Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0973256	**(X3) Date Survey Completed** 07/19/2021
Name of Provider or Supplier Ssm Health Medical Group Family Medicine Choctaw	**Street Address, City, State** 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 07/19/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with testing person #1 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to ensure an attestation statement had been signed by the laboratory director or designee for 3 of 5 events. Findings include: (1) The surveyor reviewed 2019 (third event), 2020 (first, second, and third events) and 2021 (first event) Hematology proficiency testing records with the following identified: (a) First 2020 Event - The attestation statement had not been signed by the laboratory director or designee; (b) Second 2020 Event - The attestation statement had not been signed by the laboratory director or designee; (c) First 2021 Event - The attestation statement had not been

	signed by the laboratory director or designee. (2) The surveyor reviewed the records with testing person #1, who stated on 07/19/2021 at 10:30 am, the attestation statements had not been signed by the laboratory director or designee.
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 a review of records and interview with testing person #1, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) The surveyor reviewed personnel records for competency assessments performed during 2019, 2020, and to date in 2021. There was no evidence competencies had been performed for technical consultant #2 based on job responsibilities; (2) The surveyor asked testing person #1 if a written policy to evaluate the technical consultant, based on job responsibilities, was available and if competencies had been performed during the review period. Testing person #1 stated to the surveyor on 07/19/2021 at 10:40 am, a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed.
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 records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure an analyzer and materials were stored as required by the manufacturer for 7 of 13 months. Findings include: (1) On 07/19/2021 at 09:30 am, testing person #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn Emerald analyzer; (b) The laboratory used three levels of Cell Dyn 18 Plus quality control (QC) materials to perform QC each day of patient testing. (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer and the storage requirements for the QC material: (a) The operator's manual for the analyzer on page 2-4 under "Installation Environment" required a room temperature of 18-32 degrees Centigrade (C) and 64-90 degrees (F) Fahrenheit; (b) The package insert for the QC materials required storage at 2-8 degrees C. (3) The surveyor reviewed laboratory temperature and humidity records for 13 months (July 2020 through June 2021) and identified that temperatures had not been documented during 7 of 13 months as follows: (a) July 2020 - 4 of 21 days (i) 07/08 - The room and refrigerator temperatures had not been

	documented; (ii) 07/16 - The room temperature had not been documented; (iii) 07/17 - The refrigerator temperature had not been documented; (iv) 07/22 - The room and refrigerator temperatures had not been documented. (b) August 2020 - 1 of 23 days (i) 08/05 - The refrigerator temperature had not been documented. (c) September 2020 - 1 of 22 days (i) 09/17 - The room temperature had not been documented. (d) October 2020 - 2 of 22 days (i) 10/22 - The room temperature had not been documented; (ii) 10 /27 - The room temperature had not been documented. (e) November 2020 - 1 of 22 days (i) 11/24 - The room temperature had not been documented. (f) January 2021 - 5 of 20 days (i) 01/05 - The room temperature had not been documented; (ii) 01/11 - The room temperature had not been documented; (iii) 01/18 - The room temperature had not been documented; (iv) 01/19 - The room temperature had not been documented; (v) 01/20 - The room and refrigerator temperatures had not been documented. (g) February 2021 - 3 of 19 days (i) 02/10 - The room temperature had not been documented; (ii) 02/13 - The room temperature had not been documented; (iii) 02/17 - The room temperature had not been documented. (h) March 2021 - 1 of 23 days (i) 03/10 - The room temperature had not been documented. (i) April 2021 - 2 of 22 days (i) 04/28 - The room temperature had not been documented; (ii) 04/29 - The room temperature had not been documented. (j) May 2021 - 1 of 23 days (i) 05 /14 - The refrigerator temperature had not been documented. (4) The surveyor reviewed the records with testing person #1 who stated to the surveyor on 07/19/2021 at 12:30 pm, the room and refrigerator temperatures had not been documented on the above days.