Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0978140	07/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Azizkhan Internal Medicine Associates	888 Poplar Church Road, Camp Hill, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to sign 1 of 3 Chemistry-Core API PT attestation statements in 2020 Findings include: 1. On the day of survey 07/06/2021, review of API PT records revealed, 2020 Event 1 Chemistry-Core API PT attestation statement was not signed by the LD. 2. The TP confirmed the finding above on 07/06/2021 at 10:00 am.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by:

	Based on review of the American Proficiency Institute (API) proficiency test (PT) records, lack of documentation and interview with the Testing Personnel (TP), the laboratory failed to participate in 1 of 3 hematology/coagulation proficiency events in 2020. Findings include: 1. On the day of survey, 07/06/2021 at 10:00 a.m. review of API PT records revealed the laboratory failed to participate in the Hematology /Coagulation event #1 in 2020. 2. The TP confirmed the findings above on 07/06/2021 around 10:00 a.m.
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 Proficiency Institute (API) proficiency testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate PT results for 1 of 3 Hematology/Coagulation events in 2021. Findings include: 1. On the day of survey 07/06/2021, The laboratory could not provide documentation of evaluation & review performed on the 2021 Hematology /Coagulation Event 1. The laboratory received a 80% score 2. The TP confirmed the finding above on 07/06/2021 at 10:00 a.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals and interview with the Testing Personnel (TP), the laboratory failed to include procedures for verification of performance specifications when adding a new instrument/test and reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 07/06/2019 to the day of survey. Findings include: 1. On the day of survey, 07/06 /2021 at 12:40 p.m., the laboratory could not provide procedures for the following: - Verification of performance specifications when adding a new instrument/test from 07 /06/2019 to the day of survey. - reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 11/16/2020 to the day of survey. 2. The TP confirmed the findings above on 07/06/2021 at 12: 45 p.m.
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 the Testing Personnel (TP), the Laboratory Director (LD) failed to approve and sign 3 of 3 procedures in the laboratory from 07/06/2019 to the date of survey. Findings included: 1. On the day of survey 07/06/2021, a review of the manuals revealed, the following procedures were not approved and signed by the LD prior to patient testing: - Personnel Competency. - Quality Assurance Program. - Maintenance and Quality Control Procedures. 2. The TP confirmed the findings above on 07/06/2021 at 12:00 p.m.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records review and interview with Testing Personnel (TP), the laboratory failed to ensure that an effective corrective action plan was documented for unsatisfactory, and unsuccessful proficiency testing scores for Chemistry and Hematology events in 2020 and 2021. Findings include: 1. On the day of survey 07/06/2021, review of API PT records revealed, the following PT events had an incomplete corrective actions for unsatisfactory and unsuccessful PT scores: Chemistry-Core: - 2020 event 3: 25-OH Vitamin D (50%) Ferritin (0%) UIBC, Measured (0%) - 2021 event 1: 25-OH Vitamin D (0%) TIBC, Measured (40%) Hematology/Coagulation: - 2020 Event 2: Sedimentation Rate (50%) - 2020 Event 3: Sedimentation rate (50%) 2. The TP confirmed the findings above on 07/06/2021 at 10:00 a.m.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interviewed with Testing Personnel (TP), the Laboratory Director (LD) did not ensure an approved corrective action plan was followed for 1 of 1 unsatisfactory PT performance Chemistry-Core Event 1 in 2020. Findings include: 1. On the day of survey 07/06/2021, review of API PT record revealed, the following unsatisfactory scores: Chemistry-Core: - 2020 Event 1: UIBC, measured (0%) 2. The laboratory could not provide corrective action plan documentation for the unsatisfactory score. 3. The TP confirmed the findings above on 07/06/2021 at 10:00 a.m.

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 the procedure manual, lack of documentation and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure general laboratory Quality Assessment (QA) programs were maintained to ensure the quality of laboratory services provided from 07/06/2019 to the day of survey. Findings Include: 1. The Quality Assurance Program procedure states (page 1): "Monthly reports to the laboratory director will include Monthly QC, Quarterly Audits, a proficiency testing summary, performance improvement activities, calibration verifications, incident report, patient complaints and training/competencies for all testing". 2. On the day of survey 07/06/2021, the TP could not provide QA documentation of periodic evaluation used by the laboratory to assess its preanalytical, analytical, and postanalytical processes from 07/06/2019 to the day of survey. 3. TP confirmed the findings above on 07/06/2021 at 12:25 p.m.
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 lack of documentation and interview with the Testing Personnel (TP), the laboratory director failed to ensure that prior to testing patient specimens, the testing personnel received the appropriate training for the type and complexity of the services offered from 06/22/2020 through the time of survey. Findings include: 1. On the day of survey 07/06/2021, the laboratory could not provide training records for1 of 1 testing personnel performing non waived Hematology testing on the Horiba Pentra XL 80 system. 2. The TP confirmed the finding above on 07/06/2021 at 09:45 a.m.
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 lack of documentation, review of the Personnel Competency procedure and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to evaluate and document the Competency Assessment (CA) of 1 of 1 testing personnel responsible for performing Hematology, Chemistry, and General Immunology testing from 06/22/2020 to the day of survey. Findings include: 1. The laboratory's Personnel Competency procedure states: - " CA, which includes the six procedures, must be performed for TP for each test that the individual is approved by the laboratory director to perform" (Page 1). - "The Laboratory Director is responsible for performing and documenting competencies for the Medical Technologist"(Page 2). - "Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens" (page 2). 2. On the day of survey 07/06/2021, the laboratory was unable to provide the competency assessment records for 1 of 1 TP for the following test from 06/22/2020 to 07/06/2021: - Hematology: Complete Blood Count (CBC) and Sedimentation rate. - Chemistry: Vitros5600. - General Immunology: C- reactive protein (CRP). 3. The TP confirmed the findings above on 07/06/2021 at 09:40 a.m