Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0299090	10/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Health Central Clinical Laboratory	10000 W Colonial Drive, Ocoee, 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 was conducted on 09/30/19-10/2/19 at Health Central Clinical Laboratory. 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 4:30 PM on 10/02 /19. The laboratory reported patient test results on a patient with sperm present in their urine sample without performing a manual microscopic review. The laboratory failed to validate the method to method comparison of instrument to manual microscopic examination, (D5400). The following Conditions were not met: D5400 - 493.1250 Analytic Systems D5800 - 493.1290 Postanalytic Systems D6076 - 493.1441 Laboratory Director D6168 - 493.1487 Testing Personnel
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, the laboratory failed to ensure positive identification at the time of collection, and integrity of patient specimens at the time of arrival in the laboratory. Findings: 1. Review of the ""Events Details with Cause and Actions Taken by Department" report printed on 9/30/19 showed that from 7/1/19 to 8/31/19 there were 27 out of 40 events reported that were listed as "Sub Category Name: Specimen Labeling Issue." The "Laboratory Mislabeled Specimens" report shows in 2017 there were 45 mislabeled specimens, in 2018 there were 61 mislabeled specimens and from January through August 2019 there were 57 mislabeled specimens. The "Laboratory Mislabeled Specimen" states the 2019 target is a 10% reduction (61 x 10% = 6.1). The laboratory has already missed their target and still

	have 4 months of data not included in the total number of mislabeled specimens for 2019. During an interview on 9/30/19 at 12:45 PM, Operation Manager Risk Management acknowledged that they had a specimen labeling problem. 2. Review of the "Events Details with Cause and Actions Taken by Department" report printed on 9 /30/19 from 7/1/19 to 8/31/19 showed that there were no records available to show what happened to the labeled wet prep collected on 8/6/19. Event ID# Lab-203031 is regarding a GC (Gonorrhea/Chlamydia) and Wet Prep for Patient #6. The Event Description reports that the GC swab was unlabeled, the nurse was called, and the nurse stated, "GC was done by ME." The Event Description also stated the "Wet prep swab was labeled, however, GC swab was not." Examination of the patient's test results showed results for the Neisseria gonorrhoeae and Chlamydia trachomatis but no results for the wet prep. No test results were available on the wet prep. During an interview on 9/30/19 at 3:10 PM, the Interim Laboratory Manager acknowledged that the Events Details noted they had a wet prep sample on Patient #6. During an interview on 10/1/19 at 10:45 PM, the LIS (Laboratory Information System) Coordinator stated the computer showed only the GC collection information. The wet prep was canceled by the computer system after one week.
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 failed to follow laboratory's procedure on the Iriscell Urinalysis Analyzer. Cross Reference D5411. Based on record review and interview, the laboratory failed to follow manufacturer's instructions on the Iriscell Urinalysis Analyzer. Cross Reference D5775. Based on record review and interview, the laboratory failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of urine at least twice annually. .
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 failed to follow laboratory's procedure on the Iriscell Urinalysis Analyzer. Findings: The laboratory's procedure titled "Iriscell Urinalysis System" noted to return to the microscope for confirmation

	of sperm. A review of the 6 patients (#1, #2, #3, #4, #5, #6) that Iriscell identified as flagged for possible presence of sperm from 7/26/19 to 7/29/19 showed that 3 patients' (#1, #3, #6) test results reported sperm and no comment was made stating a manual microscopic examination was performed. An email sent out 7/30/19 at 11:33 AM to laboratory staff by the Hematology Supervisor read, "Sperms and Trichomonas identified by the Iris should be confirmed microscopically before releasing the results. Also please remember to add a comment of the confirmation." Review of urinalysis patients whose test results reported the presence of sperm from 7/31/19 to 8/31/19 showed that 5 (#7, #11, #12, #14, #15) out of 9 patients' (#7, #8, #9, #10, #11, #12, 13, #14, #15) microscopic examinations were not documented. There is no way to determine if the manual microscopic examinations were performed. During an interview on 9/30/19 at 11:10 AM, Hematology Supervisor acknowledged that testing personnel were required to microscopically confirm the presence of sperm and that there were no comments for patients #1, #3, and #6. During an interview on 9/30/19 at 3:30 PM, the LIS (Laboratory Information System) Coordinator acknowledged that patients #7, #11, #12, #14, and #15 did not have any comments listed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions on the Iriscell Urinalysis Analyzer. Findings: The Iriscell's operation manual chapter 7 read, "An effective verification process should be put in place by the laboratory to avoid incorrectly reporting positive sperm counts on certain specimens that due to gender and /or age considerations may result in a criminally reportable event." A review of the 6 patients (#1, #2, #3, #4, #5, #6) that Iriscell identified as flagged for the possible presence of sperm from 7/26/19 to 7/29/19 showed that 3 patients's (#1, #3, #6) test results reported sperm and no comments were made verifying a manual microscopic examination was performed. An email sent out 7/30 /19 at 11:33 AM to laboratory staff by the Hematology Supervisor stated "Sperms and Trichomonas identified by the Iris should be confirmed microscopically before releasing the results. Also please remember to add a comment of the confirmation." Review of urinalysis patients whose test results reported the presence of sperm from 7 /31/19 to 8/31/19 showed that 5 (#7, #11, #12, #14, #15) out of 9 patients (#7, #8, #9, #10, #11, #12, 13, #14, #15) microscopic examinations were not documented. There is no way to determine if the manual microscopic examinations were performed. During an interview on 9/30/19 at 11:10 AM, Hematology Supervisor acknowledged that testing personnel were required to microscopically confirm the presence of sperm and there were no comments for patients #1, #3, and #6. During an interview on 9/30/19 at 3:30 PM, the LIS (Laboratory Information System) Coordinator acknowledged that patients #7, #11, #12, #14, and #15 did not have any comments listed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or

	instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of urine at least twice annually. Findings: Review of the quality control documentation revealed that the laboratory failed to perform and document comparisons between the Iriscell urinalysis analyzer's microscopic examination and the manual microscopic examinations. Initial calibration records for the Iriscell were dated 11/24/14. During an interview on 9/30/19 at 3:00 PM, the Hematology Supervisor stated that method to method comparison for urine microscopic examinations had not been done since the initial calibration.
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 staff interview, the laboratory failed to monitor, evaluate and correct problems in the Postanalytic systems. Findings: Cross Reference D5821. Based on record review and interview, the laboratory failed to issue a corrected report. Cross Reference D5891. Based on record review and interview, the laboratory's Quality Assessment program failed to correct problems in the Postanalytical System.
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 issue a corrected report to the authorized person using the test results. Findings: Review of the "Event Details with Cause and Actions Taken by Department," showed that for Event ID# Lab-201969 (Patient #6) was subcategorized as "Incorrect Test Results Reported." Review of test results printed on 9/30/19 at 2:54 PM, for Patient #6, showed that urinalysis test results still reported the presence of sperm and there was

	no comment noting the presence of the sperm could not be verified because a microscopic examination of the urine was not performed. During an interview on 10/1 /19 at 5:03 PM, the Laboratory Manager acknowledged that the laboratory test results had not been changed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's Risk Management program failed to correct a problems in Postanalytical System. Findings: Review of the "Events Details with Cause and Actions Taken by Department," report printed on 9/30/19 showed that from 7/1/19 to 8/31/19 there were only 2 (Event ID# Lab-201969 and Lab-202776) out of 40 events that contained comments on Cause and Action Taken. The "Events Details with Cause and Actions Taken by Department" report showed there were 27 out of 40 events with specimen labeling issues. The "Events Details with Cause and Actions Taken by Department" report failed to address what happened to the wet prep (Event ID# Lab-203031). 1. Event ID# Lab-201969 (Patient #6) showed the form failed to identify the Severity, the Level of Harm, the Time of Call to the physician, Recommendation, and Cause. The Event Details reported the severity as "6, Undetermined or Potential Injury." The Event Details reported the Level of Harm as "05. An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm." The Risk Assessment failed to identify the harm caused as a result of incorrect test results. The Event Details failed to list the Time of Call to the physician and did not specify the date of the notification. The Event Details reported nothing in recommendations. The Event Details reported the Cause as, "Unknown at this time." The Event Details report Event Description failed to include that as a result of the incorrect test results, Patient #6 was subjected to unnecessary procedure including a rape kit and full assessment, and additional testing on 8/6/19 for gonorrhoeae and chlamydia. The Event Details reported the Action Taken as "Other (describe in "Add Notes")." The "Unusual Occurrence and Corrective Action Report" listed corrective action taken as "educate the team member and review the policy." Corrective action taken for the patient was not performed or documented. Review of test results printed on 9/30/19 at 2:54 PM, for Patient #6 showed that urinalysis test results still reported the presence of sperm and there was no comment noting the presence of the sperm could not be verified because a microscopic examination of the urine was not performed. During an interview on 9/30/19 at 12:45 PM, Operation Manager Risk Management acknowledged that the "Events Details with Cause and Actions Taken by Department" and the "Unusual Occurrence and Corrective Action Report" were the risk assessment forms filled out on Patient #6. During an interview on 10/1/19 at 5:03 PM, the Laboratory Manager acknowledged that the laboratory test results were not changed. 2. Event ID# Lab-202776 reported "Cause Notes: Event did not occur in PCU." The report noted Action Taken as "No Action Required" for a specimen that was listed as "Sub Category Name: Specimen Labeling Issue. Review of the "Events Details with Cause and Actions Taken by Department" report showed there were 27 out of 40 events that listed "Sub Category Name: Specimen Labeling Issue" from 7/1/19 to 8/31 /19. The "Laboratory Mislabeled Specimens" reports shows in 2017 there were 45

	mislabeled specimens, in 2018 there were 61 mislabeled specimens, and from January through August 2019 there were 57 mislabeled specimens. The "Laboratory Mislabeled Specimen" noted that the 2019 target was a 10% reduction (61 x 10% = 6.1). The laboratory had already missed their target and they still had 4 months of data not included in the total number of mislabeled specimens for 2019. During an interview on 9/30/19 at 12:45 PM, Operation Manager Risk Management acknowledged that they had a specimen labeling problem. 3. Event ID# Lab-203031 is regarding a GC (Gonorrhea/Chlamydia) and Wet Prep for for Patient #6. The Event Description reports that the GC swab was unlabeled, the nurse was called, and the nurse stated"GC was done by ME." The Event Description also stated the "Wet prep swab was labeled, however, GC swab was not." Examination of the patient's test results showed results for the Neisseria gonorrhoeae and Chlamydia trachomatis but no test results for the wet prep. No records were available to show what happened to the labeled wet prep collected on 8/6/19 . During an interview on 9/30/19 at 3:10 PM, Interim Laboratory Manager acknowledged that the Events Details states they had a wet prep sample on Patient #6. During an interview on 10/1/19 at 10:45 PM, the LIS (Laboratory Information System) Coordinator stated the computer showed that only the GC collected and that the wet prep was canceled by the computer system after one week.
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 Included: Cross Reference D6079. Based on record review and interview, the Laboratory Director failed to have oversight for the overall operations and administration of the laboratory. Cross Reference D6101. Based on record review and interview, the Laboratory Director failed to ensure Serology testing was performed by Testing Personnel who had the specialty of Serology on their Clinical Laboratory Personnel License for 1 (#D) out of 23 (#A-#W) Testing Personnel reviewed. Based on record review and interview, the Laboratory Director failed to ensure that staff had a foreign equivalency evaluation when a foreign diploma was obtained for 2 (#B and #Q) out of 23 (#A-#W) Testing Personnel reviewed. Cross Reference D6103. Based on record review and interview, the Laboratory Director failed to ensure 23 out of 23 (#A-#W) Testing Personnel had Urine microscopic competency evaluations and 1 out of 1 Laboratory Manager had a signed competency evaluation.
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: Based on record review and interview, the Laboratory Director failed to have oversight for the overall operation and administration of the laboratory. Findings: The Laboratory Director failed to ensure positive identification at the time of collection, and integrity of patient specimens at the time of arrival in the laboratory. (See D5203) The Laboratory Director failed to ensure that the laboratory followed laboratory's procedure on the Iriscell Urinalysis Analyzer. (See D5401) The Laboratory Director failed to ensure the laboratory follow manufacturer's instructions on the Iriscell Urinalysis Analyzer. (See D5411). The Laboratory Director did not ensure the laboratory performed and documented the comparison of the two methodologies used to perform the microscopic evaluation of urine at least twice annually. (See D5775). The Laboratory Director failed to ensure the laboratory issued a corrected report. (See D5821). The Laboratory Director failed to ensure the laboratory's Risk Management program corrected problems in the Postanalytical System. (See D5891). The Laboratory Director failed to ensure Serology testing was performed by Testing Personnel who had the specialty of Serology on their Clinical Laboratory Personnel License for 1 (#D) out of 23 (#A-#W) Testing Personnel reviewed. (See D6170) The Laboratory Director failed to ensure staff had a foreign equivalency evaluation when a foreign diploma was obtained for 2 (#B and #Q) out of 23 (#A-#W) Testing Personnel reviewed. (See D6171)
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 with the Administrator of Allied Health, the laboratory failed to ensure Serology testing was performed by Testing Personnel who had the specialty of Serology on their Clinical Laboratory Personnel License for 1 (#D) out of 23 (#A-#W) Testing Personnel reviewed. Based on record review and interview with the Human Resource Business Partners, the laboratory failed to ensure Staff had a foreign equivalency evaluation when a foreign diploma was obtained 2 (#B and #Q) out of 23 (#A-#W) Testing Personnel reviewed. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States (See D6168).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

	process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager and the Laboratory Director, the Laboratory Director failed to ensure 23 out of 23 (#A-#W) Testing Personnel had Urine microscopic competency evaluations and 1 out of 1 Laboratory Manager had a signed competency evaluation. Findings Included: Review of all 23 Testing Personnel (#A-#W) revealed that no Urine microscopic competency evaluations had been completed for 2 out of 2 years reviewed (2017-2019). Review of the Laboratory Manager's employee file revealed that the 2018 Competency evaluation was not signed by the Laboratory Director. Interview with the Laboratory Manager on 10/01/19 at 2:30 PM confirmed there were no competency evaluations for the urine microscopics performed and her competency had not been signed by the Laboratory Director. Interview with the Laboratory Director via phone on 09/30/19 at 4:00 PM revealed that he was not aware that competency evaluations were not performed for Urine microscopic testing and that the Laboratory Manager's 2018 had not been signed.
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 with the Administrator of Allied Health, the laboratory failed to ensure Serology testing was performed by Testing Personnel who had the specialty of Serology on their Clinical Laboratory Personnel License for 1 (#D) out of 23 (#A-#W) Testing Personnel reviewed (See D6170). Based on record review and interview with the Human Resource Business Partners, the laboratory failed to ensure Staff had a foreign equivalency evaluation when a foreign diploma was obtained for 2 (#B and #Q) out of 23 (#A-#W) Testing Personnel reviewed. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States (See D6171).
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with the Administrator of Allied Health, the laboratory failed to ensure Serology testing was performed by Testing Personnel who had the specialty of Serology on their Clinical Laboratory Personnel License for 1 (#D) out of 23 (#A-#W) Testing Personnel reviewed. Findings Included: Review of Testing Personnel employee files revealed that Testing Person #D had a State of

	Florida license in Microbiology, Chemistry, Hematology, and Immunohematology. Review of Serology testing performed by the laboratory from 07/01/19 to 10/01/19 revealed that Testing Personnel #D ran RPR (Rapid plasma reagin), RA (Rheumatoid arthritis), and ASO (Anti-streptolysin O) testing. There were 29 tests performed by Testing Person #D during this period. Interview on 10/01/19 at 6:15 PM, revealed that Testing Person #D had a date of hire of 10/10/16 and had been performing Serology testing since training complete in 04/2017.
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 Human Resource Business Partners, the laboratory failed to ensure Staff had a foreign equivalency evaluation when a foreign diploma was obtained for 2 (#B and #Q) out of 23 (#A-#W) Testing Personnel reviewed. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. Findings Included: Review of Testing Personnel #B's education revealed that a diploma from Venezuela was obtained, however there was no proof that a foreign equivalency evaluation was performed. The date of hire was 07/07/04. Review of Testing Personnel #Q's education revealed that a diploma from Columbia was obtained, however there was no proof that a foreign equivalency evaluation was performed. The date of hire was 09/06/19. Interview on 10/01/19 at 5:30 PM with the Human Resource Business Partners revealed that they did not have foreign equivalency documentation in Testing Person #B or #Q's personnel file.