

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2133585	(X3) Date Survey Completed 01/19/2019
Name of Provider or Supplier Bsa Physicians Group, Inc D/B/A Bsa Family Medical	Street Address, City, State 3501 Soncy Ste 150, Amarillo, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.801 Condition: Enrollment and Testing of Samples 493.1215 Condition: Hematology 493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory Director 493.1409 Condition: Laboratories performing moderate complexity testing; Technical Consultant 493.1421 Condition: Laboratories performing moderate complexity testing; Testing Personnel
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 a review of the laboratory testing records, CMS report 155, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for each of the specialties and subspecialties for which it seeks certification (Hematology, Microbiology, and Urinalysis). The findings included: 1. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Hematology in 2016, 2017 or 2018 . The laboratory tested 6312 patient specimens for Complete Blood Counts using the Coulter AcT 2 diff Hematology analyzer in between</p>

September 26, 2016 and January 16, 2019. The laboratory failed to enroll in a CMS approved proficiency testing program for microbiology. The laboratory performed 82 patient tests annually in the specialty of microbiology according to the CMS 116 provided during the January 8, 2019 inspection. The Laboratory failed to enroll in a CMS a proficiency testing program for urinalysis. The laboratory performed 3084 urinalysis procedures according to the CMS 116 provided during the January 8, 2019 inspection. 2. Review of the CMS report 155 and report 153 found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 9:21 AM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for Hematology.

D5024

HEMATOLOGY
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Review of personnel files, laboratory records, quality control records and interview of facility personnel found the laboratory failed to meet the requirements for the specialty of Hematology. Findings Included: 1. The laboratory failed to have a written policy to assess the competency of the technical consultant or testing personnel. (See D5209) 2. Laboratory failed to have a procedure available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5401, D5403) 3. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Coulter AcT 2 diff Hematology Analyzer . (See D5413) 4. The laboratory failed to verify the accuracy, precision, reportable ranges and reference intervals used for the Coulter AcT 2 diff Hematology Analyzer. (see D 5421) 5. The Laboratory failed to perform and document all maintenance procedures for the Coulter AcT 2 diff Hematology Analyzer. (See D5429) 6. The Laboratory failed to have a procedure for the performance of calibration procedures for the Coulter AcT2 diff Hematology Analyzer. (See D5437) 6.The Laboratory failed to establish and maintain a quality control program for the Coulter AcT 2 diff Hematology Analyzer. (See D5441) 7. The laboratory failed to verify or establish its own mean and limits when using the Coulter 4C ES cell control to ensure the accuracy of results obtained on the Coulter AcT 2 diff hematology analyzer. (See D5469) 8. The laboratory failed to establish written policies and procedures (Quality Assurance) for an ongoing mechanism to monitor, assess and correct problems identified in the hematology analytic system for testing on the Cell Dyn Emerald Hematology Analyzer before, during and after verification in order to ensure accurate patient results. (See D5791)

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted CMS form 209, policies and procedures, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have a procedure for assessing the competency of all supervisors, consultants and testing personnel and no documentation of competency assessments performed for testing personnel. The findings included: 1. A review of the laboratory's submitted CMS form 209 found that the laboratory identified three testing personnel performing non-waived testing, and no technical consultant. 2. Review of policies and procedures found no procedure for assessing the competency of all supervisors, consultants and testing personnel. 3. A review of the laboratory's personnel records found no competency assessments performed for three of three testing personnel listed on the CMS form 209. 4. An interview with testing person one on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 9:23 AM AM confirmed that the laboratory did not have a procedure for assessing the competency of all technical consultants and testing personnel. She went on to confirm that competency assessments had not been performed for three of three testing personnel.

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:
Observations, review of the procedure manual, and interview of facility personnel found that the laboratory failed to have a written procedure available to all testing personnel for the use of the Coulter AcT 2 diff hematology analyzer. Findings included: 1. Observations made during the tour the facility found no operators manual or users guide for the Coulter AcT 2 diff hematology analyzer. 2. Review of procedures in the BSA FMC procedure manual found copies of pages from the Coulter AcT 2 diff Operators Guide as follows: pages 2-12 through 2-14 (Running Samples) page 3-1 Sample Requirements. Pages 2-8 through 2-13 (Entering Cell Control Information) Pages 2-14 through 2-15 (Update the Printer Information) 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 09:23 AM confirmed that the laboratory did not have an operators guide for the Coulter AcT2 diff hematology analyzer or any other procedures available to testing personnel for the operation of the instrument.

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 observations, review of the laboratory's policies and procedures, interview of facility personnel, the laboratory failed to include pertinent literature references for centrifuge speed and time in the procedure titled Urine Microscopic Exam Procedure. The findings included: 1. Observations made during the tour the facility found that the laboratory used the Drucker centrifuge model 613 (serial number 129732) for centrifuging urine specimens for microscopic examinations. There was no documentation on the centrifuge regarding the verification of the speed of the centrifuge. Maintenance records were requested. 2. Review of the laboratory's procedure titled Urine Microscopic Exam Procedure found on page 2 under the heading Test Performance - "ii. centrifuge at a relatively low speed (about 1500 to 3000 RPM) for 5 to 10 minutes until a moderately cohesive button is produced at the bottom of the tube." 3. Review of maintenance records provided for the Drucker centrifuge found that the last preventive maintenance check was completed on May 11, 2018. There was no documentation of centrifuge speed conducted at that time. 5. Interview of testing person one listed on the CMS report 209 laboratory personnel report conducted on January 8, 2019 at 10:12 AM confirmed that the laboratory's procedure for performing urinalysis did not include pertinent literature references for determining centrifuge speed and time. She stated that she "went online and found a procedure and copied information from it." II. Based on review of the laboratory's policies and procedures, review of the operators guide for the Coulter AcT 2 diff hematology analyzer (obtained by surveyor) and interview of facility personnel, the laboratory failed to have step-by-step instructions for the complete blood count (CBC) testing performed on the Coulter AcT 2 diff hematology analyzer. The findings included: 1. The laboratory used excerpts from the operators guide for the Coulter AcT 2 diff hematology analyzer as their own procedure for testing patient specimens, entering quality control values and updating the printer. There were no other procedures available to testing personnel which defined calibration frequency or step-by-step performance of the procedure including the interpretation of results, the reportable range for test results, or performance of quality control testing to include number, frequency and acceptability criteria. 2. Review of the operators guide found on page 5 -1 under the heading Calibration - " Beckman Coulter recommends that you calibrator instrument according to the regulations required by your inspecting agency." 3. A written procedure defining the criteria not specified in the operators guide was requested but not provided. 2. Interview of testing person one conducted on January 8, 2019 at 9:23 AM confirmed that the laboratory did not have a procedure defining calibration frequency, control acceptability criteria or reportable ranges. She went on to confirm that the laboratory did not have an operators guide when she started working in September 2016.

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:

Observations, and interview facility personnel found that the laboratory failed to monitor and record the temperature and humidity of the room where the Coulter AcT 2 diff hematology analyzer was used for patient testing. The findings included: 1. Observations made during the tour the facility found no means to monitor the temperature and humidity of the room where the Coulter AcT 2 diff hematology analyzer was used for patient testing. 2. Review of the Coulter AcT 2 diff hematology analyzer reference guide found on page 4 - one under the heading "Temperature, Ambient Operating - 16C to 35C (61F 95F) Humidity - 30 to 85% without condensation." 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 10:46 AM confirmed that the laboratory does not measure and record temperature and humidity of the room where the Coulter AcT 2 diff hematology analyzer was used for patient testing.

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:

Observations, review of laboratory records, and interview of the facility personnel found that the laboratory failed to verify the performance of the Coulter AcT 2 diff hematology analyzer met the manufacturer's performance specifications for accuracy, precision and reportable range, and did not verify the manufacturer's reference range or establish its own reference range for patient populations served by this laboratory. Findings included: 1. Review of the provided verification records for the Coulter AcT 2 hematology analyzer serial number A231397 in use September 26, 2016 found no assessment of accuracy, precision, reportable range or assessment of reference ranges for the patient populations serviced by the laboratory. The laboratory offered a carryover study dated August 1, 2016, a reproducibility report dated August 1, 2016 and a calibration report dated July 29, 2016 along with a second calibration report dated September 28, 2016. 2. Review of patient test records found 6312 Complete Blood Counts (CBC) tested between September 26, 2016 in January 16, 2019. It should be noted that the certificate of registration was issued July 17, 2017. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted

on January 8, 2019 at 9:11 AM confirmed that no other performance verification activities were done after she was employed to work in laboratory. She went on to say that the analyzer was there when she got there and she" started it up".

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 on review of the manufacturer's instructions for the Coulter AcT 2 diff hematology analyzer, review of the laboratory's maintenance records and staff interview, found that the laboratory failed to have documentation of performing maintenance procedures as defined by the manufacturer. The findings included: 1. A review of the manufacturer's instructions for the Coulter AcT 2 diff hematology analyzer found on page 6-1 of the operators guide (obtained by surveyor). "You performed maintenance procedures either on a time schedule or on an instrument cycle schedule. Keep a calendar marked with dates for maintenance and check the startup results screen for the number of cycles performed. 6.2 MAINTENANCE SCHEDULE Perform Startup Daily Perform Shutdown Daily" 2. A review of the laboratory's maintenance logs found no documentation of daily maintenance procedures. 3. Interview of testing person one conducted on January 8, 2019 at 10:46 AM confirmed that's routine maintenance procedures were not documented. She went on to confirm that she did not have an operators guide for theCoulter AcT 2 diff hematology analyzer to reference necessary maintenance procedures or the frequency.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Review of policies and procedures, the Coulter AcT 2 diff operator's guide, calibration records and interview facility personnel found that the laboratory failed to establish and follow a procedure for the calibration of the Coulter AcT 2 diff hematology analyzer. Findings included: 1. Review of the laboratory's own written procedures found no policy or procedure for the calibration of the Coulter AcT 2 diff hematology analyzer. 2. A review of the operator's guide (obtained by the surveyor) found on page 5-1 under the heading Calibration - "Beckman Coulter recommends that you calibrate your instrument according to the regulations required by your

inspecting agency." 3. Review of calibration records found that the laboratory performed calibration procedures on September 28, 2016. No other calibration records were available for review. 4. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 10:38 AM confirmed that calibration procedures had not been performed Coulter AcT 2 diff hematology analyzer since it was initially done on September 28, 2016. She went on to confirm that the laboratory had not established and written its own procedure for performance of calibration procedures, meeting the requirements of CMS as a written in the regulations.

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 a review of policies and procedures, hematology quality control records, patient test records and interview of facility personnel the laboratory failed to have a written policy available to all testing personnel defining the number, type of control and criteria of acceptability for complete blood counts (CBC) using the Coulter AcT diff 2 hematology analyzer. Findings included: 1. Review of policies and procedures found no written policy/procedure available to all testing personnel defining quality control performance and criteria of acceptability. 2. Review of quality control records for October 2017 and March 2018 found no documentation of quality control procedures performed on four of 62 dates reviewed. There was no documented quality control procedures performed on October 13 and 27, 2017, and no quality control documented for March 8 and March 15, 2018. 2. Review of patient test records found 18 patient specimens tested without quality control procedures for these dates: October 13, 2017 - no patients were tested October 27, 2017 - five patient specimens were tested without quality control procedures being done. March 8, 2018 - five patient specimens were tested without quality control procedures being done. March 15, 2018 - eight patient specimens were tested without quality control procedures. 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 10:38 AM found that the laboratory tested three levels of quality control material once each day of testing. All three levels of quality control material must be acceptable before patients are tested. She went on to confirm that no written procedure was available for quality control testing and acceptability criteria. After review of patient test results at 2:37 PM she confirmed that patients had been tested without quality control on three of 62 dates reviewed.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of hematology quality control records, patient test records and interview of facility personnel the laboratory failed to test at least two levels of quality control material before testing and reporting patient specimens for Complete Blood Counts (CBC) using the Coulter AcT diff 2 hematology analyzer. Findings included: 1. Review of quality control records for October 2017 and March 2018 found no documentation of quality control procedures performed on three of 62 dates reviewed. There was no documented quality control procedures performed on October 13 and 27, 2017, and no quality control documented for March 8 and March 15, 2018. 2. Review of patient test records found 18 patient specimens tested without quality control procedures for these dates: October 27, 2017 - five patient specimens were tested without quality control procedures being done. Patient 1238035 patient 1238060 patient 1238125 patient 1238159 patient 1238191 March 8, 2018 - five patient specimens were tested without quality control procedures being done. Patient 828876. Patient 578203 patient 707606 patient 804528. Patient 768586 March 15, 2018 - eight patient specimens were tested without quality control procedures. Patient 1347637. Patient 510576 patient 750701 patient 490242. Patient 499420. Patient 398335. Patient 398339 patient 698785 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 10:38 AM found that the laboratory's own procedure was to test three levels of quality control material once each day of testing. All three levels of quality control material must be acceptable before patients are tested. She went on to confirm that no written procedure was available for quality control testing and acceptability criteria. After review of patient test results at 2:37 PM she confirms that 18 patients had been tested without quality control on three of 62 dates reviewed.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Coulter 4C-ES controls, review of hematology quality control records from 2017 in 2018, patient test records

and staff interview found the laboratory failed to have documentation of verifying the acceptability for new lots of controls prior to placing them into use. Findings included: 1. Review of the manufacturer's instructions for the Coulter 4C-ES hematology controls under the section titled "Assigned Values and Expected Results" found: "Before the current control lot(s) expire, perform the following on your new lot (s): - confirm that recovered values are within the TABLE OF EXPECTED RESULTS or - establish your own laboratory mean." 2. Review of the laboratory's hematology control records found that the laboratory failed to confirm that recovered values for Coulter 4C-ES Cell control lots were within the table of expected results before the current control lot expired for nine of nine lots used in 2018. As follows Lot 8300 expiration February 15, 2018 Lot 8800 expiration April 9, 2018. Lot 9100 expiration May 21, 2018. Lot 9300 expiration June 18, 2018. Lot 9800 expiration August 27, 2018. Lot 7700 expiration October 22, 2018. Lot 8100 expiration December 17, 2018. Lot 7900 expiration November 19, 2018. Lot 8400 expiration January 28, 2019 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on January 8, 2019 at 10:46 AM confirmed that there was no documentation available for review to ensure that the laboratory had verified the manufacturers means prior to instituting each new lot of quality control material into use prior to the expiration date of the previous lot.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:
 Review of personnel files, laboratory records, quality control records, patient test records and interview of facility personnel found the laboratory failed to to have a written quality assurance program to monitor, assess and correct problems identified in analytic systems. Findings Included: 1. The laboratory failed to have a written policy to assess the competency of the technical consultant or testing personnel. (See D5209) 2. Laboratory failed to have a procedure available to testing personnel that had been approved signed and dated by the current laboratory director. (See D5401, D5403) 3. The laboratory failed to define and monitor the proper temperature and humidity consistent with the manufacturers' instructions for operation of the Coulter AcT 2 diff Hematology Analyzer . (See D5413) 4. The laboratory failed to verify the accuracy, precision, reportable ranges and reference intervals used for the Coulter AcT 2 diff Hematology Analyzer. (see D 5421) 5. The Laboratory failed to perform and document all maintenance procedures for the Coulter AcT 2 diff Hematology Analyzer. (See D5429) 6. The Laboratory failed to have a procedure for the performance of calibration procedures for the Coulter AcT2 diff Hematology Analyzer. (See D5437) 6.The Laboratory failed to establish and maintain a quality control program for the Coulter AcT 2 diff Hematology Analyzer. (See D5441) 7. The laboratory failed to verify or establish its own mean and limits when using the Coulter 4C ES cell control to ensure the accuracy of results obtained on the Coulter AcT 2 diff hematology analyzer. (See D5469)

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:

Review of personnel files, laboratory records, quality control records and interview of facility personnel found the laboratory director failed to provide overall management and technical direction. Findings Included: 1. The laboratory director failed to verify the accuracy, precision, reportable ranges and reference intervals used for the Coulter ACT 2 diff Hematology Analyzer. (See D6013) 2. The laboratory director failed to ensure that testing personnel were performing test methods as required to ensure accurate and reliable results. (See D6014) 3. The laboratory director failed to ensure that they laboratory was enrolled in an HHS approved proficiency testing program for each specialty and subspecialty tested by the laboratory. (See D6015) 4. The laboratory director failed to ensure that the quality control and quality assessment programs had been established and maintained to assure the quality of laboratory testing. (See D6020 and D6021) 5. The laboratory director failed to employ a technical consultant with the appropriate education and experience to provide technical oversight of the laboratory . (See D6028) 6. The laboratory director failed to ensure that all testing personnel received the appropriate training prior to testing patient specimens. (See D6029) 7. The laboratory director failed to ensure that policies and procedures were established for monitoring the performance and competency of testing personnel. (See D6030) 8. The laboratory director failed to ensure that an approved procedure manual was available to all testing personnel performing moderate complexity testing. (See D6031) 9. The laboratory director failed to specify in writing the responsibilities and duties of each consultant and testing person. (See D6032)

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(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:

Review of laboratory records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that verification activities had been conducted prior to testing patient specimens using the CoulterACT 2 diff hematology analyzer. (See D5421)

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Review of laboratory director review of laboratory records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel were performing the test methods accurately to produce reliable results. (See D5413, D5433, D5437, the 5441, D5447, D5469)

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 review of laboratory records and interview of facility personnel the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for each specialty and subspecialty that is tested by the laboratory in 2016, 2017 and 2018. (See D 2000)

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

The laboratory director failed to establish and maintain a quality control program for hematology. (See D5441, D5447, and D5469)

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.

	<p>This STANDARD is not met as evidenced by: The laboratory director failed to establish and maintain a quality assurance program to identify, monitor and correct problems in laboratory services. (See D5791)</p>
<p>D6028</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: The laboratory director failed to employ a technical consultant with the appropriate education and experience to provide technical oversight for the moderately complex procedures performed in the laboratory. (See D6033)</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Laboratory director failed to ensure that three of three testing personnel received the appropriate training prior to testing patient specimens for moderately complex procedures tested in the laboratory. (See D6065)</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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</p>

proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

The Laboratory director failed to ensure that the laboratory had a procedure to assess the competency of all testing personnel and the technical consultant responsible for patient testing to include Direct Observation, Monitoring the recording and reporting of test results, Review of quality control and proficiency testing, instrument maintenance, Assessment of test performance , and Assessment of problem solving skills. (See D 5209)

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:

The laboratory director failed to ensure that an approved written procedure for each test was available to all testing personnel outlining the step by step performance of the tests performed by the laboratory. (see D 5401 and D5403)

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:

Review of personnel records and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties of each testing personnel.

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:

Review of the CMS report 209, personnel files and interview of facility personnel found the laboratory failed to employ a technical consultant with the appropriate education and experience to provide technical oversight of the laboratory. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report signed by the laboratory director on January 4, 2019 (provided during on-site inspection January 8, 2019) found no designation of an individual for the role of technical consultant. 2. Interview of testing person one conducted on January 8, 2019 and 8:50 AM confirmed that the laboratory did not have a technical consultants meeting the regulatory requirements and that she was acting as the general supervisor.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Review of the CMS 209 Laboratory Personnel Report, testing personnel records and interview of facility personnel found that three of three testing personnel failed to have documentation of training for moderate complexity procedures prior to testing patient specimens. (See D6066)

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:

Review of the CMS 209 Laboratory Personnel Report, testing personnel records and interview of facility personnel found that three of three testing personnel failed to have documentation of training for moderate complexity procedures prior to testing patient specimens. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report signed by the laboratory director on January 4, 2019 and provided during survey, the laboratory listed three testing personnel performing moderate complexity procedures. 2. Review of personnel files found three of three testing personnel held a high school diploma. There was no documentation of training for moderate complexity procedures available for review for the three testing personnel listed on the CMS report 209 Laboratory Personnel Report. 3. Interview of testing person one conducted on January 8, 2019 at 8:50 AM confirmed that there was no documented training for moderate complexity procedures for the three testing personnel listed on the CMS report 209. She confirmed that her hire date was September 2016, testing person two had a hire date of January 2007 and testing person three had a hire date of no November 2015. She also stated that she was the one responsible for training testing personnel but she did not document the training for CBC testing on the Coulter or for any of the (waived) test kits.

D8100

INSPECTION REQUIREMENTS

CFR(s): 493.1771

Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's CLIA certificate, patient test records and staff interview, the laboratory failed to obtain a CLIA certificate prior to performing patient testing. The laboratory started patient CBC testing using the Coulter AcT 2 diff hematology analyzer on September 26, 2016 prior to the issuance of their CLIA certificate of registration on July 17, 2017. (See D8103).

D8103

BASIC INSPECTION REQUIREMENTS

CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Certificate of Registration, review of the 2016-2018 patient test records, and staff interview, the laboratory failed to obtain a CLIA certificate prior to performing patient Complete Blood Count (CBC) testing using the CoulterAct diff 2 hematology analyzer. The findings included: 1. A review of the laboratory's Certificate of Registration found the laboratory's certificate was issued by CMS on July 17, 2017. 2. Review of patient test records found that the laboratory started testing patient specimens for CBC on September 26, 2016. Further review found that 1843 patient specimens were tested for CBC between September 26, 2000 16th and July 16, 2017 prior to the issuance of the certificate of registration. 3. Interview of testing person one conducted on June January 8, 2019 at 9:11 AM confirmed that patient testing started on September 26, 2016 when she was hired.