

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2178668	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Texas Kidney Foundation	Street Address, City, State 4204 Gardendale, San Antonio, TX	
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
D0000	<p>The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories following a survey completed on 11/20/2025 resulting in a finding of IMMEDIATE JEOPARDY. The following condition(s) were not met: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of reagents stored in the laboratory's refrigerator, review of manufacturer's instructions and staff interview, the laboratory failed to have documentation of monitoring refrigerator temperature to ensure reagents were stored at temperatures required by the manufacturer for 5 of 5 waived reagents. The findings included: 1. Surveyor observation of the laboratory's refrigerator on 11/20/2025 at 1100 hours identified the following stored reagents and manufacturer required storage ranges: a) Abbott Cholestech LDX 1 box Lipid profile storage: 2 - 8C b) Abbott Cholestech LDX Controls 1 box Multianalyte controls storage: 2 - 8C c) Abbott Afinion 2 boxes HbA1C Controls storage: 2- 8C d) Stat Sensor Creatinine Controls 14 boxes Level 1 storage: 2 - 8C e) Stat Sensor Creatinine Controls 15 boxes Level 3 storage: 2 - 8C 2. The laboratory did not have documentation of monitoring</p>

	<p>refrigerator temperatures to ensure reagents were stored at the required temperature. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1150 hours in the office.</p>
<p>D3031</p>	<p>RETENTION REQUIREMENTS 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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Afinion ACR testing records from June 2025 to November 2025, and staff interview, the laboratory failed to retain documentation of package inserts for 2 of 2 test kits and 1 of 1 control kits. The findings included: 1. A review of the laboratory's testing records from June 2025 to November 2025 identified the following reagents were utilized by the laboratory: a) Afinion ACR test cartridges Lot: 10231681 Lot: 10233797 b) Afinion ACR control material: Lot: 1023167 2. Further review of the laboratory's testing records determined the laboratory failed to retain manufacturer's instructions for each of the 3 lots of ACR cartridges and control material. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1150 hours in the office.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of the laboratory's quality control records, review of patient test records, and staff interview, the laboratory failed to meet the requirements of analytic systems. The findings included: 1. The laboratory failed to have written instructions for performing ACR testing on the Abbott Afinion analyzer (refer to D5401). 2. The laboratory failed to have documentation of monitoring environmental conditions (refer to D5413). 3. The laboratory failed to have documentation of monitoring quality control values over time (refer to D5441). 4. The laboratory failed to have documentation of performing quality control testing each day of patient testing (refer to D5447). 5. The laboratory failed to have documentation of establishing a Quality Assessment program to monitor analytic systems (refer to D5791). Key ACR: Albumin/Creatinine</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

(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's records and staff interview, the laboratory failed to have written procedures for 1 of 1 assays performed on the Abbott Afinion. The findings included: 1. A review of the laboratory's records determined the laboratory failed to have documentation of written procedures for the ACR assay performed on the Abbott Afinion. 2. Further review determined the laboratory failed to have manufacturer's instructions for use as a substitute for written procedures. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview on 11/20/2025 at 1200 hours in the office. Key ACR - albumin/creatinine

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 review of the manufacturer's instructions for the Abbott Afinion analyzer, review of the manufacturer's instructions for the Abbott ACR test cartridge, review of the manufacturer's instructions for the Abbott ACR controls, review of the laboratory's days of testing, and staff interview, the laboratory failed to have documentation of monitoring temperature and humidity of the test area for 6 of 6 testing days. The findings included: 1. A review of the manufacturer's instructions for the Abbott Afinion analyzer (1116752 Rev. A, 2018/09) identified the following required environmental conditions for operation: a) temperature: 15 - 32C b) humidity: 10 - 80% 2. A review of the manufacturer's instructions for the Abbott ACR test cartridge (10002319-09, 2023/05) identified the following required environmental conditions for storage and use: a) storage: 2 - 8C use: 20 - 30C 3. A review of the manufacturer's instructions for the Abbott ACR controls (Ref 1116973) identified the following required storage temperature: a) 2 - 8C 4. A review of the laboratory's test records determined the laboratory failed to have documentation of monitoring room temperature, room humidity and refrigerator temperatures from July 12, 2025 to November 20, 2025 with testing occurring on: 7/12/2025 7/26/2025 8/30/2025 9/27/2025 10/18/2025 11/01/2025 5. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1150 hours in the office.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test records, review of the laboratory's quality control records, review of the laboratory's policies, and staff interview, the laboratory failed to have a mechanism in place to monitor quality control values over time to detect shifts and trends for 4 of 4 months. The findings included: 1. A review of the laboratory's test records determined patient testing on the Abbott Afinion analyzer utilizing the ACR test cartridge occurred on the following days: 7/12/2025 7/18/2025 7/26/2025 8/09/2025 8/21/2025 8/30/2025 9/27/2025 10/11/2025 10/18/2025 11/01/2025 2. A review of the laboratory's quality control records for the Abbott Afinion analyzers determined the laboratory performed quality control testing on the following days (listed by analyzer): a) Serial number: 20090103 QC tested: 6/11/2025 10/16/2025 b) Serial number: 20092609 QC tested: 8/21/2025 10/16/2025 c) Serial number: 20092919 QC tested: 8/21/2025 10/16/2025 d) Serial number: 20092621 QC tested: 8/21/2025 10/16/2025 e) Serial number: 20090133 QC tested: 6/11/2025 7/10/2025 f) Serial number: 20092585 QC tested: 8/21/2025 10/16/2025 g) Serial number: 20090741 QC tested: 6/11/2025 10/16/2025 3. A review of the laboratory's records determined the laboratory failed to have a quality control policy to include the monitoring of quality control values over time. 4. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1030 hours in the office. Key QC - quality control

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test records for the Abbott Afinion ACR assay, review of the laboratory's Abbott Afinion quality control records, review of patient test records and staff interview, the laboratory failed to have documentation of performing quality control testing each day of patient testing of 6 of 6 testing days. The findings included: 1. A review of the laboratory's test records for the Abbott Afinion ACR assay determined patient testing was performed on the following days: 7/12/2025 7/18/2025 7/26/2025 8/09/2025 8/21/2025 8/30/2025 9/27/2025 10/11/2025 10/18/2025 11/01/2025 2. A review of the laboratory's quality control records for the Abbott Afinion ACR assay determined quality control testing was performed on the following days (listed by analyzer serial number): a) Serial number: 20090103 QC tested: 6/11/2025 10/16/2025 b) Serial number: 20092609 QC tested: 8/21/2025 10/16/2025 c) Serial number: 20092919 QC tested: 8/21/2025 10/16/2025 d) Serial number: 20092621 QC tested: 8/21/2025 10/16/2025 e) Serial number: 20090133 QC tested: 6

/11/2025 7/10/2025 f) Serial number: 20092585 QC tested: 8/21/2025 10/16/2025 g) Serial number: 20090741 QC tested: 6/11/2025 10/16/2025 3. A review of patient test records from 7/12/2025 to 11/01/2025 identified the following patients tested on days without quality control testing being performed: a) Serial number: 20090103 test date: 7/26/2025 Sample ID: 2107253979 7088293390 4024405130 2106087650 2107070700 2104308113 2108405951 2102141557 2106609655 2109222340 2104229763 7024174662 7267771325 2104272841 2108106079 5152301139 2106056838 2105747295 2109467250 2107651642 9564405426 test date: 8/30/2025 Sample ID: 6827182734 2105084069 2102879634 2104212017 2108842429 2108954272 7203843469 2108473715 2108471946 2106877140 2108383597 test date: 09/27/2025 Sample ID: 2102622156 8329809607 2105968040 2104597217 2109431479 2107507385 8305349649 7262420859 2102646390 2104614716 2107243072 2104612704 2109131688 2103327872 2102903616 8322744197 9562407544 test date: 10/18/2025 Sample ID: 2106301459 21-6205700 2104154845 2104623057 2106050300 2109808776 2105845429 2102187375 2102396589 2104651023 2104272085 7608558739 9367774309 2104300174 2104734105 9893975049 2102735444 2107364564 7262197733 test date: 11/01/2025 Sample ID: 7262071740 2102743853 2107227303 2109920718 2107895976 2817930131 8328167980 2104524188 2106502395 9565459737 2103135281 2103807218 2109659320 2108956656 2036909533 2032435503 7262192150 6233859949 2106299972 8305843021 8329666318 2104301239 b) Serial number: 20092609 test date: 09/27/2025 Sample ID: 2106200827 2105170373 2106023644 2103313523 2107507385 8304776694 8303576143 2107974991 2107243072 2103726101 5125772812 2108976408 2107825203 2104009289 2146723547 9564513318 test date: 10/11/2025 Sample ID: 210589265 2103251615 210570354 2103675728 2105185187 test date: 10/18/2025 2109890579 2106305644 2106020663 2104203912 2107900653 2104278031 7262484279 2103467944 2108753530 5122947505 2107870173 2102325882 2109197690 2107240214 2109662776 2103056335 2104732037 2107635238 2105564016 210765083 2103800563 2106065882 2104006160 2103039900 test date: 11/01/2025 Sample ID: 2103416347 8306313722 7132634561 2102093302 2106322262 2108526399 2104043222 2105527860 2109418410 2109296606 2102488169 9565459737 9366483452 9565459737 2108374337 2107260872 7738442726 2108726116 2107581324 2108474863 2108474863 8329666317 c) Serial number: 20092919 test date: 10/11/2025 Sample ID: 830534978 6308412549 2103168283 2103105213 6786441999 210897932 210213837 8303059903 2102488208 2108382070 2103239895 d) Serial number: 20092621 test date: 08/30/2025 Sample ID: 2102677699 3213959044 2107258775 2109622126 2102141557 4322104960 2108106202 7374142338 5127492368 5127492338 2102040980 956962239 7262342496 test date: 10/18/2025 Sample ID: 2109264412 2102900565 2105051994 2108016506 7262424601 2104203600 2102187728 5122946364 2103225376 2106021846 9016449794 9015022686 2107240214 2103004105 2108488209 2108999032 9893975049 9808002103 2106675708 2103479754 2107447199 2104329931 2108954272 2102154758 test date: 11/01/2025 Sample ID: 2109003800 2106856763 210974983 2108346745 e) Serial number: 20090133 test date: 7/18/2025 Sample ID: 2102250369 test date: 7/26 /2025 Sample ID: 2104545642 7082883390 2104180688 2104302473 2105428430 2107175653 2103406274 2103719688 2108614323 7027737838 2107795182 4695007116 7262475914 5157157673 2103139179 2107849100 5127448465 4693058677 test date: 8/09/2025 Sample ID: 5129450572 2108829579 2102162712 2102142705 5127899061 528781174588 8309921390 6196775780 6203916634 f) Serial number: 20092585 No test records provided g) Serial number: 20090741 test date: 07/12/2025 Sample ID: 2107123961 2108916730 2109837609 2106205700 8329948603 2107876909 9569490702 9564587060 test date: 08/30/2025 Sample ID:

	<p>8116233870 2106298532 2103874779 2107883571 7262660466 2105596259 2107972379 9567406121 4322105095 7204999994 5127492368 2102779225 8014714382 2103166612 4. Testing personnel number 1 (as listed on Form CMS 209) confirmed quality control testing was not performed each day of patient testing in an interview conducted on 11/20/2025 at 1150 hours in the office. He stated quality control was tested on the days identified by the quality control records and the laboratory had not performed an Individualized Quality Control Plan to modify the frequency of quality control testing.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, the laboratory failed to have written Quality Assessment program to identify and correct problems with analytic systems. The findings included: 1. The laboratory failed to identify and correct that environmental condition were not being monitored (refer to D5413). 2. The laboratory failed to identify and correct that quality control values were not monitored over time (refer to D5441). 3. The laboratory failed to identify and correct that quality control testing was not performed each day of patient testing (refer to D5447).</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's records, patient test records and staff interview, the laboratory director failed to provide overall management and direction for the laboratory. The findings included: 1. The laboratory director failed to ensure environmental conditions were monitored to ensure manufacturer requirements were met (refer to D6010). 2. The laboratory director failed to ensure Quality Control and Quality Assessment programs were established (refer to D6020). 3. The laboratory director failed to ensure testing personnel had the proper education/training and experience (refer to D6029). 4. The laboratory director failed to ensure the laboratory had written policies and procedures (refer to D6030).</p>
<p>D6010</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)</p> <p>(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and</p>

	<p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Abbott Afinion, review of the manufacturer's instructions for the Abbott ACR quality control, review of laboratory records, and staff interview, the laboratory director failed to ensure environmental conditions were monitored to ensure they met manufacturer's requirements (refer to D5413).</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of the laboratory's policies and procedures, and staff interview, the laboratory director failed to ensure Quality Control and Quality Assessment programs were established to identify problems in laboratory testing. The findings included: 1. The laboratory director failed to ensure a Quality Control program was established (refer to D5441 and D5447). 2. The laboratory director failed to ensure a Quality Assessment program was established (refer to D5791).</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of the laboratory's personnel records and staff interview, the laboratory director failed to ensure laboratory personnel had documentation of education and experience to qualify for their positions. The findings included: 1. The laboratory director failed to ensure personnel had the required experience to qualify 1 of 1 technical consultants (refer to D6035). 2. The laboratory director failed to ensure personnel had the required education and training to qualify 2 of 2 testing personnel (refer to D6065 and D6066).</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records and staff interview, the laboratory director failed to have written policies and procedures for preanalytic, analytic and postanalytic areas of testing. The findings included: 1. A review of the laboratory's records determined the laboratory failed to have policies and procedures. Examples of policies and procedures the laboratory failed to have are: Personnel policies Proficiency testing policies Quality control procedures Quality Assessment policies Procedures for testing ACR on the Abbott Afinion analyzer 2. Testing personnel number 1 (as listed on Form CMS 209) on 11/20/2025 at 1000 hours in the office confirmed that laboratory did not have written policies or procedures.

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 the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of experience to qualify 1 of 1 technical consultants (refer to D6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and

(b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of experience to qualify 1 of 1 technical consultants. The findings included: 1. A review of the laboratory's submitted CMS 209 determined the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of experience to qualify the technical consultant. 3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conduction on 11/20/2025 at 1230 hours in the office.

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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of education and training to qualify 2 of 2 testing personnel. The findings included: 1. The laboratory failed to have documentation of education to qualify 2 of 2 testing personnel (refer to D6065). 2. The laboratory failed to have documentation of training to qualify 1 of 2 testing personnel (refer to D6066).

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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an

official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 2 of 2 testing personnel. The findings included:

1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 2 testing personnel who performed ACR testing on the Abbott Afinion analyzer.
2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education to qualify the 2 testing personnel to perform moderate complexity testing.
3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1215 hours in the office. Key ACR: Albumin/creatinine

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
- (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
- (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (b)(6)(ii)(E) A working knowledge of reagent stability and storage;
- (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
- (b)(6)(ii)(G) An awareness of the factors that influence test results; and
- (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of training to qualify 1 of 2 testing personnel. The findings included:

1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 2 testing personnel who performed ACR testing on the Abbott Afinion analyzer.
2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of training on the Abbott Afinion analyzer to qualify testing personnel number 2 (as listed on Form CMS 209) to perform moderate complexity testing.
3. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 11/20/2025 at 1215 hours in the office. Key ACR: Albumin/creatinine