

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2081860	(X3) Date Survey Completed 01/29/2021
Name of Provider or Supplier Americahealth Inc Idaho Falls	Street Address, City, State 1995 E 17th St, Idaho Falls, ID	
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 record review and interview with the laboratory manager on 01/29/21, the laboratory failed to report SARS-Co-V-2 test results as required for 42 of 42 days reviewed from October 02, 2020 through January 28, 2021. Findings include: 1. The laboratory performs SARS-CoV-2 serology testing on the Premier Biotech SARS CoV-2 rapid antibody as of October 02, 2020 and SARS-CoV-2 antigen testing on the Abbott ID Now platform since 01/22/2021. 2. Review of laboratory's patient test logs from 10/01/2020 to 01/29/2021 and interview with the laboratory manager on 01/29/21 revealed that laboratory does not have a process for reporting SARS-CoV-2 testing results to the state of Idaho public health or the Secretary of HHS. 3. Patient testing records revealed that SARS-CoV-2 test results were not reported as required for 21 days in October 2020, 3 days in November 2020, 7 days in December 2020, and 11 days in January 2021. 4. The laboratory patient testing records revealed that the laboratory performed (64) SARS-CoV-2 rapid antibody patient tests from 10/02/20 through 01/28/21 and (18) SARS-CoV-2 rapid antigen tests from 01/22/21 to 01/28/21 . 5. 82 SARS-CoV-2 test results were not reported as required during the period of review. 6. The laboratory manager confirmed by interview on 01/29/2021 at</p>

09:00 a.m., that the laboratory does not have a policy or procedure for reporting SARS-CoV-2 test results and had not reported SARS-CoV-2 test results since initiating SARS-CoV-2 patient testing on 10/02/2020.

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 record review for SARS CoV2 patient testing and interview with the laboratory manager on 01/29/2021., the laboratory failed to have a policy or procedure for reporting patient results . Findings include: 1. The laboratory performs SARS-CoV-2 serology testing utilizing the Premier Biotech SARS CoV-2 rapid antibody testing as of October 2, 2020 and SARS-CoV-2 antigen testing on the Abbott ID Now in its urgent care setting from January 22, 2021. 2. Review of the laboratory patient testing records and interview with the laboratory manager revealed the laboratory has not been reporting patient test results and has no policy or procedure for reporting its SARS-CoV-2 testing results. 3. The laboratory patient testing records revealed that the laboratory performed 64 SARS-CoV-2 rapid antibody patient tests from October 02, 2020 through January 28, 2021 and 18 SARS-CoV-2 antigen patient tests from January 22, 2021 to January 28, 2021. SARS CoV2 Serology Antibody testing:(64) 10/02/20-AMD_(3) 10/03/20-AMD_(1) 10/05/20-AMD_(6) 10/06/20-AMD_(2) 10/08/20-AMD_(4) 10/09/20-AMD_(1) 10/10/20-AMD_(1) 10/12/20-AMD_(2) 10/13/20-AMD_(3) 10/14/20-AMD_(2) 10/15/20-AMD_(1) 10/16/20-AMD_(2) 10/19/20-AMD_(1) 10/20/20-AMD_(2) 10/21/20-AMD_(1) 10/22/20-AMD_(1) 10/23/20-AMD_(1) 10/26/20-AMD_(5) 10/28/20-AMD_(1) 10/30/20-AMD_(1) 10/31/20-AMD_(1) 11/02/20-AMD_(2) 11/03/20-AMD_(1) 11/05/20-AMD_(1) 12/09/20-AMD_(1) 12/10/20-AMD_(2) 12/11/20-AMD_(1) 12/12/20-AMD_(2) 12/16/20-AMD_(1) 12/19/20-AMD_(1) 12/21/20-AMD_(1) 01/05/21-AMD_(1) 01/06/21-AMD_(1) 01/07/21-AMD_(2) 01/12/21-AMD_(1) 01/14/21-AMD_(2) 01/18/21-AMD_(1) 01/28/21-AMD_(1) SARS CoV2 Antigen Testing:18 01/22/20-AMD_(1) 01/25/21-AMD_(7) 01/26/21-AMD_(4) 01/27/21-AMD_(3) 01/28/21-AMD_(3) 4. The laboratory manager confirmed by interview on 01/29/2021 at 09:00 a.m., that the

laboratory does not have a policy or procedure for reporting SARS-CoV-2 test results and have not reported SARS-CoV-2 patient test results since initiating SARS-CoV-2 patient testing on 10/02/2020.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of manufacturers package inserts, observations during survey tour and interview with the laboratory manager on 01/29/2021, the laboratory failed to perform testing following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. The findings include: 1. The laboratory initiated SARS CoV-2 testing serology testing utilizing a moderate complexity testing methodology distributed by Premier BioTech. a. The manufacturers package insert procedure states "Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30C) prior to testing". The laboratory does not have a thermometer in the testing location for measuring the room temperature. The laboratory does not have documentation of room temperatures being taken. b. The manufacturers package insert states "Humidity and temperature can adversely affect results". The laboratory does not have a evidence of equipment for monitoring humidity and temperatures, and the laboratory has no documentation of recording humidity and temperature in the SARS CoV2 testing location for 14/14 patient testing days in which 18 patient SARS CoV2 serology tests were performed. c. The manufacturers package insert states "Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 20 minutes". By observation on 01/29/2021 the testing personnel did not utilize a timer during the testing performed, and by interview on 01/29/2021 at 09:20 a.m., the testing personnel verbalized that they utilized thier cell phone to measure the time to read the test results. The laboratory records revealed 18 patients were tested with without a calibrated timer from 12/09/2020 to 01/28/2021. 2. The laboratory initiated SARS CoV2 antigen testing on 01/22/2021. The manufacturers instructions state "Ensure all test components are at room temperature before use'. The labaoratory does not have a room thermometer in the testing area in which the test is performed. The laboratory does not have documentation of temperatures taken for 7/7 patient testing days in which 18 patients were tested. 3. The laboratory manager confirmed by interview on 01/29/2021 at 10:00 a.m., the failure to following the manufacturers instructions and documentation of patient testing environmental requirements.

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 record review and interview with the laboratory manager on 01/29/2021, the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer for their Abbott ID NOW SARS CoV 2 platform. The findings include. 1. The laboratory initiated patient testing on the Abbott ID NOW platform on January 21, 2021. The manufacturer package insert states "ID NOW COVID-19 kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. Test these swabs once with each new shipment received and once for each untrained operator." 2. The laboratory's patient testing log indicated three testing personnel performing patient SARS CoV2 Antigen testing on the Abbott ID NOW system who had not performed quality control (QC) testing on the testing platform prior to testing patient samples. 3. The QC log revealed one individual had performed QC on the initial kit, and this individual was not one of the testing personnel. 4. The laboratory manager confirmed by interview on January 29, 2021 at 10:00 a.m. the QC was not performed each untrained operator. 5. The laboratory records indicates the laboratory tested 18 patients from January 22, 2021 to January 28, 2021 by untrained operators who had not performed QC.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review of patient test reports for SARS CoV2 serology testing and interview with the laboratory manager on 01/29/2021, the laboratory failed to ensure its patients test reports indicates the following: The name and address of the laboratory location where the test was performed, the specimen source, the interpretation. Findings include: 1. A record review of patient test reports revealed the laboratory patient reports lacked identification of location of patient testing performed, specimen source, and disclaimer of non-FDA clearance. 2. The laboratory manager confirmed by interview on January 29, 2021 at 10:30 a.m., the lack of required information on the patient test reports. 3. The laboratory records indicates the laboratory performs 64 SARS CoV2 patient samples annually.