

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0919258	(X3) Date Survey Completed 10/21/2020
Name of Provider or Supplier American Scientific Laboratory	Street Address, City, State 8744 Shermer Rd, 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's testing menu; manufacturer's Emergency Use Authorization (EUA); patients test reports; and interview with the technical supervisor, the laboratory failed to report both positive and negative SARS-CoV-2 (COVID-19) tests results to the Illinois Department of Public Health as defined in 400.200. Findings include: 1. The laboratory performed the following tests: a. molecular (PCR) tests using a QIAstat-DX Respiratory SARS-CoV- 2 Panel by QIAGEN GmbH b. serologic (IgG/IgM) tests using COVID-19 Rapid Test Cassette (Whole Blood/Serum/Plasma) by Healgen Scientific LLC. 2. The EUA for QIAstat-DX Respiratory SARS-CoV- 2 Panel by QIAGEN GmbH instructs the laboratory as follows: "Laboratories within the United States and its territories are required to report SARS-CoV-2 positive results to the appropriate public health authorities." 3. On 10/29/20 at 10:00 AM, the surveyor requested additional documentation which includes the following: a. Copies of all patients' test reports for PCR testing from October 1, 2020 through October 20, 2020. b. Copies of all patients' test reports for IgG/IgM testing from October 1, 2020 through October 20, 2020. c. Documentation to show COVID 19 test were reported to the Illinois Department of Public Health. 4. On 10/29/20 at 11:</p>

00 AM, the surveyor received the following documentation: a. 48 patients' PCR test reports. b. 117 patients' IgG/IgM test reports. c. 17 Illinois' National Electronic Disease Surveillance Systems (I-NEDSS) reports. 5. Review of the requested documents revealed the following: a. There was no documentation to show that patients' PCR test results were reported to I-NEDSS for 47 of 48 patients' test reports reviewed. b. There was no documentation to show that patients IgG/IgM test results were reported to I-NEDSS for 106 of 117 patients' test reports reviewed. c. There were 5 I-NEDSS reports sent without corresponding test reports for either PCR or IgG/IgM. 6. On October 29, 2020 at 3:10 PM, in a phone interview, the Technical Supervisor stated that the laboratory only reported positive COVID-19 test results to I-NEDSS. 7. On October 29, 2020 at 3:20 PM, the Technical Supervisor confirmed the surveyor's findings.

D3007

FACILITIES
CFR(s): 493.1101(b)

The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures manuals; application for CLIA Certification (CMS 116); proficiency testing (PT) records; patient test records, and interview with the laboratory director, the laboratory failed to have sufficient reagents for testing for Gonorrhea (GC), Chlamydia (CH), and Trichomonas (TV) on it BD Max analyzer. Findings include: 1. The laboratory included GC, CH, and TV analytes as part of its testing menu. 2. In section VIII of the CMS 116, GC, CH, and TV were identified as "non-waived" tests the laboratory performed. 3. Records show laboratory is currently enrolled in PT for GC, CH, and TV. 4. The laboratory had run out of reagents for the tests. 5. On October 21, 2020 at 10:00 AM, the laboratory director told the surveyor that the laboratory had ceased testing GC, CH, and TV. When the surveyor asked the laboratory director to remove the subspecialty of Bacteriology from the CMS 116, she was told that because the laboratory had run out of reagents for the tests, it was "temporarily" ceasing testing for GC, CH, and TV. The laboratory director stated that they are going to resume testing once they receive their reagents. The surveyor noted that this was cited by herself in a previous survey a few years ago for the same reason. 6. There was no documentation to show the date of cessation and resuming of testing. 7. On October 21, 2020 at 10:30 AM, the laboratory director confirmed the surveyor's findings.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the laboratory's testing menu; procedures manuals; laboratory

records; and interview with the technical supervisor, the laboratory failed to meet analytic systems requirements in 493.1251 through 493.1283: 1. The laboratory performed the following tests: a. molecular (PCR) tests using a QIAstat-DX Respiratory SARS-CoV- 2 Panel by QIAGEN GmbH b. serologic (IgG/IgM) tests using COVID-19 Rapid Test Cassette (Whole Blood/Serum/Plasma) by Healgen Scientific LLC 2. There was no written procedure that described the laboratory's process for performing and reporting each test. See D5401 3. There was no documentation to show that the laboratory could demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for each test system listed in finding #1. See D5421 4. There was no written policy that described the laboratory's process for performing and documenting quality control of COVID 19 tests. See D5441

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 review of laboratory policies and procedures manuals; laboratory documents; patients test records; and interview with the laboratory director, there was no approved procedures manual for how the laboratory performs COVID 19 testing. Findings: 1. There were no written procedures that described the laboratory process for receiving, performing, documenting, and reporting COVID 19 testing. 2. Review of laboratory documents revealed that the laboratory performed the following COVID 19 tests: a. molecular tests using a QIAstat-DX Respiratory SARS-CoV- 2 Panel by QIAGEN GmbH b. serologic test using COVID-19 Rapid Test Cassette (Whole Blood /Serum/Plasma) by Healgen Scientific LLC. 3. At 1:30 PM on October 21, 2020, the surveyor reviewed 7 patients' test reports for molecular testing and 11 patients' test reports for serologic testing. Results for COVID 19 tests were reported for 7 of 7 molecular test reports reviewed and 11 of 11 serologic test reports reviewed. 4. At 2:00 PM on October 21, 2020, the laboratory director confirmed the surveyor's findings.

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 review of the laboratory's application for CLIA Certification (CMS 116); Emergency Use Authorization (EUA) letter; verification procedures; laboratory records; patients' test records; and interview with technical supervisor, the laboratory

failed to demonstrate verification of performance specifications established by the manufacturer. Findings include: 1. The laboratory listed 2 different COVID 19 tests on its CMS 116 as follows: a. Respiratory Panne1, COVID - 19 PCR, QIAstat DX b. COVID - 19 IgG/IgM - Healgen 2. EUA release dates are as follows: a. Respiratory Panne1, COVID - 19 PCR, QIAstat DX - March 30, 2020 b. COVID - 19 IgG/IgM - Healgen - March 29, 2020 3. There were no written verification policies made available to the surveyor that instruct the laboratory on how it verified its COVID - 19 IgG/IgM - Healgen testing. 4. There was no documentation to show that the laboratory verified its COVID - 19 IgG/IgM - Healgen test before it performed testing on patients' specimens. 5. The manufacturers of Respiratory Panne1, COVID - 19 PCR, QIAstat DX supplied instruction for performing verification of the analyzer. 6. In a document titled "Guidelines for Laboratory Verification of Performance of the QIAstat-Dx Respiratory SARS-CoV-2 Panel, " it states, "Each laboratory is responsible for defining their verification procedure and ensuring that they meet state and federal guidelines." 7. The guidelines instruct the laboratory to mix together 5 different organism controls (for a total of 16) using the ZeptoMetrix NATtrol Respiratory Verification Panel and NATrol Sars-Cov-2 (E/ORFlab) recombinant and to test them over 3 days. The proposed organism and expected positive/negative results are as follows: a. Sample Control Mix 1 (Influenza A H1N1, Coronal HKU, PIV 2, C. pneumoniae, and SARS-CoV-2): POSITIVE FOR ALL ORGANISMS and 15 negative results. b. Sample Control Mix 2 (Influenza B, Corona 229E, PIV 4, hMPV, and B. pertussis): POSITIVE FOR ALL ORGANISMS and 16 negative results. c. Sample Control Mix 3 (Influenza A H1N1/2009, Corona C43, PIV 3, Rhinovirus 1A, and RSVA): POSITIVE FOR ALL ORGANISMS and 15 negative results. d. Sample Control Mix 4 (Influenza A H3N2, Corona NL63, PIV, Adenovirus, and M. pneumoniae): POSITIVE FOR ALL ORGANISMS and 15 negatives. 8. There was no documentation to show that the laboratory performed verification procedures on its QIAstat-Dx Respiratory SARS-CoV-2 Panel before it performed testing on patients' specimens. 9. In a telephone interview and fax communication on October 23, 2020 at 12:00 PM, the technical supervisor told the surveyor that the laboratory performed a total of 1756 COVID 19 antibody tests from May 11, 2020 to October 20, 2020 and 382 COVID PCR tests from July 6, 202 to October 20, 2020. 10. At 12:00 PM on October 23, 2020, the technical supervisor confirmed the surveyor' findings.

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 review of manufacturer's assay information documents; Emergency Use Authorization (EUA); Instructions for Use (IFU); laboratory policies and procedures

manuals; laboratory records; patient test records; and interview with the Technical Supervisor, the laboratory failed to establish a control procedure based on the nonwaived control procedures found at 493.1256 for its COVID-19 testing. Findings: 1. The laboratory uses QIAGEN's QIAstat DX Analyzer System for PCR testing SARS-CoV2 Panel Cartridge. The manufacturer's information reads as follows: "the cartridge includes an internal control that controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process." 2. The laboratory uses COVID-19 IgG/IgM Rapid Test Cassette for serologic testing. Instructions for Quality Control (QC) reads as follows: "An internal procedural control is included in the test It confirms sufficient specimen volume and correct procedural technique." 3. IFU for QIAGEN'S QIAstat DX are as follows: "External controls are not provided with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures." 4. IFU for the COVID 19 IgG/IgM Test Cassette for serologic tests states, "Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations." 5. EUA letters for both tests state the following: "You also recommend use of external positive and negative controls, or other authorized controls to be run as outlined in the Instructions for Use." 6. There were no written policies that describe the laboratory process for performing, documenting, and monitoring its QC. 7. The surveyor selected a total of 11 serologic test records and 7 PCR test records for review. 8. Corresponding QC records for tests revealed the following: a. The laboratory documented results of internal QC for PCR tests on patients' test reports as "Controls + Detected" for 11 of 11 test records reviewed. b. There was no documentation of QC performance for serologic tests for 4 of 7 patients' test records reviewed. c. There was no documentation to show external QC was performed when patients' specimens were tested for COVID 19 for 11 of 11 PCR test results reviewed and 7 of 7 patients' test results reviewed. 9. The Technical Supervisor stated, "we started documenting QC in September 2020." 10. In a telephone interview and fax communication on October 23, 2020 at 12:00 PM, the technical supervisor told the surveyor that the laboratory performed a total of 1756 COVID 19 antibody tests from May 11, 2020 to October 20, 2020 and 382 COVID PCR tests from July 6, 2020 to October 20, 2020. 11. At 12:00 PM on October 23, 2020, the Technical Supervisor confirmed the surveyor's findings.

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 procedures manuals; laboratory records; and interview with the laboratory director, the laboratory failed to have a director who provides overall management and direction of the laboratory. Findings include: 1. The laboratory director did not ensure that the laboratory established the accuracy and precision of their COVID 19 tests prior to reporting patients' test results. See D5421 2. The

laboratory director did not ensure that quality control programs were established for COVID 19 testing prior to reporting patients' test results. See D5441 3. The laboratory director failed to ensure that COVID 19 test systems were functioning before reporting patients' test results. See D6097

D6097

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:
Based on review laboratory procedures manuals; laboratory records; patients' test records; and interview with the laboratory director, the laboratory director failed to ensure that patient test results are reported only when the system is functioning properly. Findings include: 1. There were no written policies and procedures for COVID 19 testing. See D5401 2. There were no test method verification records for the laboratory's molecular and serologic COVID 19 tests. See 5421 3. There were no quality control records available for review. See D5441 4. In a telephone interview and fax communication on October 23, 2020 at 12:00 PM, the technical supervisor told the surveyor that the laboratory performed a total of 1756 COVID 19 antibody tests from May 11, 2020 to October 20, 2020 and 382 COVID PCR tests from July 6, 202 to October 20, 2020. 5. At 12:00 PM on October 23, 2020, the technical supervisor confirmed the surveyor's findings.