Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	44D1071166	10/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ambulatory And Occupational Medicine Clinic	2302 Madison Street, Clarksville, TN	

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	During a recertification survey performed on 10/16/23, the laboratory was found out of compliance with the following conditions: 493.801 Condition: Enrollment and testing of samples 493.1205 Condition: Virology 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, staff interview, review of patient test reports, review of proficiency testing records, and staff interview, the laboratory used the Quidel Sophia Respiratory Syncytial Virus (RSV) as a non-waived test in 2022 and 2023 and was not enrolled in proficiency testing, with a total of nine patients tested and reported during the two year period. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia in use for patient testing for RSV. 2. Review of the manufacturer instructions for use revealed the test was moderately complexity for pediatric patients from the age of seven to less than nineteen. The package insert

	further stated "The Sophia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients." 3. An interview with the lead testing person on 10/16/23 at 1 pm revealed the laboratory tests patients of all ages. 4. Review of patient test reports revealed performance and reporting of RSV on patients over the age of six in 2022 and 2023 (patient #s 72754 on 11/12/22, 104331958 on 11/13/22, 78916911 on 11/13/22, 104331959 on 11/13/22, 103553564 on 11/20/22, 104619929 on 12/22/22, 104811496 on 01/18/23, 104891105 on 01/23/23, 101773733 on 07/30/23). 5. Review of the laboratory's proficiency testing records revealed there was no enrollment or participation in proficiency testing for the RSV direct antigen in 2022 or 2023. 6. Interview with the laboratory lead on 10/16/23 at 2 pm confirmed the laboratory used the RSV as a non-waived test in 2022 and 2023 and was not enrolled in proficiency testing.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services Casper Report 0155D (CMS 155), the laboratory's proficiency testing records, the laboratory's quality control (QC) records, patient test records and interview with the lead testing person, the laboratory failed to ensure participation in proficiency testing for 2023 event one for chemistry with patient testing being performed. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Triage instrument in use for performing patient testing for Myoglobin, Creatine Kinase Myocardial Band (CK-MB) and Troponin I. 2. Review of the CMS 155 revealed a score of 0% for the chemistry specialty and the CK-MB analyte for 2023 event one. 3. Review of the laboratory's proficiency testing records revealed the following: 0% for failure to participate. Ship date was 01/09/23; Event due date was 02/01/23. 4. Review of the laboratory's January 2023 Triage meter QC records revealed the performance of daily QC for the Triage meter during the time when the PT results were due. 5. Review of the laboratory's accession logs and patient test reports revealed reporting of patient results for Myoglobin, CK-MB and Troponin I on 01/21/23 for patient medical record #82488353, during the period when the PT results were due. 6. Interview with the laboratory lead on 10/16/23 at 11:30 am confirmed the laboratory failed to participate in proficiency testing for 2023 event one chemistry with patient testing being performed.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)

	Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the laboratory lead, the laboratory failed to maintain three of thirteen proficiency testing performance evaluation reports for a period of two years. The findings include: 1. Review of the laboratory's proficiency testing records revealed the performance evaluation reports for hematology were not maintained for two years for 2021 event three, 2022 event one, and 2022 event three. 2. Interview with the laboratory lead on 10/16/23 at 2 pm confirmed the laboratory failed to maintain all proficiency testing records for a period of two years for three of thirteen PT events reviewed from 2021, 2022, and 2023.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, patient test reports, lack of records and staff interview, the laboratory failed to verify the performance specifications for use of the Quidel RSV as a moderately complex test (Refer to D5421) and failed to establish performance specifications when it modified and used the Quidel Sophia RSV test outside the manufacturer's stated patient age groups in 2022 and 2023 (Refer to D5423).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, testing personnel competency assessments, and staff interview, the laboratory failed to ensure it's testing personnel competency assessment policy and documentation was in compliance with the requirements in Subpart M when it did not include all six required elements in the policy, did not include all required elements in the competency assessment documentation, and did not ensure testing personnel had been evaluated by the laboratory director who functions as the technical consultant prior to patient testing in 2020, 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the following non-waived test systems in use for patient testing: Sysmex PocH-100i Complete Blood Count (CBC) instrument Quidel Triage in use for performing cardiac marker testing (Myoglobin, Troponin, CK-MB) Quidel RSV being used as a non-waived test 2. Review of the laboratory 's policy titled "LABORATORY QUALITY ASSESSMENT & IMPROVEMENT PLAN" revealed the following under section V. Personnel

	Assessment: Problem solving was not included as part of competency assessment. Direct observations were not required to be performed by the lab director or technical consultant. Direct observations were not specified, i.e. patient testing or maintenance. Record review of quality control records, preventative maintenance records, proficiency testing records was not included as part of competency assessment requirements. Monitoring the recording and report of results was not included. Reassessment of competency when test methods or instruments change was not included as a requirement. 3. Review of the laboratory's testing personnel competency assessment records revealed the following: The forms used for assessing competency in 2020, 2021, 2022, and 2023 did not separately address the required elements for each non-waived test system. RSV was not included no any of the competency assessments performed for any of the four testing personnel in 2020, 2021, 2022, or 2023. Testing person #1-annual competency done on 08/19/20 did not address CBC and cardiac marker separately, review of maintenance records was not included in the competency assessment; annual competency done on 08/15/21 did not address CBC and cardiac marker separately for the required elements, review of maintenance records was not included in the competency assessment, annual competency done on 08/25/22 did not address CBC and cardiac markers separately, review of maintenance records was not included in the competency assessment; direct observations was not addressed; annual competency done on 09/12/23- CBC and cardiac markers were not addressed separately, review of maintenance records was not included, direct observations was not included in the competency assessment. Testing person #2: initial training done on 03/10/22 for CBC and 05/20/22 for cardiac markers. Not approved by the lab director who functions as the technical consultant until 10/04/22; 6-month competency assessment done 07/30/22-proficiency testing was not included in the evaluation, CBC and cardiac markers were not addressed separately for each required element, review of maintenance records was not included in the competency assessment; annual competency done 10/09/23-Direct observations was not included in the competency assessment. Testing person #3 initial training done on 02/25/20 for CBC and 03/25/20 for cardiac markers, not approved by the lab director who functions as the technical consultant until 11/11/20; six-month competency assessment done on 08/04/20 did not address CBC and cardiac markers separately for the required elements, and did not include review of maintenance records, annual competency dated 02/04/21 did not address CBC and cardiac markers separately for the required elements, and did not include review of maintenance records, annual competency performed on 02/04/22 did not include assessment for proficiency testing, did not include review of maintenance records, the problem-solving test did not include anything for CBC, the competency assessment performed on 10/09/23 did not address CBC and cardiac markers separately for the required elements. Testing person #4-Initial training form with a date of hire of 08/03/23 with documented training for CBC that had not been signed off or approved by the lab director who functions as the technical consultant. 4. Interview with the laboratory lead on 10/16/23 at 2:00 pm confirmed the laboratory's policy for testing personnel competency assessment was not in compliance with the requirements in subpart M when it did not include all six elements in the competency assessment policy and competency assessment documentation for each non-waived test system, and did not include reassessment of competency if test methods or instrument changes.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance

	(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the laboratory lead, the laboratory failed to evaluate two of two proficiency testing samples with non-graded scores in 2023. The findings include: 1. Review of the laboratory's proficiency testing evaluation report for 2023 event two cardiac markers revealed non-graded scores for sample CM-06 and CM-09 for Troponin I. There was no documented evaluation of the scores to determine the laboratory's accuracy. 2. Interview with the lab lead on 10/16/23 at 2 pm confirmed the laboratory did not evaluate non-graded proficiency testing scores for Troponin I performed on samples CM-06 and CM 09 for 2023 event two - cardiac marker survey.
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 observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory procedure manual failed to include panic values for the CK-MB, Myoglobin, and Troponin I, sample type and rejection criteria for the CK-MB, Myoglobin and Troponin I, sample type and rejection criteria for the Sysmex PocH-100i CBC instrument on the date of the survey (10/16/23). The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Sysmex PocH-100i CBC instrument and the Quidel Triage cardiac marker instrument in use for patient testing. 2. Review of the laboratory procedure manual revealed the following: No alert or panic testing values for the cardiac testing performed on the Quidel Triage instrument. No sample type or rejection criteria for the cardiac markers performed on the Quidel Triage instrument. No sample type or rejection criteria for the Sysmex PocH-100i CBC instrument. 3. Interview with the lab lead on 10/16/23 at 2 pm confirmed the laboratory procedure manual did not include alert values for cardiac markers performed on the Quidel Triage instrument, the sample types and

	rejection criteria for cardiac markers performed on the Quidel Triage instrument or the Sysmex PocH-100i CBC instrument.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the laboratory lead, the laboratory failed to ensure capillary collection tubes used for the collection of patient complete blood count (CBC) samples were not used past their expiration date on the date of the survey (10/16/23). The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the following: The Sysmex PocH-100i CBC instrument (serial #G4769) in use for patient CBC testing. Capillary tubes used for collection of patient fingerstick samples for CBC were expired (Lot 8106835, expiration date of 09/30/19). 2. Interview with the laboratory lead on 10/16/23 at 9:30 am confirmed the laboratory failed to ensure capillary collection tubes used for collection of patient samples for CBC were not used past their expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, staff interview, review of patient test reports, lack of records, and interview with the laboratory lead, the laboratory failed to verify the performance specifications for the use of the Quidel Sophia RSV test as a moderately complex test system in in 2022 and 2023. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia in use for patient testing for RSV. 2. Review of the manufacturer instructions for use revealed the test was waived complexity when used on children under the age of seven and moderate complexity for pediatric patients from the age of seven to less than nineteen. 3. An interview with the lead testing person on 10/16/23 at 1 pm revealed the laboratory tests patients of all ages for RSV. 4. Review of patient test reports revealed reporting of RSV performed on patients between the ages of seven and eighteen as follows: Patient 104331959, performed on 11/13/22 Patient 103553564 performed on 11/20/22 Patient 104811496 performed on 01/18/23 Patient 104891105 performed on 01/23/23 Patient 101773733 performed on 07/30/23 5. There were no records available on the date of the survey for verification of performance specifications for use of the RSV as a moderately complex test. 6. Interview with the laboratory lead on 10/16/23 at 2 pm confirmed the laboratory used

	the Quidel RSV as a moderately complex test and failed to verify the performance specificiations.
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 observation of the laboratory, review of manufacturer instructions for use, staff interview, review of patient test reports, lack of records, and interview with the laboratory lead, the laboratory failed to establish the performance specifications for the use of the Quidel Sophia RSV test outside the manufacturer's specified age groups in 2022 and 2023. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia in use for patient testing for RSV. 2. Review of the manufacturer instructions for use revealed the test was waived complexity when used on children under the age of seven and moderate complexity for pediatric patients from the age of seven to less than nineteen. 3. An interview with the lead testing person on 10/16/23 at 1 pm revealed the laboratory tests patients of all ages for RSV. 4. Review of patient test reports revealed reporting of RSV performed on patients over the age of 18 (patient #s 72754 on 11/12/22, 104331958 on 11/13/22, 78916911 on 11/13/22, 104619929 on 12/22/22). 5. There were no records available on the date of the survey for establishment of performance specifications for use of the RSV outside the manufacturer's patient age groups. 6. Interview with the laboratory lead on 10/16/23 at 2:00 pm confirmed the laboratory used the Quidel Sophia RSV test outside the manufacturer specified age groups in 2022 and 2023 and did not establish the performance specifications.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) records, record request, and staff interview, the laboratory failed to have a process in place to monitor QC for accuracy and precision over time for nine of nine lot numbers reviewed from 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Sysmex PocH-100i CBC instrument in use for patient testing. 2. Review of randomly selected QC lot numbers from the past two years revealed the following: Lot 1222 levels low, normal and high in use on 11/16/21. Lot 3164 levels low, normal and high in use on 10/19/22. Lot 3164 levels low, normal and high in use on 09/08/23. 3. A request was made to the laboratory lead on 10/16/23 at 12:30 pm for Levy Jennings graphs or other methods of monitoring for shifts and trends or monitoring for accuracy and precision over time. No records were available. 4. Interview on 10/16/23 at 2 pm confirmed the laboratory did not have a process in place for monitoring for shifts or trends for the last two years. She confirmed the laboratory did not print the Levy Jennings graphs. She stated the laboratory only reviews the results of the daily quality control.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the lab lead, the laboratory director failed to ensure laboratory personnel were protected from biological hazards when no eyewash was available in the laboratory area. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed patient testing performed for CBC and cardiac markers. No eye wash was observed inside the laboratory. 2. Interview with the lab lead on 10/16/23 at 2 pm confirmed the lab director failed ensure employees were protected from biological hazards when he did not ensure access to an eyewash was available in the laboratory area.
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 review of the laboratory's testing personnel records, review of patient test

	reports and staff interview, the laboratory director failed to ensure one of three new testing personnel had evidence of highest level of education and failed to ensure three of three new testing personnel had demonstrated accuracy prior to performing patient testing for CBC and cardiac markers in 2020, 2022 and 2023. The findings include: 1. Review of the laboratory's testing personnel records revealed the following: a. Testing person number two hire date of 01/20/22, with training on 03/10/22 for CBC and on 05/20/22 for cardiac markers, no lab director review/approval for testing until 10/04/22. b. Testing person number three hire date of 02/04/20, with training on 02/25/20 for CBC and 03/25/20 for cardiac markers, no lab director review/approval until 11/11/20. c.Testing person number four had no documentation of the highest level of education (Refer to D6064). The training and competency assessment form had not been signed by the lab director on the date of the survey (10/16/23). 2. Review of patient test records revealed the following: a. Patient testing for CBC performed on 04/02/22 (patient 87834955) and cardiac marker testing on 05/26/22 (patient 88547247) by testing person number two prior to lab director review/approval for testing. b. Patient testing for CBC and cardiac marker performed by testing person three on 08/07/20 (patient 97135631) prior to lab director approval for testing. c. Patient testing for CBC performed by testing person four on 10/11/23 (patient 107273267) without lab director approval for testing. 3. Interview with the laboratory lead on 10/16/23 at 2 pm confirmed the laboratory director failed to ensure the testing personnel had evidence of highest level of education and had demonstrated they could perform patient testing accurately prior to patient testing in 2020, 2022, and 2023.
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 observation of the laboratory, review of testing personnel records, patient test reports, and staff interview, testing person number four did not meet the regulatory requirements to perform moderately complex patient testing (Refer to D6065).
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 observation of the laboratory, review of testing personnel records, review of patient test reports, and staff interview, testing person number four did not qualify as testing person for moderately complex patient testing due to lack of evidence of the highest level of education (one of three new testing personnel). The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed non-waived test platforms in use for performing patient testing for CBC and cardiac markers (Myoglobin, CK-MB, Troponin I). 2. Review of testing personnel records revealed no documentation of the highest level of education for testing person number four. 3. Review of patient number 107273267 revealed CBC performed by testing person number four on 10/11/23. 4. Interview with the laboratory lead on 10/16/23 at 2pm confirmed that testing person number four performs patient testing for CBC and personnel records did not include evidence of the highest level of education.
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 observation of the laboratory, review of manufacturer package insert, patient test reports, lab director qualifications, and staff interview, the laboratory director did not meet the regulatory requirements for directing high complexity testing. (Refer to D6078)
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience

	directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, patient test reports, lab director qualifications, and staff interview, the laboratory director did not meet the regulatory requirements for directing high complexity testing. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia RSV test in use for patient testing. 2. Review of the manufacturer package insert revealed the test is waived when used on patients under the age of seven and moderately complex when used on patients age seven to eighteen. 3. Review of patient test reports revealed reporting of RSV on patients over the age of eighteen resulting in a laboratory-developed high complexity test. (Refer to D5423). 4. Review of laboratory director qualifications revealed the director did not meet high complexity personnel requirements. 5. Interview with the laboratory lead on 10/16/23 at 2:00 pm confirmed the laboratory was performing the RSV as a high-complexity test and the laboratory director did not meet the regulatory requirements for directing high complexity testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, patient test reports, personnel records, and staff interview, the laboratory did not have a technical supervisor who met the regulatory requirements for oversight of high complexity testing for virology in 2022 or 2023 (Refer to D6109).
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by:

	Based on observation of the laboratory, review of manufacturer package insert, patient test reports, personnel records, and staff interview, the laboratory did not have a technical supervisor who met the regulatory requirements for oversight of high complexity testing for virology in 2022 or 2023. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia RSV test in use for patient testing. 2. Review of the manufacturer package insert revealed the test is waived when used on patients under the age of seven and moderately complex when used on patients age seven to eighteen. 3. Review of patient test reports revealed reporting of RSV on patients over the age of eighteen resulting in a laboratory-developed high complexity test. (Refer to D5423). 4. Review of personnel records revealed the laboratory did not have a technical supervisor who met the high complexity testing requirements in the specialty of virology. 5. Interview with the laboratory lead on 10/16/23 at 2:00 pm confirmed the laboratory was performing the RSV as a high-complexity test and the laboratory did not have a technical supervisor who met the requirements for technical oversight of high complexity testing in the virology specialty.
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 observation of the laboratory, review of manufacturer package insert, patient test reports, testing personnel records, and staff interview, four of four testing personnel did not meet the regulatory requirements for performing high complexity testing for the RSV analyte. (Refer to 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 observation of the laboratory, review of manufacturer package insert, patient test reports, testing personnel records, and staff interview, four of four testing personnel did not meet the regulatory requirements for performing high complexity testing for the RSV analyte. The findings include: 1. Observation of the laboratory on 10/16/23 at 9:30 am revealed the Quidel Sophia RSV test in use for patient testing. 2. Review of the manufacturer package insert revealed the test is waived when used on patients under the age of seven and moderately complex when used on patients age seven to eighteen. 3. Review of patient test reports revealed RSV reporting on patients over the age of eighteen resulting in a laboratory-developed high complexity test. (Refer to D5423). 4. Review of testing personnel records revealed four of four testing personnel did not met the requirements for performing high complexity testing. 5. Interview with the laboratory lead on 10/16/23 at 2:00 pm confirmed the laboratory was performing the RSV as a high-complexity test and the laboratory testing personnel did not meet the regulatory requirements for performing high complexity testing.