

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2169813	(X3) Date Survey Completed 12/17/2024
Name of Provider or Supplier Smh Sameday Health & Imaging	Street Address, City, State 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plans (IQCP) and staff interview, the laboratory failed to have a system in place to evaluate the effectiveness of 3 out of 3 IQCPs (HemoCue, Piccolo Express, iSTAT) reviewed. The findings were: 1. Review of the laboratory's records showed an IQCP had been developed for the HemoCue analyzer which was last reviewed on 11/28/22; the IQCP for the Piccolo Express was put into effect on 3/1/24; and the IQCP for the iSTAT was approved on 12/2/24; however, the quality assessment plan for the IQCPs failed to include a method for how often the effectiveness of the IQCPs were to be evaluated. 2. Interview with the technical consultant on 12/17/24 at 10:28 AM revealed an evaluation of the IQCPs should occur on an annual basis.</p>