Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0415401	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Shah Medical Center	484 Summit St, Elgin, IL	

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
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 review of pre-survey documentation; proficiency testing (PT) records; and interview with the laboratory manager, the laboratory failed to enroll in a HHS approved proficiency testing program for its Complete Blood Counts which includes Red Blood Cells; White Blood Cells; Hemoglobins; Hematocrits; and Platelets in the specialty of Hematology for the years 2020 and 2021. Findings: 1. Pre- survey documents including "CLIA Application and Survey Summery" (CASPER Report 0096D) and "Individual Laboratory Profile" (CASPER Report 0155 D) revealed that there were no PT scores documented for PT Events 1, 2, and 3 of 2020 and PT Events 1 and 2 of 2021. 2. On survey date June 8, 2021 at 10:30 AM, the surveyor made a request for PT records for 2020 and 2021. There were no PT records from January 1, 2020 through June 8, 2021 made available to the surveyor. 3. On survey date June 8, 2021 at 10:40 AM, the laboratory manager told the surveyor that she didn't think the laboratory had enrolled for PT in 2020; and confirmed that the laboratory was not currently enrolled in a PT program for 2021, confirming the surveyor's findings.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of Quality Control (QC) records and interview with the laboratory manager, the laboratory failed to meet the applicable requirement under 493.1101 for its CBC (RBC, WBC, HGB, HCT, and Platelets) as specified. Findings: 1. Review of QC records revealed, the laboratory failed to retain manufacturer's assay information sheets for its QC materials. See tag D3031 2. On survey date June 8, 2021 at 11:30 AM, the laboratory manager confirmed the surveyor's findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY - ALSO CITED JANUARY 14, 2019 Based on review of patient test records; quality control (QC) records; and interview with the laboratory manager, the laboratory failed to retain all quality control records for its CBC testing as required. Findings: 1. On survey date June 8, 2021 at 11:00 AM, the surveyor requested patient test reports along with their corresponding QC records for the following dates: a. 03/01/2019 b. 05/31/2019 c. 07/03/2019 d. 09/03/2019 e. 09/04 /2019 f. 11/25/2019 g. 04/03/2020 2. On survey date June 8, 2021 at 11:00 AM, review of corresponding QC records for the dates above revealed that the laboratory failed to retain the manufactures assay information sheets for control materials for the following lot numbers: a. Date 03/01/2019 - lots 2181131+, 2181132+, and 218113+ b. Date 05/31/2019 - lots 2190221+, 2190222+, and 2190223+ c. Date 07/03/2019 - lots 2190521+, 2190522+, and 2190523+ d. Date 09/03/2019 - lots 2190521+, 2190522+, and 2190523+ e. Date 09/04/2019 - lots 2190521+, 2190522+, and 2190523+ f. Date 11/25/2019 - lots 2190821+, 2190822+, and 2190823+ g. Date 04 /03/2020 - lots 2200231+, 2200232+, and 2200233+ 3. On survey date June 8, 2021 at 11:30 AM, the laboratory manager confirmed the surveyor's findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on surveyor observations; review of manufacturer's assay information sheets; and interview with the laboratory manager, the laboratory failed to indicate preparation and expiration dates of its Tri-Level CBC control materials. Findings: 1. On survey date June 8, 2021 at 10:00 AM, the surveyor did a walk-through of the laboratory. The surveyor observed that the lab's current lot of Boule Con-Diff Tri-Level CBC Controls are stored on a shelf in the laboratory's refrigerator. 2. On survey date June 8, 2021 at 10:00 AM, the surveyor reviewed manufacturer's assay information for "Boule Con-Diff Tri-Level" (controls). In a section titled, "STORAGE AND STABILITY," the instructions read as follows: "When stored at 2-10 C, sealed vials are stable at least until expiration shown on the TABLE OF EXPECTED RESULTS. Open vial stability 14 days after opening when returned to the refrigerator after each use." 3. Review of the label on the vial of the laboratory's current lots of Boule Con -Diff Tri Level QC in use showed that the laboratory had not recorded the date the QC was opened, nor had the lab recorded the 14 day expiration on the vials. The surveyor could not determine if the QC vials were expired. 4. On survey date June 8, 2021 at 10: 30 AM, the laboratory manager confirmed the surveyor's findings.
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 review of manufacturer's instructions; laboratory records; calibration records; and interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures according to the manufacturer's instructions of the lab's Medonic M Series Hematology Analyzer for Complete Blood Counts (CBC). Findings: 1. Review of manufacturer's instructions for calibration of the Medonic M Series Hematology Analyzer revealed in a section titled, "Section 7:

	Calibration", it reads as follows: "Good laboratory practice requires regular checks and calibration of the measured parameters. It is recommended to calibrate the instrument every 6 months." 2. Review of laboratory records revealed that the lab's Medonic M Series Hematology Analyzer failed the background check on the following dates: a. 08/31/2020 b. 09/03/2020 c. 09/04/2020 d. 09/08/2020 e. 09/21 /2021 3. Review of Calibration records revealed calibration was last performed on 08 /07/2020. There was no documentation to show that Calibration of the lab's Medonic M Series Hematology Analyzer was performed from January 1, 2021 through June 8, 2021 (the date of the CLIA laboratory survey). 4. On survey date 06/08/2021 at 11:00 AM, the laboratory manager confirmed the surveyor's findings.
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 review of laboratory records; personnel records; and interview with the laboratory manager, the laboratory did not have a director who provides overall management and direction in accordance with 493.1407 of this subpart. Findings: 1. The laboratory director failed to ensure that the laboratory was enrolled in an approved proficiency testing program in 2020 and 2021. See tag D6015 2. There is no documentation to show Quality Assessments are performed to ensure the lab maintains the quality of services provided. See tag D6021 3. The laboratory director failed to ensure that testing personnel were educated; trained to perform testing; and assessed to ensure that testing personnel could demonstrate that they can perform Hematology Testing accurately and reliably. See tags D6029 and D6065 4. The laboratory director failed to provide an approved procedures manual for testing personnel. See tag D6031.
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 proficiency testing records and interview with the practice manager, the laboratory director failed to ensure the laboratory enrolled in an HHS approved proficiency testing (PT) program for its Complete Blood Count (CBC) testing. Findings: 1. Review of PT records revealed that the laboratory was not enrolled in PT in 2020 and 2021. See tag D2000 2. On survey date June 8, 2021 at 10: 40 AM, the laboratory manager confirmed the surveyor's findings.
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 lack of documentation; review of laboratory records; and interview with the laboratory manager, the laboratory director failed to ensure that quality assessment (QA) programs are established and maintained to assure the quality of laboratory services provided. Findings: 1. On survey date June 8, 2021 at 10:00 AM, the surveyor requested to see the laboratory's procedures manual. No procedure manual was made available to her. 2. Review of laboratory records and surveyor observations revealed the following information: a. There was no documentation to show that the laboratory retained manufacturer's assay information sheets for Quality Control (QC) material of its Hematology Analyzer. See tag D3031 b. The laboratory did not document 14-day expiration of it QC reagents. See tag D5415 c. The laboratory did not perform calibration of its Hematology Analyzer according to the manufacturer's instructions. See tag D5439. d. There was no documentation to show Quality Assessments were performed from March 1, 2019 through June 8, 2021, 3. On survey date June 8, 2021 at 11:30 AM, the laboratory manager confirmed the surveyor's findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY - ALSO CITED JANUARY 14, 2019 Based on review of pre- survey documentation; Laboratory Personnel Report (FORM 209) ; personnel records; the laboratory's application for CLIA Certification (FORM 116)and interview with the laboratory manager, the laboratory director failed to be responsible for ensuring that prior to testing patients specimens, all testing personnel (TP) have the appropriate education and experience, receive the appropriate training; and have demonstrated that they can perform all testing operations reliably. Findings: 1. Review of pre- survey documents that included Laboratory Personnel Report - CLIA (FORM 209) revealed that there was a total of 9 persons listed as TP in the laboratory. Seven (TP3, TP4, TP5, TP6, TP7, TP8, and TP9) of 9 Testing Personnel were new TP in the laboratory. 2. On survey date June 8, 2025 at 9:30 AM, review of personnel records revealed the following information: a. There was no documentation to show

	the highest level of education achieved (diploma or degree) for 4 of 7 new TP (TP 6, TP7, TP8, and TP9). b. There was no documentation of training for 7of 7 new TP (TP3, TP4, TP5, TP6, TP7, TP8, and TP9). c. There were no competency assessments for 8 of 9 TP (TP2, TP3, TP4, TP5, TP6, TP7, TP8, and TP 9) in 2020 and 2021. 3. The laboratory listed a total of 8310 Hematology (CBC) tests performed in 2020. 4. On survey date June 8, 2021 at 10:30 AM, the laboratory manager confirmed the surveyor's findings.
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: Based on lack of documentation and interview with the laboratory manager, the laboratory director failed to be responsible for ensuring that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings: 1. On survey date June 8, 2021 at 11:15 AM, the surveyor attempted to review the procedures manual to show the laboratory manager procedures laboratory personnel should be following. However, the laboratory manager could not find the procedures manual. The procedures manual was not made available to the surveyor during her time surveying (June 8, 2021 from 8:30 AM to 11:30 AM). 2. On survey date June 8, 2021 at 11:30 AM, the laboratory manager confirmed the surveyor's findings.
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 personnel records and interview with the laboratory manager, testing personnel failed to meet the minimum educational requirement to perform Hematology Testing (moderate complexity) in the laboratory 1. On survey date June 8, 2021 at 9:45 AM, review of 9 personnel records revealed that there were no diplomas or degrees to show the highest level of education for 4 of 9 TP (TP6, TP7, TP8, and TP9). See tag D6065 2. On survey date June 8, 2021 at 10:00 AM, the laboratory manager confirmed the surveyor's findings.
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 Clinical Laboratory Improvement Amendments (CLIA) Application For Certification (FORM 116)Laboratory Personnel Report (FORM 209); personnel records; and interview with the laboratory manager, testing personnel failed to meet the minimum educational requirement to perform Hematology Testing (moderate complexity) in the laboratory. Findings: 1. On survey date June 8, 2021 at 9: 30 AM, review of FORM 116 shows that the laboratory listed that it performs Hematology CBC testing using the Medonic M Series Analyzer, along with waived tests. 2. Review of FORM 209 submitted during survey date June 8, 2021 revealed that there are a total of 9 testing personnel (TP)performing moderate complexity testing in the laboratory. 3. On survey date June 8, 2021 at 9:45 AM, review of 9 personnel records revealed that there were no diplomas or degrees to show the highest level of education for 4 of 9 TP (TP6, TP7, TP8, and TP9). 4. On survey date June 8, 2021 at 10:00 AM, the laboratory manager confirmed the surveyor's findings.