Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0285781	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hca Florida Westside Hospital	8201 W Broward Blvd, Plantation, FL	

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 unannounced complaint survey #2020015973 was conducted on 11/03/20-11/05 /20 at Westside Regional Medical Center. The laboratory was not in compliance with 42 CFR Part 493, requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified at 11:40 AM on 11/05/20. Laboratory testing personnel used a mislabeled tube of blood to perform ABO blood group/ Rhesus blood group (ABO/Rh) testing, Type and Screen antibody identification, and Crossmatch for one unit of Red Blood Cells (RBC's) (D5300). Laboratory testing personnel failed to follow the procedures "BB 82 Patient Retype" for confirmatory ABO/Rh typing (D5400). The following Conditions were not met: D5300 - 493.1240 - Preanalytic Systems D5400 - 493.1250 - Analytic Systems D5800 - 493.1290 - Postanalytic Systems D6063 - 493.1421 - Testing Personnel D6076 - 493.1441 - Laboratory Director D6168 - 493.1487 - Testing Personnel
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 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. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the preanalytic system and correct identified problems. Findings: Cross Reference D5311: Based on record review and interview, the laboratory personnel failed to follow the procedure manual.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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: Based on record review and interview, the laboratory personnel failed to follow the procedure manual. Findings: Review of the Root Cause Analysis timeline states the technologist failed to perform the two patient identifier step. Review of the timeline showed on "4/23/20 17:44 Blood Bank (BB) technologist received order for "Type and Cross" (TC) 1 unit of PRBC (Packed Red Blood Cells). The patient had no previous blood bank history in Meditech. The Technologist checked the extra rack to see if a pink top tube was already in the lab. The BB technologist did not request a second specimen for confirmation since the original tube was collected using MobiLab. She discovered the label was missing the barcode, and the Echo (blood bank analyzer) instrument would not be able to read the order information, the BB technologist proceeded to print another label for the TC and placed it on the tube obstructing the original label which prevented the two patient identifier step." Review of the Discipline / Corrective Action Form states the following, "Testing Personnel failed to adhere to the Blood Bank Specimen Identification Policy (SC 11), the secondary labeling states, check the Meditech labels against the sample label with the registration label. The name and other facility specific identifiers must match." Review of the Discipline / Corrective Action Form also states, "Testing Personnel printed another label, and placed it on a different patient's blood sample tube. Laboratory Testing Personnel used a mislabeled tube of blood to perform ABO/Rh, Type and Screen, and Crossmatch for one unit of RBC's (Red Blood Cells). The patient received one unit of blood of the wrong blood type due to the testing personnel using a mislabeled tube of blood. Receiving the wrong blood type resulted in the death of the patient." The laboratory procedures were signed and dated by the Laboratory Director on 12/31/18. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, was signed and dated by the Laboratory Director on 11/03/20 and reported an estimated annual test volume of 616,868. The estimated number of Immunohematology tests performed is 19,556. During an interview on 11/05/20 at 11:07 AM, the Technical Supervisor B stated, the Laboratory Testing Personnel Q did not follow the procedure and do her second patient identifier check.
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 record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5401. Based on record review and interview, the laboratory personnel failed to follow the procedure manual. Cross Reference D5403. Based on record review and interview, the laboratory procedure manual was incomplete. Cross Reference D5407. Based on record review and interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the the revised "BB 82 Patient Retyping" procedure.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory personnel (Testing Personnel Q) failed to follow the procedure manual. Findings: The procedure titled, "BB 82 Patient Retyping" stated, "Prior to blood product issue, patients without a previous ABO Rh history will have a confirmatory ABO Rh type performed". The procedure also states, "If the original sample was collected without electronic patient identification system, the ABO/Rh confirmation is to be performed on a second blood sample, collected at a different time by a different collector." The laboratory procedures were signed and dated by the Laboratory Director on 12/31/18. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 11/03/20 and reported an estimated annual test volume of 616,868. The estimated number of Immunohematology tests performed is 19,556. During an interview on 11/04/20 at 4:32 PM. the IRL (Integrated Regional Laboratories) Quality Manager stated, the procedure was signed by the Laboratory Director on 12/31/18. During an interview on 11/03/20 at 1:06 PM, the Technical Supervisor B stated, the specimen did not have a barcode label on the tube when it arrived in the laboratory and Testing Personnel Q put the barcode label on the specimen. During an interview on 11/04/20 at 10:34 AM , the Laboratory Director stated, Testing Personnel Q misinterpreted the policy and failed to obtain a second tube of blood for the confirmatory ABO/Rh typing.
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: Based on record review and interview, the laboratory procedure manual was incomplete. Findings: The laboratory procedures were signed and dated by the CLIA Laboratory Director on 12/31/18. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 11/03/20 and reported an estimated annual test volume of 616,868. The estimated number of Immunohematology tests performed is 19,556. 1. Review of the procedure titled, "SC 17 Blood Collection Venipuncture" states, "The bar-coded labels contain the specimen requirements and test name and is to be affixed to the specimen." Review of the procedure manual, showed that the procedures titled, "BB 37 Blood Bank Specimen Collection," "BB 38 Specimen Rejection," "BB 40 ABO" and "BB 40 ABO Rh Echo and Tube Method" failed to include rejecting blood bank specimens without a barcode label except when there is a computer downtime. During an interview on 11/03/20 at 6:00 PM, the Technical Supervisor B stated, the procedures did not include rejecting blood bank specimens without a barcode label except when there is a computer downtime. 2. Review of the procedure titled, "BB 72 Transfusion Reaction Investigation" states, if a transfusion reaction is suspected "contact the treating physician immediately for instructions for patient care and to determine if a transfusion reaction workup is indicated." Review of the procedure titled, "BB 36 Immediate Notification Policy," showed the procedure failed to include immediate notification of the patient's physician for suspected transfusion reactions. During an interview on 11/04/20 at 6:08 PM, the Technical Supervisor B stated, the "BB 36 Immediate Notification" policy did not include contacting the patient's physician when there was a possible transfusion reaction. 3. Review of the procedure titled, "BB 82 Patient Retyping" stated, for "patients without previous ABO and Rh history will have a confirmatory ABO and Rh typing performed." Review of the procedures titled, "BB 40 ABO" and "BB 40 ABO Rh Echo and Tube Method," failed to state "patients without previous ABO and Rh history will have a confirmatory ABO and Rh typing performed." During an interview on 11/04/20 at 6:20 PM, the Technical Supervisor B stated, the procedures do not include the need for a confirmatory ABO and RH typing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the the revised "BB 82 Patient Retyping" procedure. Findings: The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on

	11/03/20 and reported an estimated annual test volume of 616,868. The estimated number of Immunohematology tests performed is 19,556. Review of the laboratory's procedure titled, "BB 82 Patient Retyping", showed a published date of 11/09/18. Review of the laboratory's procedure titled, "BB 82 Patient ABO Rh Confirmation", showed a published date of 04/28/20. During an interview on 11/04/20 at 4:32 PM. The Integrated Regional Laboratories (IRL) Quality Manager stated, the procedure "BB 82 Patient Retyping", was signed by the Laboratory Director on 12/31/18. During an interview on 11/04/20 at 4:34 PM, the IRL Quality Manager stated, the name for the procedure titled, "BB 82 Patient Retyping" was changed to "Patient ABO Rh Confirmation" and the procedure was updated. During an interview on 11/04/20 at 4: 35 PM, the IRL Quality Manager stated, the Laboratory Director signs the procedure manual every two years and did not sign after the procedure was updated.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the postanalytic system and correct identified problems. Findings: Cross Reference D5821: Based on record review and interview, the laboratory failed to promptly notify the patient's physician when the discrepancy in the patient's ABO Rh typing was detected.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to promptly notify the patient's physician when the discrepancy in the patient's ABO Rh typing was detected. Findings: The laboratory procedures were signed and dated by the Laboratory Director on 12/31/18. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, was signed and dated by the Laboratory Director on 11 /03/20 and reported an estimated annual test volume of 616,868. The estimated number of Immunohematology tests performed is 19,556. Review of the procedure titled, "BB 72 Transfusion Reaction Investigation" states if a transfusion reaction is suspected "contact the treating physician immediately for instructions for patient care and to determine if a transfusion reaction workup is indicated." Review of the Root

	Cause Analysis timeline states on 04/24/20 the following events occurred. 9:45 AM - "bb tech notified WRMC laboratory medical director that there is a discrepancy with the blood type of a patient. The medical director discussed with technologist that another specimen would need to be collected before anything else can be done." 10:06 AM - "new t&s was ordered." 10:39 AM - "new specimen collected." 10:43 AM - "t&s received in lab." 11:52 AM - "bb tech called icu and communicated to the charge nurse of a corrected blood type of A+ to O+. A transfusion reaction protocol was initiated by the technologist. WRMC medical director notified the IRL. EFD operations director about the blood type discrepancy." 1:05 PM - "the patient died." During an interview on 11/04/20 at 10:45 AM, the Laboratory Director stated, there was a delay in communication.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure Testing Personnel met required education and experience prior to patient testing. Findings: The Laboratory Director failed to ensure the laboratory verified the educational qualifications (degrees and foreign equivalence evaluations) of 3 (T, V, YY) out of 60 (A - HHH) Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. (See D6065)
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 record review and interview, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of 3 (T, V,YY) out of 60 (A - HHH) Testing Personnel. Findings: Cross Reference D6065: Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees and foreign equivalence evaluations) of 3 (T, V,YY) out of 60 (A - HHH) POC (Point of Care) Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States.
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 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees and foreign equivalence evaluations) of 3 (T, V, YY) out of 60 (A - HHH) Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 11 /04/2020, revealed there were 60 employees listed as moderate complexity testing personnel who perform POC (Point of Care). Review of the personnel documentation showed no documentation of the foreign equivalence evaluations for POC Testing Personnel T, V, and YY. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, was signed and dated by the Laboratory Diector on 11/03 /20 and reported an estimated annual test volume of 616,868. During an interview on 11/04/2020 at 11:22 AM, the Technical Supervisor B stated, they did not have the foreign equivalency evaluations.
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 record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6082 - Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic, analytic and postanalytic phases of testing from 04/23/20 to 11/05/20. Cross Reference D6101 - Based on record review and interview, the Laboratory Director failed to ensure Testing Personnel met required education and experience prior to patient testing.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic, analytic and postanalytic phases of testing from 04/23/20 to 11/05/20. Findings: The Laboratory Director failed to ensure the laboratory personnel followed the procedure manual. (See D5311 and D5401) The Laboratory Director failed to ensure the laboratory procedure manual was complete. (See D5403) The Laboratory Director failed to document the approval of the revised "BB 82 Patient Retyping" procedure by signing and dating the procedure. (See D5407) The Laboratory Director failed to ensure the laboratory promptly notified the patient's physician when the discrepancy in the patient's ABO Rh typing was detected. (See D5821)
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 met required education and experience prior to patient testing. Findings: The Laboratory Director failed to ensure the laboratory verified the educational qualifications (foreign equivalence evaluations) of 1 (I) out of 26 (A - Z) Laboratory Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. (See D6171)
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 interview, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of 1 (I) out of 26 (A - Z) Laboratory Testing Personnel. Findings: Cross Reference D6171: Based on record review and interview, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of 1 (I) out of 26 (A - Z) Laboratory Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States.
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, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of 1 (I) out of 26 (A - Z) Laboratory Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 11/04/20 & 11/06 /2020, revealed there were 26 employees listed as high complexity testing personnel. Review of personnel documentation showed no documentation of the foreign equivalence evaluations for Laboratory Testing Personnel I. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 11/03/20, reported an estimated annual test volume of 616,868. During an interview on 11/04/2020 at 11:22 AM, the Technical Supervisor B stated, they did not have the foreign equivalency evaluation.