

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2028399	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Chelsea Urgent Care	Street Address, City, State 15582 Highway 280 Suite 106, Chelsea, AL	
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 announced initial survey was conducted on 12/06/2023 at Chelsea Urgent Care, a clinical laboratory in Chelsea, AL. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on survey findings, an Immediate Jeopardy situation was identified, and the laboratory was notified at 12:07 PM on 12/06/2023. The following Conditions were not met: D2000 - Enrollment and Testing of Samples 493.801 D5400 - Analytic Systems 493.1250 D6000 - Moderate Complexity Laboratory Director 493.1403 D6033 - Technical Consultant Moderate Complexity 493.1409
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, a lack of any PT records, and interview with Testing Personnel #1, the laboratory failed to enroll in PT in the specialty of Hematology for the Diatron Abacus-3CP Complete Blood Count (CBC) test, for 2 of 2 events in 2023. The findings include: 1) A lack of records revealed no evidence of enrollment in PT for Hematology from date testing began to survey date of 12/06/2023.. 2) Interview of laboratory director conducted on 12/06 /2023 at 11:30AM, confirmed the laboratory was not performing any PT testing.</p>

<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review, a lack of any hematology testing records, and interview with laboratory staff, the laboratory failed to retain any Diatron Abacus-3CP hematology analyzer records for testing performed on date patient testing started on 7/12/2023 through 12/06/2023. The findings include: 1. The surveyor review revealed the laboratory lacked any records for the hematology analyzer. The laboratory failed to print quality control documents and retain them after testing started on 7/12/2023. 2. During an interview on 12/06/2023 at 12:07 PM, Testing Personnel #1 confirmed the laboratory was not keeping records for 2 years.</p>
<p>D5291</p>	<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> <p>This STANDARD is not met as evidenced by: Based on surveyor review, a lack of procedure manuals, and an interview with the Laboratory Director, the laboratory failed to establish written procedures to monitor general laboratory requirements. This was noted from the date patient testing started on 7/12/2023 through to the current survey on 12/6/2023. The findings include 1. Record review revealed no evidence of established policies and procedures for the testing personnel to follow and correct the failures within the laboratory such as: a) Patient confidentiality; b) Specimen identification and integrity; c) Complaint investigations; d) Communications; e) Personnel competency; f) Proficiency testing performance. 2. The laboratory was asked to provide documentation of policies and procedures, no documentation was provided. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of laboratory policies and procedures, a lack of any</p>

policies, procedures, manufacturer manuals and interview with the laboratory staff the laboratory failed to: 1) Ensure a written procedure was available to the laboratory personnel for Complete Blood Counts (CBC), a Hematology test. (Refer to D5401.) 2) Establish written procedures to monitor analytical laboratory requirements. (Refer to D5403). 3) Document temperatures for the refrigerator in which Hematology QC was stored. (Refer to D5413.) 4) Monitor and document room temperatures and humidity. (Refer to D5413.) 5) Ensure testing personnel checked expiration dates and did not use expired QC material. (Refer to D5417.) 6) Document the laboratory director approval of the validation procedure for new CBC test before testing began on 7/12 /2023. (Refer to D5421.) 7) Document weekly maintenance on the Abacus-3CP Hematology analyzer as per the manufacturer's requirements for five of five months in 2023. (Refer to D5429.) 8) Have a procedure in place that monitors the accuracy and precision of test performance over time. (Refer to D5441.) 9) Ensure daily Hematology quality control was documented prior to analyzing patient specimens and reporting the results. (Refer to D5481.) 10) Establish and maintain a Quality Assurance (QA) program to assure the quality of laboratory services provided. (Refer to D5791.) Due to the evidence of this condition, an Immediate Jeopardy (IJ) was called on 12/6/2023 at 12:07 PM.

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 surveyor review and an interview with Testing Personnel #1, the laboratory failed to have a written procedure for Diatron Abacus-3CP Complete Blood Counts (CBC) Hematology analyzer. The findings include: 1. Surveyor review revealed no documentation of a written procedure for CBC hematology test, this was noted for the day patient testing began on 7/12/2023 through current survey on 12/6/2023. 2. The laboratory did not have a copy of the Diatron Abacus-3CP manufacturer manual. 3. During an interview on 12/6/23 at 12:07 PM, Testing Personnel #1 confirmed the laboratory did not have a written procedure for the test above.

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:

Based on surveyor review, a lack of procedure manual, and an interview with the Laboratory Director, the laboratory failed to establish written procedures to monitor analytical laboratory requirements. This was noted from the date patient testing started on 7/12/2023 through to the current survey on 12/6/2023. The findings include: 1. Record review revealed no evidence of established policies and procedures which must include: a) Requirements for patient preparation; b) Specimen collection, labeling, storage, preservation, transportation, processing, and referral; c) Criteria for specimen acceptability and rejection; d) Calibration and calibration verification procedures; e) The reportable range for test results; f) Control procedures; g) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h) Reference intervals (normal values); i) Imminently life-threatening test results, or panic or alert values. 2. The laboratory was asked to provide documentation of policies and procedures, no documentation was provided. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

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 a review of the Abacus-3CP Quality Control (QC) package insert, the Abacus 3CP Hematology analyzer user manual, and an interview with Testing Personnel #1, the Laboratory failed to document temperatures for the refrigerator, room temperature, and humidity for the room in which the Hematology analyzer operates. The findings include: 1. A review of the Abacus-3CP QC package insert revealed "store CBC-3CP upright at 2-8 degrees Celsius." The laboratory failed to document temperatures for the refrigerator in which the Abacus 3CP Hematology Controls were stored since starting patient testing on 7/12/2023. 2. A review of the Abacus-3CP user manual revealed on page 16 under Environmental conditions, "Operating conditions... temperature: 15-30 degrees Celsius and relative humidity of 45-85%." The laboratory failed to implement a mechanism to monitor and document room temperature and humidity. 3. During an interview on 12/6/23 at 12:07 PM, Testing Personnel #1 confirmed refrigerator temperatures, room temperatures, and humidity were not monitored or documented.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Quality Control (QC) material stored in laboratory and an interview with Testing Personnel #1, the laboratory failed to ensure testing personnel did not use expired QC material. Expired controls were used for four months of patient testing. The findings include: 1. A review revealed QC for the hematology analyzer expired on 8/05/2023. The laboratory continued to use the expired QC for 4 of 4 months, until date of survey 12/06/2023. 2. During an interview on 12/6/2023 at 12:07 PM, Testing Personnel #1 confirmed the laboratory used expired QC after expiration date.

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 a review of the installation and validation records for the Diatron Abacus-3CP Complete Blood Count (CBC) Hematology analyzer, and an interview with the Laboratory Director, the laboratory failed to ensure the Laboratory Director reviewed and approved validation records prior to starting patient testing. The findings include: 1. A review of the validation documentation for the Abacus-3CP Hematology analyzer revealed the Laboratory Director failed to approve and sign the new CBC test procedure before patient testing began on 7/12/2023. 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based record review of the Hematology maintenance records, the Abacus 3CP Hematology analyzer user manual, and an interview with Testing Personnel #1, the Laboratory failed to document weekly maintenance on the Hematology analyzer for five of five months in 2023. The findings include: 1. A review of the Hematology analyzer records revealed no documentation of weekly maintenance for 7/12/2023

through current survey 12/6/2023. 2. A further review of the Abacus-3CP user manual revealed on page 74 under 8. Maintenance, "Weekly maintenance by user: Cleaning the washing head." 3. During an interview on 12/6/2023 at 12:07 PM, Testing Personnel #1 confirmed the above findings.

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 record review, a lack of any records and interview, the laboratory failed to monitor the accuracy and precision over time of Quality Control since the installation of the Abacus-3CP hematology analyzer on 7/12/2023. The findings include: 1. The record review revealed the laboratory did not have any records or evidence to document quality control and if daily check procedures were performed. The laboratory performs approximately 780 of patient tests annually, confirmed on CMS-116. Laboratory failed to ensure patient tests were accurate before releasing results to providers. 2. Review of the hematology QC revealed there was no system in place to monitor the accuracy and precision over time. The laboratory was asked to provide documentation of performing QC, no documentation was provided. 3. During an interview on 12/6/2023 at 12:07 PM, Testing Personnel #1 confirmed the above findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review, a lack of Hematology Quality Control (QC) records for the Diatron Abacus-3CP, and an interview with Testing Personnel #1, the laboratory failed to ensure daily QC was documented prior to reporting patient results. This was noted from the beginning of patient testing on 7/12/2023 through to the current survey 12/6/2023. The findings include: 1. A review reveal the laboratory lacked any QC daily documentation records for the Diatron Abacus-3CP. 2. The laboratory was asked to provide documentation of performing daily QC, no documentation was provided. The laboratory should run 3 controls every day of testing. 3. During an interview on 12/6/2023 at 12:07 PM, Testing Personnel #1 confirmed the above findings.

<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review and an interview with the Laboratory Director, the laboratory failed to establish and maintain a Quality Assessment (QA) program to assure the quality of laboratory services provided. This was noted from the date patient testing started on 7/12/2023 through to the current survey on 12/6/2023. The findings include: 1. The laboratory tour revealed no evidence of a QA plan or activities for the facility to address and correct the failures within the laboratory (Refer to D5400.). 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.</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 record review and interview, the laboratory director failed to: 1) Ensure education documentation was available for five of five TP. (Refer to D6065). 2) Ensure training for four of five TP was documented prior to analyzing patient specimens and reporting CBC (Complete Blood Counts) Hematology test results. (Refer to D6066). 3) Ensure the laboratory is enrolled in an approved proficiency testing program for each test performed. (Refer to D6015). 4) Ensure Abacus 3CP Hematology analyzer validation procedures demonstrated performance characteristics specified by the manufacturer prior to use for patient testing. (Refer to D6013). 5) Ensure Testing Personnel #1 had appropriate education and experience to be the Technical Consultant. (Refer to D6029). 6) Establish and maintain a Quality Assurance (QA) program to assure the quality of laboratory services provided. (Refer to D6021). 7) Establish competency to monitor testing personnel (TP). This was noted for five of five TP. (Refer to D6030). 8) Establish written procedures to monitor analytical laboratory requirements. (Refer to D6031). 9. Specify responsibilities and duties of each testing personnel (TP). This was noted for five of five TP. (Refer to D6032). Due to the evidence of this condition, an Immediate Jeopardy (IJ) was called on 12/6/2023 at 12:07 PM.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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</p>

director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on a review of the validation records for the Abacus 3CP Hematology analyzer, and an interview with the Laboratory Director, the laboratory director failed to approve and ensure the verification performance specification were acceptable before testing began on 7/12/2023. The findings include: 1. A review of the validation records for the Abacus 3CP Hematology analyzer revealed no documentation (signature and date) by the Laboratory Director to indicate review and approval of the procedures verifying the manufacturer's performance specifications; Patient CBC (Complete Blood Count) testing began 7/12/2023. 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing (PT) program for each test for which it performs patient testing. The findings include: 1. Record review revealed the laboratory has not enrolled in an approved PT program for Hematology since the date patient Complete Blood Counts (CBC) testing started on 7/12/2023 through 12/6/2023. 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the laboratory was not enrolled in a PT program.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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 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 record review and an interview with the Laboratory Director, the Laboratory Director failed to establish and maintain a Quality Assessment (QA) program to assure the quality of laboratory services are provided. The findings include: 1. Record review revealed no evidence of a QA plan for the facility to address and correct the

failures within the laboratory. 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

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 education record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure Testing Personnel (TP) #1 had appropriate education and experience to be the Technical Consultant. The findings include: 1. A review of education records revealed Testing Personnel #1 has an Associates in Nursing and does not qualify as Technical Consultant. The laboratory failed to provide a copy of TP#1 high school diploma.. (Refer to D6065) 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

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 surveyor review, a lack of personnel competency documentation, and an interview with the Laboratory Director, the Laboratory Director failed to establish competency evaluation process to monitor testing personnel (TP). This was noted for five of five TP. The findings include 1. Record review of TP revealed no evidence of established competency documentation for TP #1, #2, #3, #4, and #5. 2. The laboratory was asked to provide documentation of TP Hematology competencies, no documentation was provided on site. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on surveyor review, a lack of record review, and an interview with the Laboratory Director, the Laboratory Director failed to establish written procedures to monitor analytical laboratory requirements. This was noted from the date patient testing started on 7/12/2023 through to the current survey on 12/6/2023. The findings include: 1. Record review revealed no evidence of established policies and procedures which must include: a) Requirements for patient preparation; b) Specimen collection, labeling, storage, preservation, transportation, processing, and referral; c) Criteria for specimen acceptability and rejection; d) Calibration and calibration verification procedures; e) The reportable range for test results; f) Control procedures; g) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h) Reference intervals (normal values); i) Imminently life-threatening test results, or panic or alert values. 2. The laboratory was asked to provide documentation of policies and procedures, no documentation was provided. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review, a lack of personnel job descriptions, and an interview with the Laboratory Director, the Laboratory Director failed to specify responsibilities and duties of each testing personnel (TP). This was noted for five of five TP. The findings include 1. A review revealed no evidence of job descriptions for TP #1, #2, #3, #4, and #5. 2. The laboratory was asked to provide documentation of TP job descriptions, no documentation was provided. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director 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 record review and an interview with the Laboratory Director, the laboratory failed to hire a qualified Technical Consultant. Due to the evidence of this condition, an Immediate Jeopardy (IJ) was called on 12/6/2023 at 12:07 PM. The findings include: 1. Refer to D6036.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory director, the laboratory failed to hire a technical consultant with acceptable education and experience. The findings include: 1. The technical consultant (TC) did not have a bachelors degree in a chemical, physical or biological science or medical technology from an accredited institution. The laboratory did not provide any evidence that the TC had 2 years of experience providing technical oversight to a laboratory. The laboratory did not provide a copy of the TC diploma. 2. The laboratory director did not qualify to be the technical consultant based on a bachelor degree in health and lack of laboratory experience. 3. The laboratory failed to have a technical consultant responsible for the technical performance of the laboratory. 4. Based on an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

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 record review, a lack of personnel records, and an interview with the Laboratory Director, the Laboratory Director failed to provide evidence of high school diploma for 5 of 5 testing personnel. The findings include: 1. A review of the

personnel records revealed no high school diploma available for Testing Personnel #1-5. 2. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Director, the laboratory failed to document Complete Blood Count (CBC) hematology initial training for testing personnel (TP) before laboratory testing was started on 7/12/2023. The findings include: 1. A review of the Abacus-3CP installation records revealed training documentation by Diatron service engineer for only TP #1. There was no documentation of training on the Abacus-3CP Hematology analyzer provided on site for TP #2, #3, #4, and #5. 2. The analyzer was installed on 3/16/2022; the laboratory began using the analyzer for patient CBC testing on 7/12/2023. 3. During an interview on 12/6/2023 at 12:07 PM, the Laboratory Director confirmed the above findings.