

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2140712	(X3) Date Survey Completed 03/11/2021
Name of Provider or Supplier Labtest Llc Labtest Diagnostics	Street Address, City, State 8450 South West Freeway, 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	<p>An unannounced initial survey was performed on 3/11/21. I. Based on surveyor observations, review of the facility CMS-116, review of laboratory records from 2020-2021, and confirmed in interview, the laboratory was not an active clinical laboratory conducting patient testing at the time of the initial inspection on 3/11/21. Findings were: 1. Review of the CMS116 application that was received on 1/20/20 revealed a request to reinstate the CLIA certificate to begin hematology testing on 3/1/20. The CMS116 application revealed patient testing Monday, Tuesday, and Thursday from 0900 to 1230 hours. 2. Review of another CMS116 application received on 8/27/20 revealed a change of address to 8450 South West Freeway. 3. An attempt to perform an intial survey on 3/11/21 for the above address 8450 South West Freeway, Houston, TX revealed no laboratory at that address. 4. Surveyor called the facility number on the CMS116 application on 3/11/21 at 0906 hours for clarification about the laboratory location. The caller informed the surveyor to call another number (not listed on the CMS116 application). 5. Surveyor's call to that number revealed the laboratory location to be at a different address 8150 Southwest Freeway, Houston, TX. 6. Surveyor tour of the laboratory location at 8150 Southwest Freeway on 3/11/21 at 0940 hours revealed one Sysmex XN550 (SN13430) analyzer in storage unplugged; a Covid-19 antibody test kit in the laboratory refrigerator; and specimen collection tubes at a processing area. 7. An interview with the facility representative on 3/11/21 at 0935 hours confirmed that she only collected specimens and that she performed no patient testing at that location. She stated she collects the specimen and sends it to another lab for testing. She was unaware of the analyzer or test kit stored in the laboratory. 8. Review of the laboratory records from 2020 and 2021 revealed no evidence of patient testing at this location since 06/23/20. This location does not meet the definition of a laboratory under the CLIA regulations. "42 CFR 493.1 Basis and Scope. This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in 493.2 of this part. This part also applies to laboratories seeking</p>

payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification. 42 CFR 493.2 Definitions. Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories." 9. An interview with the facility manager on 3/11/21 at 1125 hours confirmed the above findings. II. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic 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; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Key: CMS- Centers for Medicare & Medicaid Services

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
 Based on a review of laboratory records from 2020 to 2021 and confirmed in interview, the laboratory failed to verify twice annually the accuracy of all tests it performed (Covid-19 IgG/IgM Antibody). The findings were: 1. Random review of the laboratory records from 2020 to 2021 revealed the laboratory performed patient testing for Covid-19 IgG/IgM for the following 18 patients. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488 Negative/Negative 6/23/20 RK123178 Negative /Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative /Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative /Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative /Negative 6/23/20 TS100397 Negative/Negative 6/23/20 ES041585 Negative /Negative 6/23/20 RR013074 Negative/Negative 6/23/20 SM051986 Negative /Negative 6/23/20 MK030687 Negative/Negative 6/23/20 AM012083 Negative /Negative 6/23/20 EL011378 Negative/Negative 6/23/20 AA101587 Negative /Negative 6/23/20 SP042584 Negative/Negative 6/23/20 AB062481 Negative /Negative 2. Review of the laboratory records from 2020 revealed no documentation of the twice annual accuracy for Covid-19 IgG/IgM test. 3. An interview with the facility manager on 3/11/21 at 1125 hours confirmed the above findings. He was unaware the laboratory was required to perform accuracy assessments.

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:

The laboratory did not have an effective mechanism by which to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for each specialty & subspecialty of testing performed by the laboratory in the following areas: Procedure manual (see D5401); Test systems (see D5413); and Control procedures (see D5449).

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 surveyor observations, review of the laboratory records from 2020-2021, and confirmed in interview, the laboratory failed to document a written procedures manual for 1 of 1 test it performed (Covid-19 IgG/IgM antibody test). Findings were:
1. Surveyor observations on 3/11/21 at 0940 hours in the laboratory revealed 1 opened box of Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette (lot 2004158, exp 202204) in the refrigerator. 2. Random review of the laboratory records from 2020 to 2021 revealed the laboratory performed patient testing for Covid-19 IgG /IgM for the following 18 patients. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488 Negative/Negative 6/23/20 RK123178 Negative/Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative/Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative/Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative/Negative 6/23/20 TS100397 Negative/Negative 6/23/20 ES041585 Negative/Negative 6/23/20 RR013074 Negative/Negative 6/23/20 SM051986 Negative/Negative 6/23/20 MK030687 Negative/Negative 6/23/20 AM012083 Negative/Negative 6/23/20 EL011378 Negative/Negative 6/23/20 AA101587 Negative/Negative 6/23/20 SP042584 Negative/Negative 6/23/20 AB062481 Negative/Negative 2. Review of the laboratory records from 2020 to 2021 revealed no documentation of a procedure signed and dated by the laboratory director for the Covid-19 IgG/IgM test 3. An interview with the facility manager on 3/11/21 at 1125 hours confirmed the above findings. He was unaware the laboratory was required to perform accuracy assessments.

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 review of manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to establish and monitor the acceptable temperature range for 1 of 1 day when Covid antibody patient testing was performed using Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette. The findings included: 1. Review of the package insert for 1 of 1 test: Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette (B21886-01, 2020-03-26) under test procedure revealed "allow test cassette, specimen and buffer to equilibrate to room temperature (15-30C) prior to testing." 2. Random review of the laboratory records from 2020 to 2021 revealed the laboratory performed patient testing for Covid-19 IgG/IgM for the following 18 patients on 6/23/20 with no documentation of the acceptable room temperature for testing. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488 Negative/Negative 6/23/20 RK123178 Negative/Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative/Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative/Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative/Negative 6/23/20 TS100397 Negative/Negative 6/23/20 ES041585 Negative/Negative 6/23/20 RR013074 Negative/Negative 6/23/20 SM051986 Negative/Negative 6/23/20 MK030687 Negative/Negative 6/23/20 AM012083 Negative/Negative 6/23/20 EL011378 Negative/Negative 6/23/20 AA101587 Negative/Negative 6/23/20 SP042584 Negative/Negative 6/23/20 AB062481 Negative/Negative 2. An interview with the facility manager on 3/11/21 at 1120 hours in the laboratory confirmed the above 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 the FDA websites, laboratory records from 2020-2021, and confirmed in interview, the laboratory failed to document complete establishment studies for 1 of 1 non-EUA approved testing performed (Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette). Findings were: 1. Review of the FDA website for COVID testing revealed no documentation of the Emergency Use Authorization for 1 of 1 testing: Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette. 2. Random review of the laboratory records from 2020 to 2021 revealed the laboratory performed patient testing for Covid-19 IgG/IgM for the following 18 patients. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488

Negative/Negative 6/23/20 RK123178 Negative/Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative/Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative/Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative/Negative 6/23/20 TS100397 Negative /Negative 6/23/20 ES041585 Negative/Negative 6/23/20 RR013074 Negative /Negative 6/23/20 SM051986 Negative/Negative 6/23/20 MK030687 Negative /Negative 6/23/20 AM012083 Negative/Negative 6/23/20 EL011378 Negative /Negative 6/23/20 AA101587 Negative/Negative 6/23/20 SP042584 Negative /Negative 6/23/20 AB062481 Negative/Negative 3. Review of the laboratory records revealed no documentation of the establishment studies: accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, preanalytical studies, and any other performance characteristic required for test performance for the above testing performed. 4. An interview with the facility manager on 3/11/21 at 1125 hours confirmed the above findings. He was unaware the laboratory was required to perform establishment studies.

D5449

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

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records from 2020 to 2021 and confirmed in interview, the laboratory failed to document 1 negative and 1 positive control for 1 of 1 day when Covid antibody patient testing was performed using Zheijiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette. The findings included: 1. Random review of the laboratory records from 2020 to 2021 revealed the laboratory performed patient testing for Covid-19 IgG/IgM for the following 18 patients on 6/23/20. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488 Negative/Negative 6/23/20 RK123178 Negative/Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative/Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative/Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative/Negative 6/23/20 TS100397 Negative/Negative 6/23/20 ES041585 Negative/Negative 6/23/20 RR013074 Negative/Negative 6/23/20 SM051986 Negative/Negative 6/23/20 MK030687 Negative/Negative 6/23/20 AM012083 Negative/Negative 6/23/20 EL011378 Negative/Negative 6/23/20 AA101587 Negative/Negative 6/23/20 SP042584 Negative/Negative 6/23/20 AB062481 Negative/Negative 2. Review of the laboratory records for the above date revealed no documentation of the negative and positive quality control performed. 3. In an interview with the facility manager on 3/11/21 at 1120 hours in the laboratory confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

A. Based on review of laboratory records from 2020-2021 and confirmed in interview, the laboratory failed to document the name and address of the laboratory location where the test was performed for 11 of 30 final reports reviewed. Findings were: 1. Random review of the laboratory records from 2020 to 2021 revealed the following 11 final patient reports for Covid-19 IgG/IgM testing with the following name and address of the laboratory who performed the test: LabTest Diagnostics Pasadena, 8150 South West Freeway, TX 77054. Coll Date: Patient ID Result (IgM/IgG) 6/25/20 EK070776 Negative/Negative 6/25/20 AA022276 Negative/Negative 6/25/20 AD082394 Negative/Negative 6/25/20 AK081995 Negative/Negative 6/25/20 SE061494 Negative/Negative 6/25/20 OK051597 Negative/Negative 6/25/20 NH081095 Negative/Negative 6/25/20 MM042590 Negative/Negative 6/25/20 JM091288 Negative/Negative 6/25/20 TT033070 Negative/Negative 6/25/20 OL091475 Negative/Negative 2. An interview with the facility manager on 3/11/21 at 1100 hours in the laboratory confirmed that the above final reports were not performed at this laboratory. He stated that only the lab records with the written results by the testing person were performed at this laboratory. He was unsure of where these tests were performed. He stated that he thinks the above testing were performed in their main laboratory in Missouri. B. Based on review of laboratory records from 2020-2021 and confirmed in interview, the laboratory failed to document the name and address of the laboratory location where the test was performed for 18 of 50 final reports reviewed. Findings were: 1. Random review of the laboratory records from 2020 to 2021 revealed the following 18 final reports for Covid-19 IgG /IgM testing with the name and address of the laboratory performing the test as: LabTest Diagnostics, 8150 South West Freeway, MO 63128. Coll Date: Patient ID Result (IgM/IgG) 6/23/20 EL111488 Negative/Negative 6/23/20 RK123178 Negative /Negative 6/23/20 AM051391 Negative/Negative 6/23/20 SA022684 Negative /Negative 6/23/20 AK101089 Negative/Negative 6/23/20 GD052473 Negative /Negative 6/23/20 NA062790 Negative/Positive 6/23/20 FY122084 Negative /Negative 6/23/20 TS100397 Negative/Negative 6/23/20 ES041585 Negative /Negative 6/23/20 RR013074 Negative/Negative 6/23/20 SM051986 Negative /Negative 6/23/20 MK030687 Negative/Negative 6/23/20 AM012083 Negative /Negative 6/23/20 EL011378 Negative/Negative 6/23/20 AA101587 Negative /Negative 6/23/20 SP042584 Negative/Negative 6/23/20 AB062481 Negative /Negative 2. An interview with the facility manager on 3/11/21 at 1100 hours confirmed that this laboratory performed the above patient testing. He stated the testing person would indicate the test result on the requisition with a 'N' and 'P' whenever he performed it. He is unaware why the final report has MO as the state and not TX.

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 written procedures, manufacturer's package insert instructions, patient test results, establishment study records, and verified by interview the Laboratory Director failed to provide overall management and direction. Refer to D6082, D6086, D6093

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 review of the FDA website, laboratory records from 2020- 2021 and confirmed in interview, the laboratory director failed to ensure that the testing system developed and used for 1 of 1 test performed in the laboratory provide quality laboratory services for all aspects of test performance. Findings were: 1. Review of the FDA website for Covid testing found the Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette was listed on the 'Removal Lists of Tests that Should No Longer Be Used and/or Distributed for COVID-19' 2. Review of the FDA website: Certain COVID-19 Serology/Antibody Tests Should Not Be Used - Letter to Clinical Laboratory Staff and Health Care Providers revealed the following: "The FDA recommends laboratories and health care providers: Stop using the antibody tests listed on FDA ' s "removed" test list. Evaluate, given the patient ' s clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test. Remove from your stock any remaining tests that are listed on FDA ' s "removed" test list. Report any issues with using COVID-19 tests to the FDA" 3. Random review of the laboratory records from 2020-2021 revealed documentation the laboratory performed 18 Covid Antibody patient using the above test kit that was not EUA approved by the FDA. Coll Date: Patient ID Result (IgM/IgG) 6/23/20
EL111488 Negative/Negative 6/23/20 RK123178 Negative/Negative 6/23/20
AM051391 Negative/Negative 6/23/20 SA022684 Negative/Negative 6/23/20
AK101089 Negative/Negative 6/23/20 GD052473 Negative/Negative 6/23/20
NA062790 Negative/Positive 6/23/20 FY122084 Negative/Negative 6/23/20
TS100397 Negative/Negative 6/23/20 ES041585 Negative/Negative 6/23/20
RR013074 Negative/Negative 6/23/20 SM051986 Negative/Negative 6/23/20
MK030687 Negative/Negative 6/23/20 AM012083 Negative/Negative 6/23/20
EL011378 Negative/Negative 6/23/20 AA101587 Negative/Negative 6/23/20
SP042584 Negative/Negative 6/23/20 AB062481 Negative/Negative 4. Review of the laboratory records available revealed no corrective actions recommended by the FDA for the above patients tested. 5. An an interview with the facility manager on 3/11/21 at 1120 hours in the laboratory confirmed the above findings.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to

	<p>determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of the FDA websites, laboratory records from 2020-2021, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete establishment studies for 1 of 1 non-EUA approved testing performed (Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette). Refer to D5423</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control 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 laboratory records from 2020 to 2021 and confirmed in interview, the laboratory director failed to ensure the laboratory documented 1 negative and 1 positive control for each day of Covid antibody patient testing was performed using Zhejiang Orient Gene Biotech Co. Covid-19 IgG/IgM Rapid Test Cassette. Refer to D5449</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 personnel records and confirmed in interview, it was revealed that 1 of 1 testing personnel performing high complexity testing did not have the appropriate education credentials required to perform high complexity testing (refer to D6171).</p>
<p>D6171</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(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</p>

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 personnel files and interview of facility personnel it was revealed that the facility failed to have documentation that all testing personnel were qualified to perform high complexity testing at the time of the survey. Findings were: 1. Review of laboratory records revealed 1 testing person performed high complex testing on 6/23/20. 2. Review of the personnel records revealed no educational documentation available for review at the time of the survey to qualify the testing person to perform high complexity testing. 3. An interview with the facility manager on 3/11/21 at 1120 hours in the laboratory confirmed the above findings.