Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0519936	(X3) Date Survey Completed 07/07/2021
Name of Provider or Supplier Community Health Center Of Central Wyoming	**Street Address, City, State** 5000 Blackmore Road, Casper, WY	
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	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's Billing Summary Report, review of reporting documentation, and staff interview, the laboratory failed to report 487 SARS-CoV-2 negative test results from 9/28/20 through 7/7/21. The findings were: 1. Review of the "Billing Summary Report" from 9/28/20 through 7/7/21 showed the laboratory had performed 579 SARS-CoV-2 tests. 2. Review of the laboratory's reporting documentation from 9/28/20 through 7/7/21 showed the laboratory had reported 92 positive SARS-CoV-2, as required, to the State Public Health Laboratory, however the laboratory had not reported the 487 negative test results. 3. Documentation revealed that SARS-CoV-2 negative test reports were not reported, as required, for 3 days in September 2020; 18 days in October 2020; 21 days in November 2020; 17 days in December 2020; 21 days in January 2021; 19 days in February 2021; 17 days in March 2021; 18 days in April 2021; 20 days in May 2021; 17 days in June 2021; and 4 days from 7/1/21 through 7/7/21. 4. Interview with the laboratory manager on 7 /7/21 at 11:45 AM revealed she was unaware of the regulation which required the

	reporting of both positive and negative test results. In addition, the laboratory manager confirmed the negative test results had not been reported to the State Public Health Laboratory.
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 new test method verification study review, lack of documentation, quality control record review, review of the patient testing log, and staff interview, the laboratory failed to ensure the Cepheid respiratory virus panel was verified for precision (D5421) prior to testing patient samples and failed to ensure two levels of quality control were performed each day of testing (D5447).
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 lack of documentation and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The findings were: Review of the laboratory's procedure manuals showed no evidence a policy and procedure had been developed in regard to reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. Interview with the laboratory manager on 7/7/21 at 11:45 AM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 test results.
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 lack of documentation, review of the Diesse Mini Cube ESR (erythrocyte sedimentation rate) procedure and staff interview, the laboratory failed to include 2 of the 14 required elements in the procedure manual for 1 of 1 manuals reviewed (Diesse Mini Cube ESR). The laboratory had performed approximately 167 ESRs since the test system was implemented on 9/29/20. The findings were: 1. Review of the Diesse Mini Cube ESR procedure, approved on 9/29/20, showed "...Precautions Limitations: The clinical significance of an ESR obtained from an abnormal sample, such as icteric, lipemic, cold agglutinins, anemic condition, hemolysis, or any pathological condition which may interfere with a clear red blood cell to plasma interface should be determined by the provider ordering the test. ESR measurements in samples without a clear interface are subject to a high degree of variability." There was no documentation the laboratory had a procedure for what to do if a specimen did not have a "clear red blood cell to plasma interface". Further review of the procedure showed no documentation of what course of action the laboratory would take if a test system became inoperable. 2. Interview with the laboratory manager on 7/6/21 at 3:10 PM revealed testing personnel observed the interface of the testing device after completion of the test and manually estimated the ESR to compare with the instrument's results. In addition, if the specimen contained an interfering substance the sample would be sent to a reference laboratory for testing. At that time the laboratory manager confirmed the procedure failed to include all of the required elements.
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 new instrumentation and new test method verification study review, lack of documentation, and staff interview, the laboratory failed to verify precision for 2 of 2 new testing methodologies (Diesse Mini Cube, Cepheid Respiratory Panel [SARS-CoV-2, respiratory syncytial virus (RSV), influenza A, influenza B]) and failed to verify the reportable range and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing (Diesse Mini Cube). Since implementation of the new testing methodologies the laboratory performed approximately 167 ESRs (erythrocyte sedimentation rate) and 64 respiratory virus panels. The findings were: 1. Review of the 9/29/20 new instrument verification study for the Diesse Mini Cube failed to show the performance specification of precision and reportable range of ESRs had been verified by the laboratory prior to testing patient samples. In addition, the laboratory failed to confirm

	the manufacturer's normal values were appropriate for the laboratory's patient population. Review of the Diesse Mini Cube ESR procedure, approved on 9/29/20, showed the laboratory was using the reportable range and normal range provided by the manufacturer. 2. Review of the new test method verification study for the respiratory panel which included SARS-CoV-2, RSV, influenza A, and influenza B performed on the Cepheid analyzer failed to show the performance specification of precision had been verified by the laboratory prior to testing patient samples. 3. Interview with the laboratory manager on 7/6/21 at 2:05 PM confirmed the laboratory had not completed the verification studies to include precision and reportable range, and had not verified the manufacturer's ESR normal values were appropriate for the laboratory's patient population.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control record review, review of the patient testing log, lack of documentation, and staff interview, the laboratory failed to perform two levels of quality control each day of testing from 3/1/21 through 7/5/21 for the Cepheid respiratory virus panel which included SARs-CoV-2, respiratory syncytial virus, influenza A and influenza B. The laboratory performed 64 respiratory virus panels from the implementation date of 3/1/21. The findings were: 1. Review of the quality control records showed the laboratory performed a positive and a negative control for the Cepheid respiratory virus panel on 2/2/21. Review of the patient testing log showed 64 respiratory virus panels had been performed from 3/1/21 through 7/5/21. There was no documentation a positive and negative control had been run on each day of patient testing. 2. Interview with the laboratory manager on 7/6/21 at 1:20 PM revealed it was her understanding since the test method had been given an Emergency Use Authorization by the FDA a risk assessment for an Individualized Quality Control Plan was not necessary and the laboratory was only required to perform quality control once per lot number or shipment. The laboratory manager confirmed the laboratory had failed to perform positive and negative control materials each day of respiratory virus panel testing.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the "Competency Assessment" policy, review of the CMS-209 Laboratory Personnel Report form, lack of documentation, and staff interview, the laboratory director failed to ensure the policy and procedure was complete to ensure mid-level testing personnel that performed moderate complexity testing were evaluated for competency. Five mid-level providers (PA #1, PA #2, PA #3, NP #1, NP #2) performed KOH (potassium hydroxide) preparations and WP (wet mount preparations). The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed 5 testing personnel (PA #1, PA #2, PA #3, NP #1, and NP #2) were listed as testing personnel on the second shift. Interview with the laboratory manager on 7/6/21 at 1:15 PM revealed mid-level providers performed KOH and WP testing in the clinic after the laboratory closed at 5 PM. 2. During an interview with the human resource director on 7/7/21 at 2:45 PM he stated PA #1 was hired on 8/5/19; PA #2 was hired on 2/8/21; PA #3 was hired on 10/1/19, NP #1 was hired on 6/18/19, and NP #2 was hired on 12/22/20. 3. Review of the laboratory's testing log showed PA #1 performed a KOH/WP analysis on 8/31/19, 1/15/21, 3/27/21, and 6/17/21; PA #2 performed a KOH/WP analysis on 5/20/21 and 6/14/21; PA #3 performed a KOH/WP analysis on 8/24/20 and 3/25/21; and NP #2 performed a KOH/WP analysis on 6/19/21. 4. Review of the "Competency Assessment" policy, last modified on 2/9/21, failed to include a procedure for ensuring the competency of mid-level providers who performed moderate complexity laboratory testing. 5. Interview with the laboratory manager on 7/7/21 at 12:40 PM confirmed the Competency Assessment policy did not include a procedure to ensure the competency of mid-level providers.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's KOH (potassium hydroxide) and WP (wet prep) testing log, review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the technical consultant for mycology and parasitology failed to ensure 5 of 5 testing personnel (PA (physician assistant) #1, PA #2, PA #3, NP (nurse practitioner) #1, NP #2) were evaluated semi-annually for competency in reading and reporting KOH preparations and WPs. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed 5 testing personnel (PA #1, PA #2, PA #3, NP #1, and NP #2) were listed as testing personnel on the second shift. Interview with the laboratory manager on 7/6/21 at 1:15 PM revealed mid-level providers performed KOH and WP testing after the laboratory closed at 5 PM. 2. During an interview with the human resource director on 7/7/21 at 2:45 PM he stated PA #1 was hired on 8/5/19; PA #2 was hired on 2/8/21; PA #3 was hired on 10/1/19, NP #1 was hired on 6/18/19, and NP #2 was hired on 12/22/20. 3. Review of the laboratory's testing log showed PA #1 performed a KOH/WP analysis on 8/31/19, 1/15/21, 3/27/21, and 6/17/21; PA #2 performed a KOH/WP analysis on 5/20/21 and 6/14/21; PA #3 performed a KOH/WP analysis on 8/24/20 and 3/25/21; and NP #2 performed a KOH/WP analysis on 6/19/21. 4. Review of the laboratory's

	documentation showed no evidence PA #1, PA #2, PA #3, NP #1, or NP #2 had been evaluated for competency prior to testing patient samples or at any time thereafter. 5. Interview with the laboratory manager on 7/6/21 at 1:15 PM and again on 7/7/21 at 12: 40 PM confirmed the competency evaluations had not been completed for the mid-level providers.