

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2264770	(X3) Date Survey Completed 07/08/2024
Name of Provider or Supplier American Health Sciences	Street Address, City, State 17w703 Butterfield Rd - Ste A, Oakbrook Ter, 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 laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to retain patient requisition records for one of three SARS-CoV-2 patients reported on 05/30/2023 (Refer to D3027); and failed to retain instrument run records and patient results for two of three SARS-CoV-2 patients reported on 05/30/2023 (Refer to D3031).</p>
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with</p>

testing personnel (TP 1), the laboratory failed to retain test requisition records for one of three SARS-CoV-2 patients reported on 05/30/2023. Findings include: 1. Review of laboratory records revealed SARS-CoV-2 patient documentation on 05/30/2023 for the following three patients: a) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023, Run Date: 05/30/2023; b) Patient X: "American Health Sciences dba AHS Labs SIMPLEREPORT - Test Date: 05/30/2023 6:45 PM, Covid-19 result: Negative, Result Reported date: 05/30/2023 6:45 PM, Test Date: 05/30/2023 6:45 PM, Test correction status: Original; c) Patient Z: " ...AHS LABS TESTING REQUISITION FORM - 5-30-23, SID: 302, Location: (blank). 2. Review of laboratory records and lack of documentation revealed the laboratory failed to retain the test requisition record on 05/30/2023 for Patient X. 3. On 07/08/2024, at 3:22 p. m., an interview with TP 1 confirmed the above findings.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to retain instrument run records and patient test results for two of three SARS-CoV-2 patients reported on 05/30/2023. Findings include: 1. Review of laboratory records revealed SARS-CoV-2 patient documentation on 05/30/2023 for the following three patients: a) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023; b) Patient X: "American Health Sciences dba AHS Labs_SIMPLEREPORT - Test Date: 05/30/2023 6:45 PM, Covid-19 result: Negative, Result Reported date: 05/30/2023 6:45 PM, Test Date: 05/30/2023 6:45 PM, Test correction status: Original; c) Patient Z: " ... AHS LABS TESTING REQUISITION FORM - 5-30-23, SID: 302, Location: (blank). 2. Review of laboratory records and lack of documentation revealed the laboratory failed to retain the instrument run record for Patient X on 05/30/2023. 3. Review of laboratory records and lack of documentation revealed the laboratory failed to retain instrument run record and patient results for Patient Z on 05/30/2023. 4. On 07/08/2024, at 3:22 p.m., an interview with TP 1 confirmed the above findings.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if

applicable.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to ensure test requisitions documented the authorized person requesting the tests and the identification of the submitting laboratories for 12 of 12 SARS-CoV-2 patient test requests in 2023. Findings include:

1. Review of laboratory records and patient test reports revealed 12 test run dates requested for SARS-CoV-2 testing from January 2023 through May 2023: a) Patient A: Accession Number - XXX4601, Collection Date: 01/21/2023 Run Date: 01/22/2023; b) Patient B: Accession Number - XXX6901, Collection Date: 02/02/2023 Run Date: 02/05/2023; c) Patient C: Accession Number - XXX3201, Collection Date: 03/11/2023 Run Date: 03/13/2023; d) Patient D: Accession Number - XXX4411, Collection Date: 03/15/2023 Run Date: 03/16/2023; e) Patient E: Accession Number - XXX6001, Collection Date: 03/20/2023 Run Date: 03/21/2023; f) Patient F: Accession Number - XXX(illegible), Laboratory Specimen Number: 460 Collection Date: 04/11/2023, Run Date: 04/11/2023; g) Patient G: Accession Number - XXX1204, Collection Date: 04/12/2023 Run Date: 04/14/2023; h) Patient H: Accession Number - XXX6305, Collection Date: 05/01/2023 Run Date: 05/02/2023; i) Patient I: Accession Number - XXX8101, Collection Date: 05/11/2023 Run Date: 05/11/2023; j) Patient J: Accession Number - XXX8201, Collection Date: 05/16/2023 Run Date: 05/16/2023; k) Patient K: Accession Number - XXX8301, Collection Date: 05/23/2023 Run Date: 05/23/2023; l) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023.
2. Review of laboratory records and lack of documentation revealed the laboratory failed to document the complete name, address, and authorized person of the requesting laboratory for 12 of 12 SARS-CoV-2 test requisition forms in 2023 (Patient A through Patient L).
3. On 07/08/2024, at 3:22 p.m., an interview with TP 1 confirmed the above 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 laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to define acceptable temperature and humidity ranges for monitoring laboratory operating conditions (Refer to D5413); failed to demonstrate performance specifications established by the manufacturer for the Solana SARS-CoV-2 test system (Refer to D5421); and failed to perform positive and negative control procedures with each run for SARS-CoV-2 patient tests from January 2023 through May 2023. (Refer to D5445).

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 review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to define room temperature and relative humidity ranges per manufacturer's instructions (Solana SARS-CoV-2) for the Quidel Solana SARS-CoV-2 test system for five of five months (January 2023 through May 2023). Findings include: 1. Review of the "Quidel Solana SARS-CoV-2 Assay" instructions for use revealed the following information: "Technical Specifications - ... Operating Conditions - Only for indoor use - Temperature between +15C and +35C ... Highest relative humidity 80% for temperatures up to 31C ..." 2. Review of laboratory records and patient test reports revealed 12 test run dates requested for SARS-CoV-2 testing from January 2023 through May 2023: a) Patient A: Accession Number - XXX4601, Collection Date: 01/21/2023 Run Date: 01/22/2023; b) Patient B: Accession Number - XXX6901, Collection Date: 02/02/2023 Run Date: 02/05/2023; c) Patient C: Accession Number - XXX3201, Collection Date: 03/11/2023 Run Date: 03/13/2023; d) Patient D: Accession Number - XXX4411, Collection Date: 03/15/2023 Run Date: 03/16/2023; e) Patient E: Accession Number - XXX6001, Collection Date: 03/20/2023 Run Date: 03/21/2023; f) Patient F: Accession Number - XXX (illegible), Laboratory Specimen Number: 460 Collection Date: 04/11/2023, Run Date: 04/11/2023; g) Patient G: Accession Number - XXX1204, Collection Date: 04/12/2023 Run Date: 04/14/2023; h) Patient H: Accession Number - XXX6305, Collection Date: 05/01/2023 Run Date: 05/02/2023; i) Patient I: Accession Number - XXX8101, Collection Date: 05/11/2023 Run Date: 05/11/2023; j) Patient J: Accession Number - XXX8201, Collection Date: 05/16/2023 Run Date: 05/16/2023; k) Patient K: Accession Number - XXX8301, Collection Date: 05/23/2023 Run Date: 05/23/2023; l) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023. 3. Review of the "AHS LABS TEMPERATURE LOG: R TEMP / HUMIDITY" and lack of documentation revealed the laboratory failed to define room temperature and relative humidity ranges for the Quidel Solana SARS-CoV-2 test system for five of five months (January 2023 through May 2023). 4. On 07/08/2024, at 2:00 p.m., TP 1 confirmed the above findings. B. Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to monitor and record refrigerator and heating block temperatures per manufacturer's instructions (Solana SARS-CoV-2) for five of five months (January 2023 through May 2023). Findings include: 1. Review of the "Quidel Solana SARS-CoV-2 Assay" instructions for use revealed the following information: "STORAGE AND HANDLING OF KIT REAGENTS - The Assay Kit should be stored at 2 degrees C to 8 degrees C until the expiration date listed on the outer kit box. MATERIALS REQUIRED BUT NOT PROVIDED - ...Heat block capable of 95 degrees C +/- 2 degrees C temperature..." 2. Review of laboratory records and patient test reports revealed 12 test run dates requested for SARS-CoV-2 testing from January 2023 through May 2023: a) Patient A: Accession Number - XXX4601, Collection Date: 01/21/2023 Run Date: 01/22/2023; b) Patient B: Accession Number - XXX6901, Collection Date: 02/02/2023 Run Date: 02/05/2023; c) Patient C: Accession Number - XXX3201, Collection Date: 03/11/2023 Run Date: 03/13/2023;

d) Patient D: Accession Number - XXX4411, Collection Date: 03/15/2023 Run Date: 03/16/2023; e) Patient E: Accession Number - XXX6001, Collection Date: 03/20/2023 Run Date: 03/21/2023; f) Patient F: Accession Number - XXX(illegible), Laboratory Specimen Number: 460 Run Date: 04/11/2023, Report Date: 04/11/2023; g) Patient G: Accession Number - XXX1204, Collection Date: 04/12/2023 Run Date: 04/14/2023; h) Patient H: Accession Number - XXX6305, Collection Date: 05/01/2023 Run Date: 05/02/2023; i) Patient I: Accession Number - XXX8101, Collection Date: 05/11/2023 Run Date: 05/11/2023; j) Patient J: Accession Number - XXX8201, Collection Date: 05/16/2023 Run Date: 05/16/2023; k) Patient K: Accession Number - XXX8301, Collection Date: 05/23/2023 Run Date: 05/23/2023; l) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023.

3. Review of laboratory records and lack of documentation revealed the laboratory failed to monitor and record refrigerator and heating block temperatures per manufacturer's instructions (Solana SARS-CoV-2) for five of five months (January 2023 through May 2023). 4. On 07/08/2024, at 2:00 p.m., TP 1 confirmed the above 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 laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to demonstrate performance specifications established by the manufacturer for the Solana SARS-CoV-2 test system utilized for patient testing from January 2023 through May 2023. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to demonstrate and record the accuracy, precision, reportable range of test results, and verify normal values for the Quidel Solana test system (SN: 21022416, PN: 1289800) prior to reporting SARS-CoV-2 patient test results from January 2023 through May 2023. 2. On 07/08/2024, at 10:19 a.m., TP 1 confirmed the above findings.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to perform positive and negative control procedures with each instrument run for 9 of 12 SARS-CoV-2 patient test run dates reviewed from January 2023 through May 2023. Findings include: 1. Review of the "Facility AHS Labs, Test system Quidel Solana, Test system primary SOPS including Covid 19" revealed the following information: "QUALITY CONTROL The Solana SARS-CoV-2 Assay incorporates several controls to monitor assay performance. - A positive control (such as a positive patient sample) should be processed and tested with each batch of specimens ... - The external negative control may be treated as a patient specimen ..." 2. Laboratory records revealed 12 SARS-CoV-2 patient test run dates reviewed from January 2023 through May 2023: a) Patient A: Accession Number - XXX4601, Collection Date: 01/21/2023 Run Date: 01/22/2023; b) Patient B: Accession Number - XXX6901, Collection Date: 02/02/2023 Run Date: 02/05/2023; c) Patient C: Accession Number - XXX3201, Collection Date: 03/11/2023 Run Date: 03/13/2023; d) Patient D: Accession Number - XXX4411, Collection Date: 03/15/2023 Run Date: 03/16/2023; e) Patient E: Accession Number - XXX6001, Collection Date: 03/20/2023 Run Date: 03/21/2023; f) Patient F: Accession Number - XXX(illegible), Laboratory Specimen Number: 460 Collection Date: 04/11/2023, Run Date: 04/11/2023; g) Patient G: Accession Number - XXX1204, Collection Date: 04/12/2023 Run Date: 04/14/2023; h) Patient H: Accession Number - XXX6305, Collection Date: 05/01/2023 Run Date: 05/02/2023; i) Patient I: Accession Number - XXX8101, Collection Date: 05/11/2023 Run Date: 05/11/2023; j) Patient J: Accession Number - XXX8201, Collection Date: 05/16/2023 Run Date: 05/16/2023; k) Patient K: Accession Number - XXX8301, Collection Date: 05/23/2023 Run Date: 05/23/2023; l) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023. 3. Review of laboratory records and lack of documentation revealed the laboratory failed to perform positive and negative control procedures with each instrument run for 9 of 12 SARS-CoV-2 patient test run dates in 2023 (Patients C through E and Patients G through L). 4. On 07/08/2024, at 2:00 p.m., an interview with TP 1 revealed, "No QC was conducted, no QC kits, too expensive."

D5787

TEST RECORDS
 CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to identify the TP performing and reporting 8 of 12 SARS-CoV-2 patient tests from January 2023 through May 2023. Findings include: 1. Review of laboratory records revealed 12 patient samples tested for SARS-CoV-2 from January 2023 through May 2023: a) Patient A: Accession Number - XXX4601, Collection Date: 01/21/2023 Run Date: 01/22/2023; b) Patient B: Accession Number - XXX6901, Collection Date: 02/02/2023 Run Date: 02/05/2023; c) Patient C: Accession Number - XXX3201, Collection Date: 03/11/2023 Run

Date: 03/13/2023; d) Patient D: Accession Number - XXX4411, Collection Date: 03/15/2023 Run Date: 03/16/2023; e) Patient E: Accession Number - XXX6001, Collection Date: 03/20/2023 Run Date: 03/21/2023; f) Patient F: Accession Number - XXX(illegible), Laboratory Specimen Number: 460 Collection Date: 04/11/2023, Run Date: 04/11/2023; g) Patient G: Accession Number - XXX1204, Collection Date: 04/12/2023 Run Date: 04/14/2023; h) Patient H: Accession Number - XXX6305, Collection Date: 05/01/2023 Run Date: 05/02/2023; i) Patient I: Accession Number - XXX8101, Collection Date: 05/11/2023 Run Date: 05/11/2023; j) Patient J: Accession Number - XXX8201, Collection Date: 05/16/2023 Run Date: 05/16/2023; k) Patient K: Accession Number - XXX8301, Collection Date: 05/23/2023 Run Date: 05/23/2023; l) Patient L: Accession Number - XXX8501, Collection Date: 05/30/2023 Run Date: 05/30/2023. 2. Review of laboratory records and lack of documentation revealed the laboratory failed to identify the TP performing and reporting 8 of 12 SARS-CoV-2 patient tests from January 2023 through May 2023 (Patient B through Patient D, Patient F, and Patient I through Patient L). 3. On 07/08/2024, at 2:00 p.m., TP 1 confirmed the above findings.

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, lack of documentation, CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP 1), the laboratory failed to ensure two of two testing personnel met the qualification requirements for SARS-CoV-2 testing in 2023. (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 review of laboratory records, lack of documentation, CMS - 209 (Laboratory Personnel Report), and interview with testing personnel (TP 1), the laboratory failed to ensure two of two (TP 1 and TP 2) testing personnel were qualified for SARS-CoV-2 testing in 2023. Findings include: 1. Review of the CMS-209 (07/03/2024) identified two moderate complexity testing personnel, TP 1 and TP

2. 2. Review of laboratory personnel records and lack of documentation revealed the laboratory failed to retain United States equivalency education documentation to qualify two of two (TP 1 and TP 2) TP for moderate complexity SARS-CoV-2 testing in 2023. 3. On 07/08/2024, at 10:55 a.m., TP 1 confirmed the above findings.