Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2161589	01/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Exam Corp Lab	9024 N Milwaukee Ave, Niles, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory owner the laboratory director failed to attest to the routine testing of proficiency testing (PT) samples for two of three PT events in 2021 for chemistry and hematology. Findings Include: 1. Proficiency testing records from the American Association of Bioanalysts (AAB) were reviewed for 2021. 2. Review of AAB PT records for hematology and chemistry revealed the laboratory testing personnel and laboratory director failed to attest that PT samples were handled in the same manner as patient samples for the following events: Chemistry a. 2021 - Event 2 b. 2021 - Event 3 Hematology a. 2021 - Event 2 b. 2021 - Event 3 3. On survey date 12-29-21, at 2:40 pm the findings were confirmed by the laboratory owner.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records and interview with the laboratory owner; the laboratory failed to meet general immunology testing

	requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to ensure specimen integrity was maintained throughout the testing process by failing to follow the laboratory's specimen labeling requirements for COVID-19 specimens for five of five patient specimens reviewed. See D5203. 2. The laboratory failed to monitor the room temperature and humidity of the laboratory where the Quidel Solana analyzers were located to ensure accurate and reliable operation, affecting 631 patient test results and the laboratory failed to monitor storage of Quidel Solana SARS-CoV-2 assay reagents to ensure accurate and reliable operation, affecting 631 patient test results. See D5413. 3. The laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for SARS-CoV-2 testing performed on the two Quidel Solana analyzers, affecting 631 patient tests. See D5421. 4. The laboratory failed to include two control materials (positive and negative) for each molecular amplification procedure for SARS-CoV-2 testing on the Quidel Solana analyzers, affecting 631 patient test results. See D5455.
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 review of laboratory records, direct observations, and interviews with the laboratory owner; the laboratory failed to ensure specimen integrity was maintained throughout the testing process by failing to follow the laboratory's specimen labeling requirements for COVID-19 specimens for five of five patient specimens reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Specimens Processing", which stated on page one of two under the heading of "Specimen Rejection Criteria": "1. Specimen is labeled with Name of Patient, Date of Collection and for microbiology source and time of collection, if this information is missing it is called unlabeled and it will be rejected." 2. During tour of the laboratory facility on 12-29-2021, at 5:37 pm, a patient specimen was identified that failed to include the required elements as indicated in the laboratory's specimen processing procedure. a. No name b. No collection date and time c. Source 3. During tour of the laboratory facility on 12-30-2021, at 11:04 am, four additional patient specimens were identified that failed to include the required elements as indicated in the laboratory's specimen processing procedure. a. Incomplete name (First name only) b. No collection date and time c. Source 4. On survey date 12-30-2021, at 2:400 pm, the laboratory owner confirmed the laboratory was not following the specimen handling procedure as outlined in the laboratory policy and procedure manual.
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: A. Based on direct observation, review of laboratory records, and interview with the laboratory owner; the laboratory failed to monitor the room temperature and humidity of the laboratory where the Quidel Solana analyzers were located to ensure accurate and reliable operation, affecting 631 patient test results. Findings Include: 1. Direct observation of the laboratory facility on 12-29-2019 at 1:08 pm identified the room where two Quidel Solana analyzers were located. No thermometer was observed in the room to monitor room temperature and humidity. 2. Review of preventative maintenance logs for 2020 through 2022 found no documented recordings of room temperature and humidity where the Quidel Solana analyzers were located. 3. Review of the Quidel Solana operations manual on page 67 revealed the following operating conditions: "Operating Conditions - Only for indoor use - Temperatures between +15 to 35 Celsius - Elevation up to 2000 meters high - Highest relative humidity 80% for temperatures up to 31 Celsius" 5. Interview with the laboratory owner on 12-29-2021, at 6:44 pm, confirmed room temperature and humidity were not monitored for the room where the Quidel Solana analyzers were located. 6. Review of test volume records found the laboratory reported 631 patient test results for SARS-CoV-2 on the Quidel Solana analyzers when temperatures and humidity were not monitored. 7. On survey date 12-30-2021, at 2:40 pm the findings were confirmed by the laboratory owner. B. Based on direct observation, review of laboratory records, and interviews; the laboratory failed to monitor storage of Quidel Solana SARS-CoV-2 assay reagents to ensure accurate and reliable operation, affecting 631 patient test results. Findings Include: 1. Direct observation of the laboratory facility on 12-29-2019 at 1:08 pm identified a Thermo Scientific ULT185-5-V Ultra Low Temperature Benchtop -80 Celsius (C) freezer used to store master mix reagents for the Quidel SARS-CoV-2 assay performed on the Quidel Solana analyzers. 2. Review of preventative maintenance logs for 2021 through 2022 found no documented recordings of the -80C freezer where the Quidel SARS-CoV-2 assay master mix reagents were stored. 3. Review of the Quidel Solana SARS-CoV-2 assay instructions for use manual on page 4 of 14 indicated the following storage conditions: "Store the Master Mix at -70 Celsius or below" 5. Interview with laboratory testing personnel #3 on 12-29-2021, at 4:35 pm, confirmed the temperature of the -80 C freezer was not monitored and recorded. 6. Review of test volume records found the laboratory reported 631 patient test results for SARS-CoV-2 on the Quidel Solana analyzers when storage temperatures for the master mix were not monitored and recorded. 7. On survey date 12-30-2021, at 2:40 pm the findings were confirmed by the laboratory owner.
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 direct observation, review of laboratory records, and interview with the laboratory owner; the laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for SARS-CoV-2 testing performed on the two Quidel Solana analyzers, affecting 631 patient tests. Findings Include: 1. Direct observation of laboratory equipment during a tour of the laboratory facility, on 12-29-2021, at 1:08 pm, identified two Quidel Solana analyzers, serial numbers 20021839 and 20021833. 2. Laboratory records indicate patient testing started on 11-23-21 for SARS-CoV-2 on the Quidel Solana analyzers. 2. Review of laboratory records for the Quidel Solana SARS-CoV-2 assay found no documented verification of performance specifications for the two Quidel Solana analyzer prior to the start of patient testing. 3. Review of test volume records revealed the laboratory performed 631 tests for SARS-CoV-2 on the Quidel Solana analyzers since the start of patient testing 11-23-21 to 12-30-2021. 4. On survey date 12-30-21, at 2:40 pm, the laboratory owner confirmed the laboratory failed to have verification of performance documentation for the two Quidel Solana analyzer for the SARS-CoV-2 assay performed.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the laboratory owner; the laboratory failed to include two control materials (positive and negative) for each molecular amplification procedure for SARS-CoV-2 testing on the Quidel Solana analyzers, affecting 631 patient tests. Findings Include: 1. Direct observation of laboratory on 12-29-21 at 1:08 pm, identified two Quidel Solana analyzers used for SARS-CoV-2 testing. 2. Review of the laboratory procedure manual identified the procedure, "Solana SARS-CoV-2 assay", which indicated a "maximum of 12 tests can be performed per test run in a single Solana instrument". The procedure goes on to state " a positive control (such as a positive patient sample) should be processed and tested with each batch of specimens" and "the external negative control may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen". 3. Review of Patient/Quality Control logs for testing dates in December of 2021 found the laboratory failed to perform positive and negative quality controls with each batch of patient specimens for six of six patient testing dates reviewed. Test Date Patients Tested Controls Performed 12-04-21 10 None documented 12-06-21 Run #1 10 None documented 12-06-21 Run #2 3 None documented 12-06-21 Run#3 11 None Documented 12-10-21 Run#1 11 Positive Only 12-10-21 Run#2 11 Positive Only 12-10-21 Run#3 11 Positive Only 12-11-21 Run#1 9 Positive Only 12-11-21 Run#2 11 Positive Only 12-12-21 8 Positive Only 12-18-21 Run#1 11 Positive Only 12-18-21 Run#2 11 Positive Only 12-18-21 Run#3 11 Positive Only 12-18-21 Run#4 11 Positive Only 12-18-21 Run#5 11

	Positive Only 12-18-21 Run#6 9 Positive Only 12-18-21 Run#7 11 Positive Only 12-18-21 Run#8 8 None documented 5. Further review of the December 2021 patient testing/quality control logs found the laboratory failed to perform two levels of control materials for each amplification procedure and no documented negative control samples were identified for any testing run or date of testing. 6. Review of the laboratory test volume records found 631 patients were tested for SARS-CoV-2 using the Quidel Solana analyzer. 7. Interview with the laboratory owner on 12-30-2021, at 2:40 pm, confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records, and interviews with the laboratory owner and testing personnel; the facility failed to have a laboratory director (LD) that provided overall management and direction in accordance with 493.1407 of this subpart. Findings Include: 1. The LD failed to ensure a safe environment to protect testing personnel from biological hazards related to COVID-19 specimen disposal for two of two months since the start of Quidel Solana SARS-CoV-2 testing in 2021. See D6011. 2. The LD failed to ensure verification procedures were adequate to determine the accuracy, precision, and all other pertinent performance characteristics for COVID-19 testing performed using the Quidel Solana SARS-CoV-2 assay, affecting 631 patients who had testing performed using this system. See D6013. 3. The LD failed to ensure testing personnel were performing the Quidel Solana SARS-CoV-2 assay as required for accurate and reliable results, affecting 631 patients' test results. See D6014. 4. The LD failed to document review of proficiency testing (PT) records for two of three PT events reviewed in 2021 for chemistry and hematology. See D6018. 5. The LD failed to ensure an approved corrective action plan was followed for unacceptable urine sediment, high density lipoprotein, and eosinophil percentage proficiency testing (PT) analytes for event two and three of 2021. See D6019.
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 direct observation and interview with the laboratory owner the laboratory director (LD) failed to ensure a safe environment to protect testing personnel from biological hazards related to COVID-19 specimen disposal for two of two months since the start of Quidel Solana SARS-CoV-2 testing in 2021. Findings Include: 1.

	Direct observation of patient testing for COVID-19 using the Quidel Solana SARS-CoV-2 assay on 12-29-21 at 4:35 pm documented testing personnel #3 disposing of biohazardous waste from patient specimens into a container not identified for biohazardous materials. 2. Review of laboratory records found the laboratory started COVID-19 testing using the Quidel Solana system on November 23, 2021. 3. On survey date 12-30-21, at 2:40 pm, the surveyor findings were confirmed by the laboratory owner.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the laboratory owner the laboratory director (LD) failed to ensure verification procedures were adequate to determine the accuracy, precision, and all other pertinent performance characteristics for COVID-19 testing performed using the Quidel Solana SARS-CoV-2 assay, affecting 631 patients. Findings Include: 1. Direct observation of laboratory equipment during a tour of the laboratory facility, on 12-29-2021, at 1:08 pm, identified two Quidel Solana analyzers, serial numbers 20021839 and 20021833. 2. Review of laboratory records found no verification of performance documentation for the two Quidel Solana analyzers used for SARS-CoV-2 assay performed by the laboratory. 3. Review of the laboratory test volume records found 631 patients were tested for SARS-CoV-2 using the Quidel Solana analyzers since the start of patient testing in November of 2021. 4. On survey date 12-30-21, at 2:40 pm, the surveyor findings were confirmed by the laboratory owner.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the laboratory owner the laboratory director (LD) failed to ensure testing personnel were performing the Quidel Solana SARS-CoV-2 assay as required for accurate and reliable results, affecting 631 patients' test results. Findings Include: 1. Direct observation of laboratory equipment during a tour of the laboratory facility, on 12-29-2021, at 1:08 pm, identified two Quidel Solana analyzers, serial numbers 20021839

	and 20021833. 2. Direct observation of laboratory testing on 12-29-21. at 4:35 pm for the Quidel Solana SARS-CoV-2 testing identified the following issues: a. Heat block temperature set to 97 Celsius b. No temperature/humidity documented. The vent fan for the -80 Celsius benchtop freezer blows directly on one of the Quidel Solana analyzers. See D5413. c. TP#3 added master mix to the negative control sample after a visual inspection of reaction tubes revealed it had less total sample volume than the other samples. Interview with TP#3 at 5:20 pm on 12-29-21 confirmed that an additional estimated amount of master mix was added to the negative control sample tube. d. Results for the 6 negative patients were reported when sample volume issue was identified for the negative control. 3. Review of the Quidel SARS-CoV-2 assay instructions for use stated the following: a. On page 4 of 14 indicated "heat the process buffer tubes at 95 Celsius +/- 2 Celsius for 5 minutes"/ b. On page 4 of 14 indicated "For accurate results, pipette carefully using only calibrated equipment. Use of inaccurate volumes may give erroneous amplification". 4. Review of Quidel Solana patient test result records found multiple testing dates when quality control testing failed to be performed. See D5455. 5. Review of Quidel Solana patient test results identified that on 12-24-21 two samples were collected in saline and tested with the SARS-CoV-2 assay. Review of the Quidel Solana SARS-CoV-2 instructions for use indicated under the" materials required but not provided" that samples should be collected in the following transport media "BD/Copan UTM, CDC Viral Transport Media, Remel M4RT, Quidel Transport Media (QTM)". 6. Further review of the Quidel Solana SARS-CoV-2 instructions for use under "Conditions of Authorization for the Laboratory and Patient Care Settings" stated "Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to us the Solana SARS-CoV-2 Assay are not permitted". 7. Review of the laboratory test volume records found 631 patients were tested for SARS-CoV-2 using the Quidel Solana analyzers since the start of patient testing in November of 2021. 8. On survey date 12-30-21, at 2:40 pm, the surveyor findings were confirmed by the laboratory owner.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory owner the laboratory director failed to document review of proficiency testing (PT) records for two of three PT events reviewed in 2021 for chemistry and hematology. Findings Include: 1. Proficiency testing records from the American Association of Bioanalysts (AAB) were reviewed for 2021. 2. Review of AAB PT records for hematology and chemistry revealed the laboratory director failed to review PT results for the following events: Chemistry a. 2021 - Event 2 b. 2021 - Event 3 Hematology a. 2021 - Event 2 b. 2021 - Event 3 3. On survey date 12-29-21, at 2:40 pm the findings were confirmed by the laboratory owner.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory owner the laboratory director failed to ensure corrective action plans were followed for unacceptable analyte failures for two of three proficiency testing (PT) events in 2021 for chemistry and hematology. Findings Include: 1. Proficiency testing records from the American Association of Bioanalysts (AAB) were reviewed for 2021. 2. Review of AAB PT records for hematology and chemistry revealed the laboratory director failed to ensure corrective actions plans were followed for the following analyte failures: Chemistry a. 2021 - Event 2 - High Density Lipoprotein (HDL)- 20% (missed samples 7, 8, 9, and 10) b. 2021 - Event 3 - Microscopic urine sediment - 50% (missed sample 11) Hematology a. 2021 - Event 2 - Eosinophil % - 20% (missed samples 6, 7, 8, and 9) 3. On survey date 12-29-21, at 2:40 pm the findings were confirmed by the laboratory owner.
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 review of laboratory records and interview with the laboratory owner; the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. One of three TP listed on the CMS-209 (Laboratory Personnel Report), failed to meet the qualification requirements for moderate complexity testing. See 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 review of laboratory records and interviews with the laboratory owner; the laboratory failed to have qualifying documents for one of three moderate complexity testing personnel (TP) listed on the CMS-209. Findings Include: 1. No education documents were available to review for TP#3. 2. On survey date 12-30-2021, at 2:40 pm, the surveyor findings were confirmed by the laboratory owner.