Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0679889	05/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wyoming State Hospital Laboratory	831 Highway 150 South #733b, Evanston, 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
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 the CMS-116 form, 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 laboratory had performed 126 SARS-CoV-2 patient test using a molecular platform since the test was implemented in January 2022. The findings were: 1. Review of the CMS-116 form showed the laboratory performed molecular testing for SARS-CoV-2 using the BD MAX molecular system. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 3. Interview with the laboratory manager on 5 /23/22 at 3:53 PM confirmed the laboratory did not have a written procedure for reporting positive and negative SARS-CoV-2 patient 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 procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 2 of 2 procedure manuals reviewed (BD MAX, Sysmex XN-430). The findings were: 1. Review of the BD MAX System and the Sysmex XN-430 procedure manuals showed the procedures did not contain all of the required sections. The procedure manuals failed to include the following: a. The laboratory's system for entering results in the patient record and reporting patient results. b. A description of the course of action to take if a test system became inoperable. 2. Interview with the laboratory manager on 5/23/22 at 2:57 PM confirmed the procedure manual did not contain all of the required elements.