Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2096521	07/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Exclusive Physicians, Pllc	911 E 9 Mile Rd Suite 100, Ferndale, MI	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 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. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Technical Supervisor, the laboratory failed to follow manufacturer's instructions for quality control performance for two (July 2022 to July 2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Siemens Multistix" manufacturer's instructions revealed a section stating, "Test positive and negative controls with new lots, new shipments of reagents and when you open a new bottle of reagent strips. test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent strips integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match." 2. A review of the laboratory's quality control results for its Siemens Multistix testing revealed results of controls performed on 4/15/24 and no other results from July 2022 to July 2024. 3. A review of the laboratory's "Siemens Clinitek Microalbumin 2" manufacturer's instructions revealed a section titled "Quality Control" stating, "Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent strips integrity; train new users; and when patients' clinical conditions or symptoms do not match." 4. A review of the quality control documentation revealed a lack of positive and negative controls performed for the Siemens Clinitek Microalbumin 2 from July 2022 to July 2024. 5. A review of the laboratory's "Afinion HbA1c" manufacturer's instructions revealed a section titled "Frequency of control testing" stating, "Controls should be analyzed: with each new shipment of Afinion HbA1c Test Kits, with each new lot of Afinion AbA1c Test kits, at least every 30 days, when training new

	operators, and anytime an unexpected test result is obtained." 6. A review of the Afinion HbA1c quality control documentation revealed a lack of controls performed at least every 30 days from July 2022 and July 2024 and only performed controls on 5 /9/23, 7/28/23, and 4/15/24. 7. A review of the laboratory's "Coag-Sense Prothrombin Time PT/INR Monitoring System" manufacturer's instructions revealed a section titled "Quality Control" stating, "Each Test Strip kit is shipped with two Low Control Strips, two High Control Strips and Control Activation Solution. The plasma is generated from a pool of normal donors where the Vitamin K dependent proteins are removed and added back at different levels to represent the 'Low' and 'High' level ranges. Real plasma allows for a fully functional liquid control test of both the reagent's ability to generate a clot and the analyzer's ability to detect a clot. When done correctly, control testing confirms the performance of both the Meter and Test Strips and should be completed for each new lot of Test Strips, as soon as each lot is received, within the stated shelf life" 8. A review of the quality control documentation revealed a lack of control testing performed for the Coag-Sense Prothrombin Time test system from July 2022 to July 2024. 9. An interview on 7/10/24 at 11:41 am with the Technical Supervisor confirmed the laboratory failed to perform quality control testing for the CLIA-waived testing kits listed above. B. Based on record review and interview with the Technical Supervisor, the laboratory failed to follow manufacturer's instructions for reagent use for two (July 2022 to July 2024) of two years reviewed. Findings include: 1. The surveyor observed a paper reagent bottle holder with the Consult Diagnostics Strep A testing kit with two bottles that did not have matching lot numbers on 7/9/24 at 7:10 pm: a. Reagent 1 Lot number 0000709692 with the expiration date of 7/2/25. b. Reagent 2 Lot number 0000659515 with the expiration date of 3/31/25. 2. The surveyor observed a bag of six Consult Diagnostics Strep A testing kit bottles with two bottles of Reagent 1 and four bottles of Reagent 2 in the basket next to the paper reagent bottle holder with different lots. 3. A review of the laboratory's "Consult Diagnostics Strep A Test Dipstick Kit" manufacturer's instructions revealed a section stating, "Only use reagents provided in the kit." 4. An interview on 7/9/24 at 7:40 pm with the Technical Supervisor confirmed the laboratory had been mixing different lots of reagents against the manufacturer's instructions. C. Based on record review and interview with the Technical Supervisor, the laboratory failed to follow Accula SARS-CoV-2 Test Cassette manufacturer's instructions for use of testing kits beyond the expiration date for five (February 2024 to July 2024) of 5 months since the cassettes expired. Findings include: 1. The surveyor observed two boxes of Accula SARS-CoV-2 test cassettes with the expiration date of 2/15/2024 on 7/9/24 at 7:30 pm. 2. A review of the "Accula Test SARS-CoV-2" instructions for use revealed a section stating, "Do not use kit or reagents past the expiration date." 3. An interview on 7/9/24 at 7:30 pm with the Technical Supervisor confirmed the test cassettes had exceeded the expiration date.
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 observation, record review and interviews, the laboratory failed to ensure contamination of its molecular testing area was minimized (refer to D3003) and failed to operate as a separate laboratory to comply with 493.43 (refer to D3009).
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: . Based on observation and interviews, the laboratory failed to ensure contamination of its molecular testing area was minimized for four (March 2024 to July 2024) of four months since the laboratory blocked the entryway into the general laboratory space. Findings include: 1. The surveyor observed the laboratory space on 7/9/24 at 6: 10 pm. The laboratory consisted of two connected spaces: one for hematology and chemistry testing and the other for molecular testing. Both had separate access points on each end, but a refrigerator was installed in front of the chemistry and hematology laboratory section's door. Staff working in that area or staff dropping off specimens are required to walk through the molecular testing area to get to the chemistry and hematology testing areas. Staff do not wear laboratory coats and the laboratory does not utilize dead air boxes or biosafety cabinets. 2. An interview on 7/10/24 at 9:41 am with Testing Personnel #2 revealed the refrigerator blocking access to the chemistry and hematology laboratories was installed in March 2024. 3. An interview on 7/10/24 at 12:13 pm with Testing Personnel #1 confirmed staff are frequently walking through the molecular laboratory area creating a risk for contamination.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on observation, record review, and interviews, the laboratory failed to operate as a separate laboratory to comply with 493.43 for one (5/28/24 to 6/28/24) of one month of laboratory operations at 911 East Nine Mile Road in Ferndale Michigan. Findings include: 1. The surveyor observed the laboratory testing area, instrumentation, reagents, control and calibration materials are shared with Laboratory B located at the same address on 7/9/24 at 6:10 pm. 2. A review of the laboratory's Form CMS-209 revealed the laboratory shared testing personnel with Laboratory B. 3. The surveyor requested the laboratory's policies and procedures, quality assessment program, proficiency testing, verification of accuracy, competency assessments, staff training, maintenance records, temperature monitoring, and control procedures that were separate and distinct from Laboratory B on 7/9/24 at 7:56 pm and the documentation was not available. 4. An interview on 7/9/24 at 10:00 pm with the

	Laboratory Director, the owner of the medical practice, and the Technical Supervisor confirmed the laboratories were not separate and distinct.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure the optimum integrity of patient specimens for Complete Blood Count (CBC) testing (refer to D5203) and failed to follow its competency assessment policies (refer to D5209).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to ensure the optimum integrity of patient specimens for Complete Blood Count (CBC) testing for two (Patients #4 and #5) of six patient test records reviewed. Findings include: 1. A review of patient test records revealed the following patients with CBC testing performed more than 24 hours after collection: a. Patient #4 had their specimen collected on 5/15/24 at 8:41 am and testing reported on 5/16/23 at 2:47 pm. b. Patient #5 had their specimen collected on 5/29/24 at 8:28 am and testing reported on 5/31/24 at 9:56 am. 2. An interview on 7/10/24 at 2:58 pm with the Technical Supervisor confirmed the specimens had exceeded 24 hours from collection to test reporting.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to follow its competency assessment policies for one (Testing Personnel #5) of one testing personnel hired since January 2024. Findings include: 1. A review of the laboratory's "Employee Evaluations" policy revealed a section stating, "All new lab

	employees will have a competency evaluation after their initial training, at the 6 month interval, 12 months and every year thereafter. The Competency Evaluation form will be filled-out. The evaluations will include the Director, Technical Consultant and Testing Personnel." 2. A review of Testing Personnel #5's competency assessment documentation dated 4/12/24 revealed a lack of assessment for each area of testing performed: molecular testing, chemistry testing using the Abbott Architect, and hematology testing using the Sysmex analyzer. The documentation also did not include the Director and Technical Consultant. 3. An interview on 7/10/24 at 1:44 pm with the Technical Supervisor confirmed the laboratory had not assessed and documented competency for Testing Personnel #5 for each testing area for which testing is performed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to follow its specimen collection, labeling, acceptability, and rejection policies (refer to D5403 A), failed to establish specimen acceptability and rejection procedures for its Complete Blood Count (CBC) testing (refer to D5403 B), failed to ensure calibrators and blood specimen collection tubes had not exceeded expiration dates (refer to D5417) and failed to perform corrective action when Alanine Transaminase testing controls were out of range (refer to D5783).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: . A. Based on observation and interview with the Medical Assistant, the laboratory failed to follow its specimen collection, labeling, acceptability, and rejection policies for one urine specimen collection observed. Findings include: 1. A review of the laboratory's "Specimen Collection" policy revealed a section stating, "The container must have a label that will adhere under refrigeration. The label must include the patient's identification and the date and time of specimen collection and the labels must be placed on the container, not on the lid." 2. The surveyor observed a full urine specimen cup with a patient label on the lid and no other identifiers on the cup on 7/10 /24 at 2:45 pm. 3. An interview with the Medical Assistant on 7/10/24 at 2:45 pm confirmed the urine specimen was not labeled in accordance with the laboratory's policy. B. Based on record review and interview with the Technical Supervisor, the laboratory failed to establish specimen acceptability and rejection procedures for its Complete Blood Count (CBC) testing for two (Patients #4 and #5) of six patient test records reviewed. Findings include: 1. A review of patient test records revealed the following patients with CBC testing performed more than 24 hours after collection: a. Patient #4 had their specimen collected on 5/15/24 at 8:41 am and testing reported on 5 /16/23 at 2:47 pm. b. Patient #5 had their specimen collected on 5/29/24 at 8:28 am and testing reported on 5/31/24 at 9:56 am. 2. The surveyor requested the laboratory's policy regarding patient specimen stability for its CBC testing on 7/10/24 at 2:58 pm. 3. An interview on 7/10/24 at 2:58 pm with the Technical Supervisor confirmed the laboratory had not established a specimen stability policy to ensure optimum integrity of patient specimens.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Supervisor, the laboratory failed to ensure calibrators and blood specimen collection tubes had not exceeded expiration dates for nine items observed. Findings include: 1. The surveyor observed the following expired materials available for use in the laboratory on 7/9/24 at 6:10 pm: a. One Lipoprotein A (LpA) calibrator bottle with an open date of 06/19/2024 and expired 7/3/24. b. One unopened box of LpA calibrators expired 7/3/24. c. One Lipase calibrator with an expiration date of 7/6/24. d. One Lipid calibrator with an expiration date of 7/6/24. e. One box of HIV Ag/Ab Combo calibrators with an expiration date of 6/21/24. f. One box of HAVAB-G calibrators with an expiration date of 7/6/24. g. Four Navy top vacutainer blood collection tubes with the expiration date of 6/30/24. 2. An interview on 7/9/24 at 7:40 pm with the Technical Supervisor confirmed the items listed above had exceeded their expiration dates.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 record review and interview with the Technical Supervisor, the laboratory failed to perform corrective action when Alanine Transaminase testing controls were out of range for 20 of 29 testing dates reviewed from 6/1/24 to 7/10/24. Findings include: 1. A review of the laboratory's "Quality Control Data Interpretation Procedure" revealed a section stating, "Are eight consecutive control observations on one side of the mean and further than 1 SD from the mean? (Yes = Rejection)" and "Do 10 consecutive control values fall on the same side of the mean? (Yes = Rejection)." 2. A review of the laboratory's Alanine Transaminase controls from 6/1 /24 to 7/10/24 revealed both control levels were trending below the mean. The following dates had failed controls: a. Failed by having eight or more consecutive runs below one standard deviation: i. 6/8/24 ii. 6/10/24 iii. 6/11/24 b. Failed by having 10 consecutive control values fall on the same side of the mean: i. 6/7/24 ii. 6/8/24 iii. 6 /10/24 iv. 6/12/24 v. 6/13/24 vi. 6/14/24 vii. 6/18/24 viii. 6/19/24 ix. 6/20/24 x. 6/21 /24 xi. 6/22/24 xii. 6/25/24 xiii. 6/26/24 xiv. 6/27/24 xv. 6/28/24 xvi. 7/1/24 xvii. 7/2 /24 xviii. 7/3/24 xix. 7/9/24 xx. 7/10/24 3. A review of the laboratory's most recent proficiency testing event scores revealed the laboratory had received a score of 80% for Alanine Transaminase performance. 4. An interview on 7/10/24 at 1:30 pm with the Technical Supervisor confirmed the control results were trending below the mean and indicated trending is checked only every other month by the Technical Consultant. No corrective action was performed for dates with failed controls.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the Laboratory Director failed to ensure compliance with waived testing manufacturer's instructions for quality control performance (refer to D6079 A), failed to ensure compliance with waived testing manufacturer's instructions for reagent use (refer to D6079 B), failed to ensure compliance with Accula SARS-CoV-2 Test Cassette manufacturer's instructions for use of testing kits beyond the expiration date (refer to D6079 C), failed to ensure the laboratory operated as a separate laboratory to comply with 493.43 (refer to D3009), failed to ensure corrective actions were performed when Alanine Transaminase testing controls were out of range (refer to D6096), failed to ensure high complexity testing personnel were qualified (refer to D6101), and failed to ensure testing personnel were competent in all areas where they perform testing (refer to D5209).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A. Based on record review and interview, the Laboratory Director failed to ensure compliance with waived testing manufacturer's instructions for quality control performance. Refer to D1001 A. B. Based on record review and interview, the Laboratory Director failed to ensure compliance with waived testing manufacturer's instructions for reagent use. Refer to D1001 B C. Based on record review and interview, the Laboratory Director failed to ensure compliance with Accula SARS-CoV-2 Test Cassette manufacturer's instructions for use of testing kits beyond the expiration date. Refer to D1001 C. D. Based on observation, record review, and interview, the Laboratory Director failed to ensure the laboratory operated as a separate laboratory to comply with 493.43. Refer to D3009.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure corrective actions were performed when Alanine Transaminase testing controls were out of range. Refer to D5783.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure high complexity testing personnel were qualified. Refer to D6171.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 record review and interview, the Laboratory Director failed to ensure testing personnel were competent in all areas where they perform testing. Refer to D5209.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure high complexity testing personnel were qualified (Refer to D6171), testing personnel failed to follow its specimen collection, labeling, acceptability, and rejection policies for urine specimen collection (refer to D6175), testing personnel failed to ensure the optimum integrity of patient specimens for Complete Blood Count (CBC) testing (refer to D6179 A), and testing personnel failed to identify when Alanine Transaminase testing controls were out of range (refer to D6179 B).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have

	either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) 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)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to ensure high complexity testing personnel were qualified for one (Testing Personnel #5) of five testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel qualifications revealed Testing Personnel #5 was performing high complexity molecular testing and lacked qualification documentation. 2. An interview on 7/10/24 at 1:44 pm with the Technical Supervisor qualification documentation was not present for Testing Personnel #5 performing high complexity testing. 3. The laboratory was given an additional seven days to provide the missing qualifications and it was not received.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by:

	. Based on observation, record review, and interview, the testing personnel failed to follow its specimen collection, labeling, acceptability, and rejection policies for urine specimen collection. Refer to D5403.
D6179	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5) Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director. This STANDARD is not met as evidenced by: . A. Based on record review and interview, testing personnel failed to ensure the optimum integrity of patient specimens for Complete Blood Count (CBC) testing. Refer to D5203. B. Based on record review and interview, testing personnel failed to identify when Alanine Transaminase testing controls were out of range. Refer to D5783.