

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2154145	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Healthstar Diagnostic Center	Street Address, City, State 120 Adcock Rd, Ste B, Hot Springs, AR	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Through a review of the laboratory test menu, a review of proficiency testing events for 2020 and 2021, lack of documentation, and interviews with laboratory personnel, it was determined the laboratory failed to enroll in proficiency testing for BUN (Urea). Survey findings include: A. A review of the laboratory's test menu revealed the laboratory performed BUN (Urea) on the Vitros 5600. B. The surveyor reviewed six chemistry proficiency testing events in 2020 (both Chemistry Core and Chemistry Miscellaneous) and three chemistry proficiency testing events in 2021 (both Chemistry Core and Chemistry Miscellaneous). There was no documentation that the laboratory performed testing for BUN (Urea) in 2020 or 2021 and no documentation that the laboratory was enrolled in proficiency testing for BUN (Urea). C. In an interview, at 10:51 on 8/17/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory was not enrolled in proficiency testing for BUN (Urea).</p>
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</p>

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:

Through a review of the IQCP (Individualized Quality Control Plan) for testing performed on the BD Max analyzer, it was determined the IQCP was missing the required element of Quality Assessment. Survey findings include: A. The laboratory performs moderate complexity STD (sexually transmitted disease) and COVID testing on the BD Max analyzer. B. The laboratory developed an IQCP for the tests performed on the BD Max in order to perform quality control every 30 days. A review of the IQCP revealed that it was missing the required Quality Assessment element. C. In an interview, at 1:18 p.m. on 8/17/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the IQCP did not include Quality Assessment.