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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	53D2169813	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Smh Sameday Health & Imaging	1470 Sugarland Dr, Suite 1, Sheridan, 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 lack of documentation and staff interview, the labortory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The findings were: 1. 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. 2. Interview with the technical consultant and lead testing personnel on 7/22/21 at 11:30 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: Surveyor: Yennie, Jean 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 (Siemens epoc Blood Analysis System, HemoCue WBC). The findings were: 1. Review of the epoc Blood Analysis System and HemoCue WBC procedure manuals, signed by the laboratory director on 8/23/20, failed to include a description of what to do if the operating system became inoperable. 2. Interview with the technical consultant and lead testing personnel on 7/22/21 at 9:45 AM confirmed the procedure manuals failed to include the required element.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Surveyor: Yennie, Jean Based on lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the Siemens epoc Blood Analysis System test card (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, pH, partial pressure of oxygen, partial pressure of carbon dioxide, and lactate) analyzed on the Siemens epoc instrument for 11 months of testing (8/24/20 to 7/22/21). The laboratory performed approximately

	696 routine chemistry tests per year. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes on the Siemens epoc Blood Analysis System test card had been verified since the initial verification study completed on 8/24/20. 2. Interview with the technical consultant and lead testing personnel on 7/22/21 at 9:40 AM confirmed the calibration verification had not been completed.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Surveyor: Yennie, Jean Based on review of the new instrumentation and test method verification study, lack of documentation, and staff interview, the laboratory director failed to ensure the verification study was completed to verify the performance specifications of accuracy, precision, and reportable range for 1 of 2 test systems reviewed (Siemens epoc Blood Analysis System). The laboratory performed approximately 696 routine chemistry tests per year. The findings were: 1. Review of the Siemens epoc Blood Analysis System new instrumentation and test method verification study, signed by the laboratory director on 9/1/20, showed studies for precision, accuracy, and reportable range had been completed, however an analysis of the data to verify the performance specifications had not been included in the report. 2. Interview with the technical consultant and lead testing personnel on 7/22/21 at 9:40 AM confirmed the verification study failed to include an analysis of the data.