Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	04D2154145	05/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Healthstar Diagnostic Center	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
D0000	This is the recertification survey of the laboratory conducted on 5/31/2019. The following condition level deficiency was cited: 493.1250 Analytic System
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of the laboratory policies and procedures, a review of Quality Control Reports for January through May 2019, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5441 - the laboratory failed to have control procedures to monitor over time the accuracy of the test system D5783 - the laboratory failed to document corrective actions when quality control results failed to meet the laboratory's established criteria for acceptability
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)

	Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to have control procedures to monitor over time the accuracy of the test system. Survey findings include: A. Through a review of the laboratory's policies and procedures it was determined the laboratory had no policy to define shifts and trends in quality control or to define a method of monitoring the accuracy of the quality control over time. B. In an interview at 10:52 on 5/30/2019 the laboratory director (as listed on the form CMS-209) confirmed the laboratory had no policy for addressing shifts and trends in quality control results or written policies for monitoring quality control over time.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of the laboratory quality control policy, a review of Quality Control Reports for January through May 2019, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when quality control results failed to meet the laboratory's established criteria for acceptability. Survey findings include: A. A review of the Quality Control policy revealed the following written policies for evaluating quality control: "If the control result falls within 2 SD (standard deviation) range, patient results can be reported."; "When control results are beyond the SD limit, repeat the control on the same cup, if the control is still out, pour fresh control from sample control vial into a new cup and run control.....Cause of outlier must be corrected before any testing on a patient is reported." B. Through a review of the Quality Control Reports for January 2019 through May 2019 it was determined chemistry quality control results were flagged on the reports as being outside the 2 SD range but had no documentation of corrective action. Examples are as follows: Glucose Level 1 Control was flagged out of 2 SD three of twenty-seven runs in January 2019, and two of thirty-three runs in March 2019; Glucose Level 2 Control was flagged out of 2 SD three of twenty-seven runs in January 2019, five of thirty-one runs in February 2019, and five of thirty-six runs in March 2019; Albumin Level 1 Control was flagged out of 2 SD two of twenty-eight runs in January 2019, one of thirty-three runs in March 2019, and eleven of forty-three runs in April 2019; Albumin Level 2 Control was flagged out of 2 SD five of thirty-three runs in March 2019; %A1c Level 1 Control was flagged out of 2 SD four of twenty-three runs in

	January 2019, six of twenty-three runs in February 2019, ten of twenty-three runs in March 2019, and eight of twenty-six runs in April 2019; %A1c Level 2 Control was flagged out of 2 SD one of twenty-three runs in January 2019, three of twenty-one runs in February 2019, three of twenty-three runs in March 2019, and six of twenty-five runs in April 2019; LH (Luteinizing Hormone) Level 3 Control was flagged out of 2 SD one of twenty-three runs in January 2019, five of twenty-one runs in February 2019, and two of twenty-five runs in March 2019; Potassium Level 1 Control was flagged out of 2 SD one of twenty-six runs in January 2019, and three of thirty-six runs in March 2019; Potassium Level 2 Control was flagged out of 2 SD ten of twenty-six runs in January 2019, twelve of thirty runs in February 2019, six of thirty-three runs in March 2019 and two of twenty-five runs in April 2019; Cholesterol Level 1 Control was flagged out of 2 SD three of twenty-five runs in January 2019, one of twenty-one runs in February 2019, eight of twenty-two runs in March 2019, and ten of twenty-six runs in April 2019; and Cholesterol Level 2 Control was flagged out of 2 SD three of twenty-four runs in January 2019, four of twenty-four runs in March 2019, and nine of twenty-six runs in April 2019. C. Through a review of patient test volumes documented by laboratory staff on the Quality Control Reports for January through April of 2019, it was determined that 1022 patient Glucose results, 303 patient Albumin results, 474 patient A1c results, 12 LH results, 2259 patient Potassium results, and 1573 patient Cholesterol results were reported when quality control results were outside of the 2 SD acceptable range and corrective actions were not documented. D. In an interview at 10:52 on 5/30/2019, the laboratory director (as listed on the form CMS-209) stated that she thought the -2s and + 2s flags meant that quality control results were within the 2 SD range and confirmed that no corrective actions were taken for results flagged as outside of 2 SD.