

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0978140	<b>(X3) Date Survey Completed</b> 07/15/2025
<b>Name of Provider or Supplier</b> Azizkhan Internal Medicine Associates	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, and interview with Technical Consultant (TC ) #1, the laboratory director/owner failed to ensure that 1 of 1 laboratory personnel met the minimum qualifications specified in the Pennsylvania (PA) Clinical Lab Act to perform supervisor responsibilities from 7/1/2025 to 7/15/2025. Findings include: 1. On the day of survey, 7/15/2025 at 1:30 pm, review of personnel credentials and the Laboratory Personnel Report (Pennsylvania State) onsite revealed Testing Personnel (TP) #1 (PA LPR document) was performing the duties of a General Supervisor from 7/1/2025 to 7/15/2025. 2. Review of personnel credentials revealed that TP#1 attained a Bachelor of Science degree in Medical Technology in May 2022. 3. Further review of laboratory records revealed that TP#1 had reviewed documents pertaining to quality assurance, quality control reports, temperature records, and test logs. 4. The laboratory was unable to provide the acceptable documentation of 6 years experience for TP#1 needed to perform the duties of a supervisor in the state of Pennsylvania from 7/1/2025 to 7/15/2025. 5. TC#1 confirmed the findings above on 7/15/2025 at 02:00 pm.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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. In addition, retain the following:</p>

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with Technical Consultant (TC) #1, the laboratory failed to retain records for background counts on 1 of 1 Horiba Pentra XL80 used for complete blood cell count (CBC) testing performed from 9/1/2023 to 9/11/2023. Findings include: 1. On the day of the survey, 7/15/2025 at 11:45 am, the laboratory failed to provide documentation for the background counts performed on 1 of 1 Horiba Pentra XL80 used for CBC testing from 9/1/2023 to 9/11/2023. 2. TS #1 confirmed the finding above on 7/15/2025 at 12:30 pm.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of the Laboratory's Quality Assurance (QA) Program policy, lack of documentation, and interview with Technical Consultant (TC) #1, the laboratory failed to follow the laboratory's written QA policy for 8 of 8 quarters from 8/22/2023 to 7/15/2025. Findings include: 1. The laboratory's Quality Assurance Program policy stated, "The Regulations specify ten different standards to be included in a laboratory's quality assurance program. Standard 1 Patient Test Management Standard 6 Personnel Assessment Standard 2 Quality Control Assessment Standard 7 Communications Standard 3 Proficiency Testing Standard 8 Complaint Investigations Standard 4 Test Comparisons Standard 9 Quality Assurance Review with Staff Standard 5 Relate Results to Clinical Data Standard 10 Quality Assurance Records The Quality Assurance Monthly Report contains: Patient Test management, Quality Control Assessment, and Complaint Investigations. The Quality Assurance Quarterly Report contains Patient Test Management, Quality Control Assessment, Proficiency Testing Assessment, Personnel Assessment, Communications, and Quality Assurance Review with Staff." 2. On the day of the survey, 7/15/2025 at 11:30 am, the laboratory failed to provide documentation of the Quality Assurance Quarterly Report performed for 8 of 8 quarters from 8/22/2023 to 7/15/2025. 3. TC #1 confirmed the above findings on 7/15/2025 at 12:30 pm.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
 Based on observation of the laboratory, review of laboratory temperature records, and interview with Technical Consultant (TC) #1, the laboratory failed to monitor room temperatures to ensure proper storage of reagents were met for 224 of 692 days from 8/22/2023 to 7/15/2025. Findings include: 1. On the day of survey, 7/15/2025, at 1:00 pm, during the tour of the laboratory, the surveyor observed the following supplies stored in the laboratory: - 3 XPert COV2/FLU/RSV kits. Storage requirements 2C to 28C . - 1 each of Sed Plus Normal and Abnormal QC. Storage requirements 18C to 30C . - 1 OSOM H Pylori kit. Storage requirements 2C to 30C . - 2 OSOM Mono kits. Storage requirements 15C to 30C . - 1 OSOM HCG kit. Storage requirements 15C to 30C . - 3 Siemens Multistix. Storage requirements 15C to 30C . 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures to ensure the proper storage of reagents for 224 of 692 days when the laboratory was not performing testing from 8/22/2023 to 7/15/2025. 3. TC #1 confirmed the findings above on 7/15/2025 at 1:30 pm.

**D5783**

**CORRECTIVE ACTIONS**  
 CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's quality control (QC) records, lack of documentation, and interview with the Technical Consultant (TC) #1, the laboratory failed to provide documentation of the corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing performed on 1 of 1 Horiba Pentra XL 80 analyzer on 6/26/2025. Findings Included: 1. On the day of survey, 7/15/2025 at 12:30 pm, review of the laboratory's QC records revealed that the following analytes from the complete blood count with automated differential for the Low Level QC were flagged by 1 of 1 Horiba Pentra XL 80 analyzer as unacceptable with a comment of rejected analysis on 6/26/25: Absolute Neutrophils Absolute Lymphocytes Absolute Monocytes Platelet Count Mean Platelet Volume 2. The laboratory could not provide documentation of the corrective actions taken for QC performed on the Horiba Pentra XL 80 that did not meet the laboratory's established acceptable criteria. 3. The laboratory reported the following patients when QC did not meet the laboratory's established acceptable criteria on 6/26/2025: - Specimen ID# 6880-0 - Specimen ID# 34408-0 - Specimen ID # 43643-0 - Specimen ID# 45-0 - Specimen ID# 16515-0 - Specimen ID # 26866-0 - Specimen ID# 8835-0 - Specimen ID# 4172-0 - Specimen ID # 3744-0 - Specimen ID# 4172-0 - Specimen ID# 10650-0 - Specimen ID# 32259-0 - Specimen ID# 34501-0 - Specimen ID# 9427-0 - Specimen ID# 42272-0 - Specimen ID# 31325-0 - Specimen ID# 15057-0 - Specimen ID# 30559-0 - Specimen ID# 28310-0 - Specimen ID# 1141-0 - Specimen ID# 20322-0 4. The laboratory could not provide documentation that the patient test results were evaluated to determine if the results were adversely affected due to QC failures. 5. The TC #1 confirmed the findings above on 7/15/2025 at 1:45 PM.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and interview with Technical Consultant (TC) #1, the laboratory director (LD) failed to ensure that 2 of 2 procedures were approved and available to personnel that performed testing from 8/22/2023 to 7/15/2025. Finding Include: 1. On the day of survey, 7/15/2025 at 10:00 am, review of the laboratory's current procedure manual revealed the LD failed to ensure the following 2 of 2 procedures were approved and available to personnel that performed any aspect of the testing process in the laboratory from 8/22/2023 to 7/15/2025: - Critical Value Policy - Temperature Monitoring 2. The TC #1 confirmed the finding above on 7/15/2025 at 12:00 pm.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of personnel qualification records and interview with Technical Consultant (TC) #1, the laboratory failed to ensure that 1 of 1 TP (CMS 209 TP#2 dated 7/1/2025) performing the duties of a TC met the minimum qualification requirements (493.1411) for moderate complexity hematology testing from 6/17/2023 to 6/17/2025. Refer to D6034.

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to ensure that 1 of 1 TP (CMS 209 TP #2) performing the duties of a technical consultant met the qualification requirements (493.1411) for moderate complexity hematology testing from 8/22/2023 to 7/15/2025. Findings include: 1. On the date of survey, 6/17/2025 at 11:30 am, review of laboratory records revealed 1 of 1 TP (CMS 209, TP#2) was performing the duties of a TC from 6/17/2023 to 6/17/2025. a). Performing personnel competency assessment records in 2025 2. The laboratory provided the following credentials for TP#2 on 7/15/2025: - HEW Certification 3. Further review of the CMS 209 on the date of survey revealed TP #2

was not listed as a TC. 4. TC #1 confirmed the above findings, TP #2 did not meet the minimum requirements to perform the duties of a TC, on 7/15/2025 at 1:30 pm.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manuals, lack of documentation, and interview with the Technical Consultant (TC) #1, the TC failed to evaluate the test performance of 2 of 2 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for chemistry and hematology examinations performed from 8/22/2023 to 7/15/2025. Findings Include: 1. On the day of survey, 7/15/2025, at 10:30 am, review of the laboratory's "Personnel Competency and Technical Consultant Designee Guidelines policy stated, "The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observation of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observations of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; and 6. Assessment of problem solving skills. 2. The laboratory failed to provide documentation for the evaluation of test performance of 2 of 2 TP (CMS 209, TP #1 and #2) through internal blind testing or external PT testing for chemistry and hematology examinations performed from 8/22/2023 to 7/15/2025. 3. TC #1 confirmed the findings above on 7/15/2025 at 12:30 pm.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manuals, lack of documentation, and interview with the Technical Consultant (TC) #1, the TC failed to evaluate the assessment of problem solving skills for 2 of 2 testing personnel (TP) for chemistry and hematology examinations performed from 8/22/2023 to 7/15/2025. Findings Include: 1. On the day of survey, 7/15/2025, at 10:30 am, review of the laboratory's "Personnel Competency and Technical Consultant Designee Guidelines policy stated, "The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observation of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observations of performance of instrument maintenance and

function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: and 6. Assessment of problem solving skills. 2. The laboratory failed to provide documentation for the evaluation of the assessment of problem solving skills for 2 of 2 TP (CMS 209, TP #1 and #2) for chemistry and hematology examinations performed from 8/22/2023 to 7/15/2025. 3. TC #1 confirmed the findings above on 7/15/2025, at 12:30 pm.