policy and procedures, review of laboratory records and staff interview, the laboratory failed to follow its written quality assessment (QA) policy. Findings include: 1. Review of the laboratory's policy and procedures in use at the time of the survey revealed no instructions for performing QA and no documentation of QA activity between September 2018 and the date of the survey. 2. Review of policies and procedure manuals stored with records of testing performed in 2017 revealed the laboratory has a comprehensive QA policy which includes instructions, charts and checklist. 3. Interview with the testing personnel and office manager on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor revealed neither were aware of the QA policy and confirmed there is no documentation of QA activity from September 2018 to the present.

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 review of operating specifications for the Sysmex XP 300 Hematology analyzer (Sysmex), review of laboratory records, lack of records to review and staff interview, the laboratory failed to document the temperature and humidity of the room where the Sysmex is operated. Findings include: 1. Review of operating specifications for the Sysmex revealed the room temperature where the instrument is operated should be between 15-30 degrees centigrade and the relative humidity of the area should be between 30-85 percent. 2. Review of the laboratory's records revealed no documentation or evidence that the temperature and humidity of the area where the Sysmex is located is monitored and recorded. 2. Interview with the testing personnel and office manager on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor confirmed the temperature and humidity is not monitored.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality control (QC) records for testing performed on the Sysmex XP 300 Hematology analyzer and staff interview, the laboratory failed to monitor over time, the accuracy and precision of test performance. Findings include: 1. Review of QC records revealed no evidence of Levey-Jennings (LJ) charts, calculation of means and standard deviations or other means for reviewing control values to determine shifts or trends and monitoring over time the accuracy and precision of test performance . 2. Interview with the office manager and testing personnel on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor, confirmed LJ charts have not been printed for any testing performed, statistical parameters have not been calculated and the laboratory is not reviewing QC values for shifts and trends.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and staff interview, the laboratory failed to document corrective action taken when results of controls performed on the Sysmex XP 300 Hematology analyzer fell outside the acceptable range. Findings include: 1. Review of laboratory records revealed no documentation of corrective action. 2. Interview with the testing personnel on December 17, 2018 at approximately 11:30 am in the office assigned to the surveyor confirmed there is no documentation of corrective action taken when controls fall outside the acceptable range(s).

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory test records and staff interview, the laboratory failed to include the identity of the testing personnel on the test records. Findings include: 1. Review of patient test records revealed no documentation showing the identity of the testing personnel who performed the test. 2. Interview with the testing personnel on December 17, 2018 at approximately 11:30 am in the office assigned to the surveyor confirmed the identity of the person performing the testing is not documented.

<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, the laboratory failed to include normal values on patient reports. Findings include: 1. Review of patient test reports revealed no normal values listed on the reports. 2. Interview with the testing personnel on December 17, 2018 at 11:30 am in the office assigned to the surveyor confirmed normal values are not listed on patient reports.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Findings include: Refer to D6020, D 6021, D6029 & D6030</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and staff interview, the laboratory director failed to ensure the laboratory's QC program was established and maintained. Finding include: 1. Review of QC records also revealed no documentation of review by the laboratory director or a qualified technical consultant. 2. Interview with the testing personnel on December 17, 2018 at approximately 11:30 am in the office assigned to the surveyor confirmed there is no documentation of QC review by the laboratory director or a qualified technical consultant. Also refer to D 5441</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to ensure the laboratory's quality assessment program was maintained. Findings include: Refer to D 5291

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 laboratory personnel records, lack of records to review and staff interview, the laboratory director failed to ensure that prior to testing patient samples, the testing personnel has the appropriate education, experience and training to perform testing and has demonstrated the ability to perform and report accurate results.
Findings include: 1. Review of the testing personnel's records revealed no documentation of education, no documentation of training to perform testing on the Sysmex 300 hematology analyzer, and no documentation showing the testing personnel's ability to perform and report accurate test results. 2. Interview with the testing personnel and office manager on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor confirmed education, experience and training records for the testing person are not available and there is no documentation showing that prior to testing patient samples, the testing personnel demonstrated the ability to perform and report accurate results.

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 laboratory policies and procedures, review of laboratory personnel records and staff interview, the laboratory director failed to ensure policies and procedures are established and followed to assess and monitor employee competency. Findings include: 1. Review of laboratory policies and procedures revealed no policy or procedure for assessing employee competency. 2. Interview with the testing personnel and office manager on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor confirmed the laboratory does not a a policy and procedure for assessing employee competency.

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 laboratory's personnel records, review of the Center for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), review of laboratory records and staff interview, the laboratory failed to employ a qualified technical consultant. Findings include: Refer to D 6035

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 laboratory's personnel records, review of the Center for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), review of laboratory records and staff interview, the laboratory failed to employ a qualified technical consultant. Findings include: 1. Review of the laboratory's CMS 209 form shows the laboratory director (LD) is also listed as the technical consultant. 2. Review of the LD's qualifications revealed he is not qualified to be a technical consultant. 3. Review of laboratory records revealed no documentation of review, supervision or oversight by a technical consultant. 4. Interview with the office manager on December 17, 2018 at approximately 12 pm confirmed the laboratory does not have a technical consultant.

D6067

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of testing personnel records, lack of records to review and staff interview, the laboratory failed to have documentation showing the testing personnel had the required training prior to analyzing patient samples. Finding include: 1. Review of testing personnel records revealed no documentation of training to perform testing in the speciality of Hematology and no documentation of training to operate the Sysmex XP 300. 2. Interview with the office manager and testing personnel on December 17, 2018 at approximately 12:30 pm in the office assigned to the surveyor confirmed there are no records or documentation of training.