Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0415401	01/14/2019
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
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 that was also cited during the survey of 2015. Based on review of laboratory records and interview with testing personnel; the laboratory failed to retain all records as it pertains to the quality of the analytic system of its CBC analyzer. Findings include: 1. On survey date 01/14/19, the surveyor requested 6 patients test records, along with the corresponding QC documentation for the date of patients" testing, as well as the manufacturer's assay information sheets for the corresponding QC lots. 2. Review of laboratory records revealed the laboratory did not retain the manufacturer's assay information sheets for 5 of 6 dates for the following lots of QC material: a. 05/30/2017 - lot # 2170221+ (Low Control); lot # 2170222+ (Normal Control); and lot # 2170223+ (High Control). b. 11/17/2017 - lot # 2170831+ (Low Control); lot # 2170832+ (Normal Control); and lot # 2170833+ (High Control). c. 01/16/2018 - lot # 2171131+ (Low Control); lot # 2171132+ (Normal Control); and lot # 2171133+ (High Control). d. 04/27/2018 - lot # 2180231+ (Low Control); lot # 2180232+ (Normal Control); and lot # 2180233+ (High Control). e. 09/05/2018 - lot # 2180531+ (Low Control); lot # 2180532+ (Normal Control); and lot # 2180533+ (High Control). 3. On 01/14/19 at 11:30 AM, testing personnel confirmed the surveyor's findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of pre-survey documents and proficiency testing (PT) records and interview; the laboratory failed to retain all proficiency testing records for at least 2 years. Findings include: 1. Review of pre-survey documents that included PT scores for CASPER Report 0096D revealed that there were PT scores for all PT events for 2016, 2017, and 2018. 2. Review of laboratory PT records revealed that there was no documentation available for review for 3 of 3 PT events of 2017. Testing personnel told the surveyor that the PT records for 2017 could not be found. 3. On 01/14/19 at 10:30 AM, testing personnel 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: Based on review of pre-survey documentation and personnel records and interview; the laboratory director failed to 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. Findings include: 1. Review of pre-survey documents that included "Laboratory Personnel Report - CLIA" (CMS FOR 209) revealed that there were a total of 7 persons listed as testing personnel for moderate complexity testing in the laboratory. Three out of 7 testing personnel were new testing personnel in the laboratory. 2. Review of personnel records revealed the following information: a. There was no documentation to show the highest level of education achieved for 2 of 3 new testing personnel. b. There was no documentation of training for 2 of 3 new testing personnel. c. There was no documentation to show that competency assessments were performed for 2 of 3 new testing personnel. 3. On 01/14/18 at 10:30 AM, testing personnel confirmed the surveyor's findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

	processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the application for CLIA Certification; Laboratory Personnel Report - CLIA; procedures manual; and personnel records, and interview; the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting, and whether consultant or director review is required prior to reporting patient test results. Findings include: 1. Review of the laboratory's application for certification revealed that the laboratory performed the following tests: a. Waived tests (PT-INR, A1C, UA, UA MICROALBUMIN) b. Complete Blood Counts (CBCs) 2. Review of Laboratory Personnel Report - CLIA revealed that the laboratory had a total of 7 testing personnel in the laboratory. 3 of 7 test personnel were new testing personnel. 3. Review of the laboratory's procedures manual revealed that the laboratory director had not specified, in writing, which tests each testing person was authorized to perform for 3 of 7 testing personnel. 4. Review of personnel records revealed that the laboratory director had not specified, in writing, which tests each testing person was authorized to perform for 3 of 7 testing personnel. 5. On 01/14/19 at 10:00 AM, testing personnel confirmed the surveyor's findings.