Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0179861	09/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Medical Center	119 Wilson Road, Bentleyville, PA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which microbiology, chemistry and hematology tests were performed from 09/13/2021 to the date of the survey. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. The laboratory performs patient testing Monday through Friday from 08:00 am to 05:00 pm according to the information in the CMS-116 form. 3. Review of the laboratory personnel report (Pennsylvania State) form on 09/14/2023 showed that the laboratory director (LD) acts as the only general supervisor for the laboratory. The LD directs one other laboratory. 4. On the day of the survey, 09/14/2023 at 09:01 am, during an interview, the TP#1 stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing according to chapter 5 section 5.23 of the Pennsylvania State regulations for clinical laboratories.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the Laboratory Director failed to ensure 1 of 1 chemistry PT results and 3 of 3 hematology PT results were reviewed and corrective actions were taken for unsatisfactory PT in 2022. Findings include: 1. On the day of survey, 09/14/2023 at 09:55 am, review of the AAB-MLE PT records revealed that the laboratory did not document corrective actions for the following 1 of 1 unsatisfactory PT results for chemistry and 3 of 3 unsatisfactory PT results for hematology in 2022: 2022 Routine Chemistry 2nd Event: 80% for Iron. 2022 Hematology 3rd Event: 80% for Red Blood Cell Count (RBC). 80% for Hematocrit (HCT). 80% for Platelet Count. 2. TP#1 confirmed the findings above on 09/14/2023 around 01:50 pm.
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 review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the laboratory failed to verify the accuracy for 2 of 2 analytes for AAB-MLE PT tests in 2022. Findings include: 1. On the day of survey, 09/14/2023 at 09:55 am, review of AAB-MLE PT records revealed that the laboratory did not verify the accuracy for the following 2 of 2 non graded analytes: - Triiodothyronine - MLE 2022, 1st event and MLE 2022, 2nd event - Ferritin - MLE 2022, 1st event 2. TP#1 confirmed the findings above on 09/14/2023 around 01:50 pm.
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 review of the laboratory records, lack of documentation and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the laboratory failed to demonstrate and document verification of performance specifications for accuracy and precision for 14 of 14 analytes on the Abbott Cell-Dyn Emerald analyzer before

	reporting patient test results in November 2021. Findings include: 1. On the day of survey, 09/14/2023 at 09:21 am, the laboratory could not provide verification of performance specifications for accuracy and precision activities performed on the Abbott Cell-Dyn Emerald analyzer for the following analytes before reporting patient test results in November 2021: - White Blood Cell Count (WBC) - Lymphocytes (Lymph) - Monocytes (Mono) - Granulocyte - Lymphocytes % (Lym %) - Monocytes % (Mono %) - Granulocyte % - Red Blood Cell Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) 2. TP#1 confirmed the findings above on 09/14/2023 around 01:50 pm.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the technical consultant (TC) failed to assess the 6-months competency for 1 of 4 testing personnel (TP) performing hematology testing from 10/2021 to the day of survey. Findings include: 1. On the day of survey, 09/14/2023 at 10:58 am, the laboratory could not provide 6-months competency assessment records for 1 of 4 TP (CMS 209, personnel # 4) who started performing hematology testing in the laboratory in October 2021. 2. TP#1 confirmed the findings above on 09/14/2023 around 01:50 pm.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with the Testing Personnel #1 (TP) (CMS 209 personnel #2), the technical consultant (TC) failed to evaluate and document the annual competency for 1 of 4 testing personnel (TP) who performed hematology testing from 10/2021 to the day of survey. Findings include: 1. On the day of survey, 09/14/2023 at 10:58 am, the laboratory could not provide the annual competency assessment records for 1 of 4 TP (CMS 209, personnel # 4) who started performing hematology testing in the laboratory in October 2021. 2. TP#1 confirmed the findings above on 09/14/2023 around 01:50 pm.