

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2034771	(X3) Date Survey Completed 02/22/2024
Name of Provider or Supplier Access Dx Laboratory Llc	Street Address, City, State 8920 Kirby Dr, Houston, 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	An announced validation survey was completed on February 22, 2024, and the facility was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 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 establishment studies, manufacturer instructions, policies/procedures, specimen shipment/transport log, patient test records, submitted patient test volumes and staff interview, the laboratory failed to ensure the overall quality of the preanalytic systems and correct identified problems for four of four test platforms used by the laboratory in 2023, urinary tract infections (UTI), respiratory pathogens panel (RPP), COVID, and cytogenetics testing. Findings included: 1. The laboratory failed to document monitoring of specimen transport conditions to ensure specimen stability. Refer to D5311A. 2. The laboratory failed to follow its own policy for specimen acceptability/rejection. Refer to D5311B. 3. The laboratory failed to ensure clients follow laboratory's sample packaging and shipping policies. Refer to D5311C. 4. The laboratory's quality assurance failed to identify and correct problems with specimen collection, transport and acceptability. Refer to D5393.</p>

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory's establishment studies, manufacturer instructions, a random sampling of the laboratory's specimen shipment/transport log, submitted patient test volumes and staff interview, the laboratory failed to document monitoring of specimen transport conditions to ensure specimen stability for samples used to perform 368,697 of 368,697 tests in 2023. Findings included: 1. Review of laboratory's establishment studies for its specimen collection/transport devices/kits revealed: a. "90 Day Stability Study Validation Report" for the DNAGenotek ORACollect.DX saliva collection kit (approved 01/13/2021) stated "The specimen is shipped at ambient conditions". There was no definition of ambient conditions /temperature range acceptability. b. "Urine Preservative Specimen Transportation" establishment study for the Becton, Dickinson (BD) Vacutainer C&S (culture and sensitivity) Preservative Urine Tubes (completed on 11/08/2022) revealed: "Conclusion ... The following environmental conditions are considered acceptable for preservative tube specimen shipping: 1. Room temperature (~20-25C [Degrees Celsius]) 2. 2-8C Refrigerator 3. 9-25C Refrigerator 4. Courier vehicle" Courier vehicle transport temperature range was not defined. c. There were no studies completed and approved prior to December 2023 for temperature range and length of sample stability once the specimen was placed in the collection system for the Precision (Changzhou) Medical Instruments PhusionGPO Disposable Virus Sampling Kits for nasal and throat samples. 2. Review of manufacturer instructions for use for the laboratory's sample collection/transport devices revealed: a. The "DNAGenotek ORACollect.DX Product Handbook" (document PD-HB-00010 Issue 5/2023-01) stated: "Post-collection Store ORACollect.DX saliva samples at room temperature for up to 60 days." The manufacturer did not define "room temperature" for sample stability in this device. b. The "BD Vacutainer Urine Products" (document VDP40397 (02) 02/2021, available online) stated: "Intended Use of BD Vacutainer C&S Preservative Urine Tubes ...up to 48 hours at room temperature..." The manufacturer did not define "room temperature" for sample stability in this device. c. The "PhusionGPO Disposable Virus Sampling Kit Instructions for Use" (no document identification number or issue date available) stated: Samples can be preserved in Inactivated Medium (transparent color) at room temperature for 96 hours or preserved in the Non-activated Medium (red color) at 2-8C for 48 hours." The manufacturer did not define "room temperature" for sample stability in this device. 3. Review of a sampling of the laboratory's specimen shipment/transport log revealed the laboratory did not document monitoring of transport conditions of samples upon receipt. 4. Review of laboratory's submitted 2023 test volumes revealed the laboratory performed 368,697 tests annually from samples transported in the above collection /transport media/devices. 5. In an interview on 02/21/2024 at 1101 hours at the off-site sample receiving center, the laboratory's Director of Quality Assurance (as indicated on submitted Exit/Entrance Conference Document) stated that the specimen transport conditions were not monitored, confirming the findings. B. Based on review

of laboratory's policies/procedures, random patient test records, annual test volumes and staff interview, the laboratory failed to follow its own policy for specimen acceptability/rejection for 4 of 42 patient samples reviewed from July 2023. Findings included: 1. Review of laboratory's policy "136240.838 RECEIVING SOP" (Version 1.0, approved 01/13/2022) revealed: "All specimens have a specific stability period from when the specimen was collected. Any specimen that passes the stability period must be rejected." And, "UTI (urinary tract infection) - 48 hours" 2. Review of random patient test records for July 2023 revealed the following 4 of 42 records reviewed showed urine samples were received and tested beyond the acceptable stability period of 48 hours: Sample: 150329142 Test: UTI PROx Collected: 06/30/2023 Received: 07/03/2023 Elapsed time: 72 hours Sample: 150329167 Test: UTI PROx Collected: 06/30/2023 Received: 07/03/2023 Elapsed time: 72 hours Sample: 151012671 Test: UTI PROx Collected: 07/14/2023 Received: 07/17/2023 Elapsed time: 72 hours Sample: 150998300 Test: UTI PROx Collected: 07/21/2023 Received: 07/24/2023 Elapsed time: 72 hours 3. Review of laboratory's test volumes for 2023 revealed the laboratory performed testing on approximately 890 UTI samples annually. 4. In an interview on 02/21/2024 at 1320 hours in the office, the laboratory's General Supervisor number 2 (as indicated on submitted Form CMS 209) confirmed the findings. C. Based on surveyor's observations, review of laboratory's policies /procedures, instructions to clients, FedEx packaging and labeling instructions, patient test records and staff interview, the laboratory failed to ensure clients follow laboratory's sample packaging and shipping policies for 2 of 2 shipment envelopes observed. Findings included: 1. Surveyor's observations on 02/21/2024 at 1120 hours at the laboratory's off-site specimen receiving center revealed two FedEx Clinical Pak soft side envelopes in the trash. The envelopes were not marked for Exempt Human Specimen or Category B Infectious Substance. Surveyor was unable to determine what samples have been transported in the Clinical Pak envelopes. 2. In an interview at the time of observation, receiving personnel (see survey notes) stated that all patient samples were received in one of the three liquid collection/transport media used by the laboratory. The samples always came packed in biohazard bags which were then placed in the FedEx Clinical Pak envelope. She also stated that she did not check for proper sample category designation on the envelopes. She confirmed the laboratory receives all samples in liquid preservative/medium, but the laboratory did not receive samples in Category B packaging. 3. Review of laboratory's policy/procedure "136240.580 Packaging and Transporting Biological Substances SOP" (version 1.0, effective 05/21/2021, last reviewed 07/24/2023) revealed: "Category B infectious substances include diagnostic or clinical specimens." And, "6.3 Secondary container - leak-proof secondary packaging that the primary container is placed within, such as Ziplock bag or a Screw-cap plastic container. 6.4 Sturdy outer packaging - hard-sided outer container used for transport." And, "7.2 Pack the specimen container inside a secondary container. ... 7.4 Place the secondary container inside the outer packaging for transport. ... 7.6 The outer packaging must be marked with the appropriate label: 7.6.1 Clinical Samples - Exempt Human Specimen 7.6.2 Category B - a UN3373 Biological Substance Category B Label." 4. Review of laboratory's instructions to client for the Urinary Tract Infection, Respiratory Pathogens Panel, COVID and Flu samples revealed the instructions for shipping did not reflect the laboratory's policies for shipping of Category B samples. The instructions stated: "Shipping instructions: 1. Place the specimen collection tube into the biohazard bag. 2. Insert any supporting documentation (...) into the FedEx Clinical Pak along with the specimens. 3. Place the biohazard bag into FedEx Clinical Pak and ensure the Clinical Pak is properly sealed prior to shipping. - Please do not pack more than 30 collected samples per Clinical Pak." There was no mention of Category B labeling, or hard-sided outer container. 5. Review of FedEx instructions for use of the Clinical Pak envelopes (available online)

revealed: "The FedEx Clinical Pak can be used to ship dried samples when packaged according to the dried sample guidelines." And, "If the dried sample is placed in a receptacle with a liquid preservative, then follow the packaging guidelines for liquids." And, "Blood, urine, containing or suspected of containing infectious substances must be shipped according to applicable government, International Air Transport Association (IATA), and International Civil Aviation Organization (ICAO) regulations. For the purposes of this guide, clinical samples are generally defined as non-infectious human or animal materials..." And, "If you need an overpack for shipments containing Biological Substance, Category B (UN 3373) materials, use the FedEx UN 3373 Pak." 6. Review of laboratory's patient test volumes for 2023 revealed the laboratory received approximately 12,460 patient samples annually for testing of infectious agents. 7. In an interview on 02/21/2024 at 1130 hours at the off-site sample receiving center, the laboratory's Chief Operating Officer (as indicated on submitted Exit/Entrance Conference Document) confirmed the findings.

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(b)(c)

The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's establishment studies, manufacturer instructions, policies/procedures, specimen shipment/transport log, submitted patient test volumes and staff interview, the laboratory's quality assurance failed to identify and correct issues with specimen transport and/or acceptability for 3 of 3 specimen collection and transport systems used by the laboratory in 2023. Refer to D5311A, B, and C.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor's observations, review of manufacturer instructions, policies /procedures, patient test volumes and staff interview, the laboratory failed to document monitoring of storage temperature for 3 of 3 collection devices/kits used by the laboratory for collection and transport of patient samples in 2022 and 2023. Findings included: 1. Surveyor's observations on 02/21/2024 at 1050 hours in the facility's off-site storage and distribution center revealed the laboratory stored the following sample collection devices/kits ready for distribution to its clients: a. Approximately 480 Becton, Dickinson (BD) Vacutainer urine collection kits (lot

2314263, expiration date 2024-05-31, and lot 3039736, expiration date 2024-08-31) b. Approximately 3,250 DNAgenotek ORAcollect.DX saliva collection systems (lot IA501, expiration date 09/13/2025) c. Approximately 32,600 Precision (Changzhou) Medical Instruments PhusionGPO Disposable Virus Sampling Kits for nasal and throat sample collection (product PCY-AB-M3; lot 2210CYABM3V01, expiration date 01/13/2025) There was no thermometer observed in the storage room for monitoring of temperature to ensure collection devices integrity/stability. 2. Review of manufacturer's instructions for use for the above collection devices/kits revealed: a. For the BD Vacutainer urine collection kits (document BD SDS_US Version:1.3, Last revised date:12/29/2021): "Safe storage conditions: ... Store in closed original container at temperatures between 4C (Degrees Celsius) and 25" b. For the ORAcollect.DX saliva collection systems (document PD-HB-00010 Issue 5/2023-01): "Pre-collection ORAcollect.DX can be stored between 15C and 25C." c. For the PhusionGPO Disposable Virus Sampling Kits (no document identification number or issue date available): The documents provided did not specify storage temperature. Note: Product box or device itself did not have storage temperature specified. The laboratory did not define storage temperature for this product. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for receiving, storing, sorting, packaging, and distributing of specimen collection devices/kits to the laboratory's clients, to ensure the devices/kits' integrity is preserved throughout the process. 4. Review of laboratory's patient test volumes for 2023 revealed the above collection devices/kits were used to collect samples for approximately 368,697 tests performed by the laboratory annually. 5. In an interview on 02/21/2024 at 1101 hours in the off-site storage room, the laboratory's Director of Quality Assurance (as specified on submitted Exit/Entrance Conference Document) stated that the storage room's temperature was not monitored, confirming the findings.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on review of laboratory's establishment studies, patient test volumes and staff interview, the laboratory failed to document/complete performance verification for specimen stability and transport conditions for 2 of 3 specimen collection/transport devices/media used by the laboratory in 2023, the ORAcollect.DX saliva collection kit and the PhusionGPO Disposable Virus Sampling Kit. Findings included: 1. Review of laboratory's "90 Day Stability Study Validation Report" for the DNAgenotek ORAcollect.DX saliva collection kit (approved 01/13/2021) revealed the laboratory did not define ambient temperature/acceptable temperature range for shipping of samples. 2. Review of laboratory's establishment studies for the for the Precision (Changzhou) Medical Instruments PhusionGPO Disposable Virus Sampling

Kits revealed the study was completed in September 2022. There was no documentation of approval for use of the device by laboratory director prior to December 2023. 3. Review of laboratory's 2023 test volumes revealed the laboratory performed approximately 1,962 tests from samples collected in the ORAcollect.DX saliva collection kit, and approximately 47,604 tests from samples collected in the PhusionGPO Disposable Virus Sampling Kit. 4. In an interview on 02/21/2024 at 1320 hours in the off-site storage room, the laboratory's General Supervisor number 2 (as indicated on submitted Form CMS 209) confirmed the findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, maintenance records for 2023, and staff interview, the laboratory failed to have documentation of performing all required weekly maintenance procedures on four ViiA7 analyzers for seventeen of seventeen weeks reviewed from August 5, 2023 to November 30, 2023. Findings include: 1. A review of the laboratory's policy titled 'RNaseP Quantification SOP' revealed the following: "ViiA7 Maintenance a. Weekly Maintenance 1. Back up instrument settings 2. Perform ViiA7 Instrument Self-Test 3. Power off computer that controls ViiA7 4. Save files to Z drive>QC>Maintenance Sheets>ViiA7 Maintenance 5. Clean the Plate Adaptor, Sample Block and Heated Cover with 95% Ethanol 6. Back up experiment files from Desktop>Copy Number Runs to the Z Drive to Backup Folder 7. Once Files are Backed up, Delete files from ViiA7 and the Copy Number Run Folder" 2. A review of the laboratory's maintenance records revealed the laboratory failed to have documentation of performing the ViiA7 Instrument Self-Tests and powering off the computers for the seventeen weeks from August 5, 2023 to November 30, 2023 on the following 4 ViiA7 analyzers used for patient testing: - ViiA7- 1 Serial Number 278881962 - ViiA7- 3 Serial Number 278881960 - ViiA7- 2 Serial Number 278881961 - ViiA7 -4 Serial Number 278880838 3. In an interview on 2/22/24 at 11:40 hours in the conference room, after review of the records, general supervisor #2 (as indicated on the CMS 209 form) confirmed the above findings.

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 review of the laboratory's establishment studies, manufacturer instructions, policies/procedures, specimen shipment/transport log, patient test records, submitted

	<p>patient test volumes and staff interview, the laboratory director failed to address the overall quality of the laboratory for 4 of 4 test platforms used by the laboratory in 2023, urinary tract infections (UTI), respiratory pathogens panel (RPP), COVID, and cytogenetics testing. Findings included: 1. The laboratory director failed to ensure pre-analytic quality of laboratory services was maintained. Refer to D6082. 2. The laboratory director failed to ensure laboratory's quality assurance identified and corrected issues in pre-analytic systems. Refer to D6094.</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies, manufacturer instructions, policies/procedures, specimen shipment/transport log, patient test records, submitted patient test volumes and staff interview, the laboratory director failed to ensure pre-analytic quality of laboratory services was maintained for 4 of 4 test platforms used by the laboratory in 2023, urinary tract infections (UTI), respiratory pathogens panel (RPP), COVID, and cytogenetics testing. Refer to D5311A, B and C.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the 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 establishment studies, manufacturer instructions, policies/procedures, specimen shipment/transport log, patient test records, submitted patient test volumes and staff interview, the laboratory director failed to ensure laboratory's quality assurance for pre-analytic processes identified and corrected issues with specimen transport and/or acceptability for 4 of 4 test platforms used by the laboratory in 2023, urinary tract infections (UTI), respiratory pathogens panel (RPP), COVID, and cytogenetics testing. Refer to D5393.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to ensure three of eighteen testing personnel met the</p>

minimum education requirements for performing high complexity testing. (See D6171)

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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of foreign education equivalency for three of eighteen testing personnel performing high complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 2/21/24) revealed the laboratory identified 18 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records found no documentation of foreign equivalency evaluation of education obtained outside the United States for the following testing personnel: - Testing person #2 - Testing person #9 - Testing person #14 3. In an interview on 2/21/24 at 11:25 hours in the office, after review of the records, general supervisor #2 (as indicated on the CMS 209 form) confirmed the above findings.