Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0973256	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health Medical Group Family Medicine Choctaw	15679 Ne 23rd Street, Choctaw, OK	

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 recertification survey was performed on 06/06/19. The laboratory was found out of compliance with the following CLIA regulations with standard deficiencies cited: 493.801: D2000: Condition: Enrollment and Testing of Samples 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity The findings were reviewed with testing person #1, technical consultant, office manager, and the office administrator at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to enroll in an HHS approved proficiency testing program for the testing performed by the laboratory. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e., WBC-White Blood Count, RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet count, etc.) using the Cell Dyn Emerald hematology analyzer; (2) The surveyor asked testing person #1 for proficiency testing records from 2018 through the present. Testing person #1 stated to the surveyor, the laboratory had not enrolled in proficiency testing for the First and Second events of

	2018 but had enrolled in the program in time to participate in the Third event of 2018 and enrolled in proficiency testing for 2019; (3) The surveyor reviewed the laboratory's proficiency testing enrollment form which stated the laboratory enrolled in proficiency testing for 2018 on 11/12/18. The surveyor explained to testing person #1 laboratories are required by CMS to enroll in an HHS approved proficiency testing program for each of the specialties and subspecialties for which it seeks certification; (4) Examples of patients with CBC testing performed when the laboratory failed to enroll and participate in proficiency testing included the following: (a) Patient #1 - Testing performed on 01/11/18 (b) Patient #2 - Testing performed on 02/01/18 (c) Patient #3 - Testing performed on 03/14/18 (d) Patient #4 - Testing performed on 04 /13/18 (e) Patient #5 - Testing performed on 05/04/18 (f) Patient #6 - Testing performed on 06/22/18 (g) Patient #7 - Testing performed on 07/16/18 (h) Patient #8 - Testing performed on 08/03/18 (i) Patient #9 - Testing performed on 09/17/18 (j) Patient #10 - Testing performed on 10/11/18 (k) Patient #11 - Testing performed on 11 /01/18
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1 and the technical consultant, the laboratory failed to verify the accuracy of proficiency testing results which had not been evaluated by the proficiency testing program. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory used the Cell Dyn Emerald hematology analyzer to perform CBC (Complete Blood Count) testing that included a total Platelet Count; (2) The surveyor reviewed proficiency testing records from 08/25/17 through 06/06/19 and identified the proficiency testing program had not evaluated the laboratory's Platelet Count response for 1 of the 5 samples in the First Hematology event of 2019: (a) Sample Hem-02: (i) The laboratory reported, "39"; (ii) The proficiency testing programs expected response was, "49-83"; (iii) In addition, the proficiency testing program had not graded the laboratory's response due to "No Consensus" among the participants. (3) The surveyor then reviewed the proficiency testing program's "Performance Review and Corrective Action Sheet" included in the documents. It stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failure or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective actions for failures and must perform a self-evaluation using statistics presented in the 'Participant Data' for samples not graded."; (4) There was no documentation in the records which showed for the proficiency sample listed above, the laboratory: (i) Identified the non-graded response (ii) Obtained the Participant Data (iii) Evaluated their response against the proficiency testing program's expected response. (5) The surveyor reviewed the findings with testing person #1 and the technical consultant who stated to the surveyor the laboratory did not identify the non-graded response, failed to obtain the Participant Data, and failed to self-evaluate their response to verify accuracy of the testing.

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 records, manufacturer's instructions, interview with testing person #1 and the technical consultant, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Findings include: PEER QUALITY CONTROL REPORTS (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC-White Blood Count), RBC-Red Blood Count), Hematocrit, Platelet Count, etc.) using the Cell Dyn Emerald hematology analyzer. In addition, testing person #1 stated to the surveyor: (a) Three levels (Low, Normal, and High) of Abbott Cell Dyn 1800+ QC (Quality Control) materials were analyzed each day of patient testing; (b) The laboratory's QC data was submitted each month to the manufacturer's peer data program, "STATS Report" for review. (2) The surveyor reviewed the manufacturer's instructions included in the STATS Report. It stated, "SDI (Standard Deviation Index) is a graphical presentation of your laboratory's data on current lot." "In general, any SDI of 2.0 or greater deserves some attention because your method shows a systematic difference from the group. The Standard Deviation Index is provided for selected parameters."; (3) The surveyor then reviewed QC records (i.e. STATS Reports) for 5 months and identified 15 QC lot numbers had been utilized during the review period: (a) 09/01/17-10/19/17: (i) Low Level, Lot #L7184 (ii) Normal Level, Lot #N7184 (iii) High Level, Lot #H7184 (b) 11/21/17-12/21/17: (i) Low Level, Lot #L7268 (ii) Normal Level, Lot #N7268 (iii) High Level, Lot #H7268 (c) 01/01/18-02/28/18: (i) Low Level, Lot #L7352 (ii) Normal Level, Lot #N7352 (iii) High Level, Lot #H7352 (d) 04/01/18-06/01/18: (i) Low Level, Lot #L8071 (ii) Normal Level, Lot #N8071 (iii) High Level, Lot #H8071 (e) 01/01/19-02 /20/19: (i) Low Level, Lot #L8323 (ii) Normal Level, Lot #N8323 (iii) High Level, Lot #H8323 (4) The STATS Reports indicated for 2 of the 15 lot numbers reviewed, the laboratory obtained an SDI value greater than 2.0, for the review period 09/01/17-10/19/17, as follows: (a) Normal Level, Lot #N7184: (i) An SDI of -2.87 was obtained for the analyte Platelet Count. (b) High Level, Lot #H7184 (i) An SDI of -3.14 was obtained for the analyte RBC; (ii) An SDI of -2.66 was obtained for the analyte Hematocrit; (iii) An SDI of -2.30 was obtained for the analyte Platelet Count. (5) The surveyor could not find documentation in the QC records that the laboratory: (a) Identified the biased SDI's (b) Investigated the cause of the SDI's (c) Took corrective action (i.e., review maintenance, calibration, affect on patient testing, etc.) (6) The surveyor reviewed the findings with testing person #1 and the technical consultant who stated to the surveyor, the laboratory failed to review the peer QC data for SDI's greater than 2.0 to identify biases, failed to investigate the cause of the SDI's greater than 2.0, and failed to take corrective action for biased QC results; (7)

	Examples of patient testing performed during the time the laboratory failed to review the peer QC data, included the following: (a) Patient #12: Testing performed on 09/21 /17 (b) Patient #13: Testing performed on 10/19/17 LEVEY JENNINGS GRAPHS (1) During the survey, the surveyor reviewed QC records (i.e. LJ (Levey Jennings) graphs) from 09/01/17 through 4/30/19. During the review period 09/01/17 to 10/19 /17, for Lot #7184 the surveyor identified the laboratory's QC results showed negative biases of RBC and Platelet count (the control results were consistently below the established mean): (a) RBC: (i) Low Control: 61 of 81 control results were below the mean; (ii) Normal Control: 66 of 75 control results were below the mean; (iii) High Control: 66 of 71 control results were below the mean. (b) Platelet count: (i) Low Control: 69 of 73 control results were below the mean; (ii) High Control: 67 of 73 control results were above the mean. (2) The surveyor could not locate evidence in the records the above biases had been identified and addressed; (3) The surveyor reviewed the records with testing person #1 and the technical consultant, who stated to the surveyor, the QC biases listed above had not been identified or addressed; (4) See above for examples of patient testing performed when QC biases had not been identified and addressed.
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: Based on a review of records, manufacturer's instructions, and interview with testing person #1 and the technical consultant, the laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing quality assessment due to the following issues identified during the survey: (a) The laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process of testing performed in the laboratory. Refer to D5441.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, interview with testing person #1 and the technical consultant, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing performed in the laboratory. Refer to D6015; (2) The laboratory director failed to ensure the laboratory reviewed proficiency testing reports to evaluate the laboratory's performance and to identify

	problems that required corrective action. Refer to D6018; (3) The laboratory director failed to ensure the laboratory established and maintained an effective quality control program to assure the quality of laboratory servies. Refer to D6020; (4) The laboratory director failed to ensure the laboratory established and maintained an effective quality assessment program to assure the quality of laboratory services. Refer to D6021.
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 a review of records and interview with testing person #1, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing performed in the laboratory. Findings included: (1) The laboratory director failed to ensure the laboratory enrolled in a proficiency testing program for CBC testing. Refer to D2000.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records, and interview with testing person #1 and the technical consultant, the laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify problems that required corrective action. Findings include: (1) The laboratory director failed to ensure the accuracy of testing when the proficiency testing program did not evaluate submitted results. Refer to D5215.
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: Based on a review of records, manufacturer's instructions, and interview with testing person #1 and the technical consultant, the laboratory director failed to ensure a quality control program had been established and maintained to assure the quality of laboratory services provided by the laboratory. Findings include: (1) The laboratory director failed to ensure laboratory had control procedures put into place that would detect immediate errors and monitored over time the accuracy and precision of test performance. Refer to D5441.
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 a review of records, manufacturer's instructions, and interview with testing person #1 and the technical consultant, the laboratory failed to ensure an effective quality assessment program had been established and maintained to assure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory had an effective quality assessment program due to the issue identified during the survey. Refer to D5791.