Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0179861	09/13/2021
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
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 clinical staff competency assessment (CA) policy and interview with testing personnel (TP) #1, the laboratory failed to follow their written procedure to assess the competency 1 of 2 (TP) for each individual test system they performed in 2021. Findings include: 1. The clinical staff competency assessment policy, point #2 states, "Competency assessment must be assessed a minimum of twice in the first year of employment of testing personnel and annually there after". 2. On the day of survey, 09/13/2021, the laboratory was unable to provide CA records for the first year of employment for 1 of 2 TP (TP#1 started testing on 08/27/2020), for each test system performed in the departments of Clinical chemistry, Hematology, immunology and Virology in 2021. 3. The TP# 1 confirmed the findings above on 09 /13/2021 around 12:05 pm.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with testing personnel (TP)#1, the laboratory failed to have all laboratory procedures signed and dated by the current

	laboratory director (LD) from 09/13/2019 to 09/13/2021. Findings include: 1. On the day of survey, 09/13/2021, a review of a sampling of the laboratory procedures, revealed the laboratory procedures in use were not signed by the LD. 2. TP# 1 confirmed the findings above on 09/13/2021 around 2:05 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 testing personnel (TP) #1, the laboratory failed to demonstrate and document verification of performance specifications for accuracy and precision on the Ortho Clinical Diagnostics Vitros-ECiQ for Covid-19 antibody testing before reporting patient test results in 2020. Findings Include: 1. On the days of survey 09/13/2021, the laboratory could not provide verification of performance specifications for accuracy and precision activities performed on the Ortho Clinical Diagnostics Vitros-ECiQ for Covid-19 testing before reporting patient test result in 2020. 2. TP# 1 confirmed the finding above on 09/13/2021 around 1:00 p.m.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation and interview with testing personnel (TP) #1, the laboratory failed to establish a maintenance policy to assess the maintenance/function of 3 of 3 thermometers used to monitor the laboratory room, freezer and refrigerator temperatures and 4 of 4 Thermo Scientific Finnpipettes in use on 08/13/2021. Findings Include: 1. On the day of survey, 09/13/2021, observation of the laboratory revealed, the following thermometers and mechanical pipettes in use in the laboratory on 09/13/2021: 4 of 4 Thermo Scientific Finnpipettes: 2 ml Fixed Volume. 100 -1000 micro liter. 3 ml Fixed Volume. 5 ml Fixed Volume. 3 of 3 unlabeled thermometers 2. The laboratory could not provide a maintenance policy for the thermometers and pipettes. 3. The laboratory could not provide

	purchase records or previous maintenance/function check records performed on the thermometers and pipettes. 4. TP#1 confirmed the findings above on 09/13/2021 around 02:50 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration verification records and interview with testing personnel (TP) #1, the laboratory failed to perform calibration verification on the Ortho Clinical Diagnostics Vitros-ECiQ for Vitamin D, Vitamin B and Covid-19 twice annually in 2020 and 2021. Findings Include: 1. On the day of survey, 09/13/2021, a review of calibration verification records revealed, the laboratory did not perform calibration verification on the Ortho Clinical Diagnostics Vitros-ECiQ for Vitamin D, Vitamin B and Covid-19 at least twice annually in 2020 and 2021. 2. TP#1 confirmed the finding above on 09/13/2021 around 02:00 pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on review of laboratory daily room temperature and humidity records and interview with testing personnel (TP) #1, the laboratory failed to document corrective actions taken when the temperatures and humidity exceeded acceptable ranges from 01/10/2020 to 08/13/2021. Findings include: 1. The laboratory daily room temperature and humidity records states, "Corrective action taken (circle applicable action)." "Corrective action Key: A. Immediately contact supervisor/management if room temp is greater than 80 degrees Celsius or less that 60 degrees Celsius or room humidity is greater than 60% or less than 30%. B. Relocate reagents and specimens to nursing refrigerator located at nursing station in packaged in biohazard - marked baggies. C. After determining functional cause of temp/humidity issue, monitor continuously unit for the next 8 hours shift". 2. On the day of survey, 09/13/2021, review of the laboratory daily room temperature and humidity records revealed, the laboratory did not documents the following days room temperature and humidity exceeded acceptable ranges in 2020 and 2021. - Room Temperature Acceptable Range (68-77 degrees Fahrenheit): 01/10/2020 - 79 degrees Fahrenheit. 02/04/2020 - 78 degrees Fahrenheit. 03/12/2020 - 80 degrees Fahrenheit. 03/13/2020 - 80 degrees Fahrenheit. 05/15/2020 - 78 degrees Fahrenheit. 08/13/2020 - 64 degrees Fahrenheit. 08/13/2020 - 66 degrees Fahrenheit. 09/28/2020 - 67 degrees Fahrenheit. 09/29/2020 - 68 degrees Fahrenheit. 09/20/2020 - 66 degrees Fahrenheit. 01/06/2021 - 67 degrees Fahrenheit. 01/18/2021 - 67 degrees Fahrenheit. 01/19/2021 - 66 degrees Fahrenheit. 02/23/2021 - 64 degrees Fahrenheit. 02/25/2021 - 67 degrees Fahrenheit. 02/26/2021 - 66 degrees Fahrenheit. 03/19/2021 - 55 degrees Fahrenheit. 04/06/2021 - 66 degrees Fahrenheit. - Humidity Acceptable Range (15-55%): 02/08/2021 - 12%. 03/05/2021 - 14%. 03/08/2021 - 12%. 03/13/2021 - 13%. 03/14/2021 - 13%. 06/10/2021 - 59%. 06/14/2021 - 58%. 06/21/2021 - 60%. 06/28/2021 - 61%. 06/29/2021 - 57%. 07/09/2021 - 56%. 08/05/2021 - 56%. 08/09/2021 - 57%. 08/12/2021 - 57%. 08/17/2021 - 60%. 08/20/2021 - 57%. 08/23/2021 - 61%. 08/24/2021 - 62%. 08/31/2021 - 57%. 09/01/2021 - 59%. 09/02/2021 - 59%. 09/07/2021 - 59%. 09/08/2021 - 60%. 09/13/2021 - 58%. 3. The laboratory could not provide a laboratory daily room temperature and humidity corrective actions procedure. 4. TP#1 confirmed the findings above on 09/13/2021 around 2:30 pm. Please See Below: The temperatures on the Corrective action key are incorrect: **** 80 degrees Celsius = 176 degrees Fahrenheit. **** 60 degrees Celsius = 140 degrees Fahrenheit.
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 review of quality assessment records, lack of documentation and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure that QA programs were established and maintained to assure the quality of laboratory services provided from 09/13/2019 to 09/13/2021. Findings Include: 1. On the date of survey, 09/13/2021, review of monthly QA documents revealed the following records were not signed by the LD or filled out completely to assure the quality of laboratory services provided from in 2021: - March: not completed. - April: not signed by LD. -

	May: not signed by LD. - June: not completed. - July: not signed by LD. - August: not signed by LD. 2. The laboratory could not provide a QA procedure. 3. TP#1 confirmed the findings above on 09/13/2021 around 1:20 pm.
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: Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the testing personnel (TP) #1, the laboratory failed to ensure 1 of 2 TP preforming moderate complexity testing is qualified. Refer to D6065
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 review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the testing personnel (TP) #1, the laboratory failed to ensure 1 of 2 TP performing moderate complexity testing is qualified. Findings Include: 1. The CMS 209 form signed by the Laboratory Director (09/13/2021), lists Individual #3 as TP#2. 2. On the day of survey, 09/13 /2021, TP#1 could not provide education credentials for TP #2 who was hired 09 /2021. 3. TP#1 confirmed the findings above on 09/13/2021 around 3:00 pm.