Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2104538	10/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Hospital & Clinic, Inc	2175 Us Hwy 31 N, Deatsville, AL	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2019 API (American Proficiency Institute) Proficiency Testing records and an interview with Testing Personnel #1, the laboratory failed to document reviews of three out of six of the returned survey evaluations results, and failed to document corrective action for one out of six surveys with results less than 100 % (percent). The findings include: 1. A review of the Hematology Proficiency Testing records revealed the laboratory failed to print the API evaluations / scores for 2018-Event #2 (July 2018) and 2019-Event #2 (July 2019). The scores for the 2019-Event #1 survey had been printed, however there was no documentation of review (as indicated by a signature and date) for this or the two aforementioned surveys. 2. A further review of the API 2019-Event #2 Hematology survey results (printed for the surveyor while on-site) revealed a score of 80% for White Blood Cells. There was no documentation of investigation or corrective action for these results less than 100% since the laboratory had failed to print the scores until the day of the survey. 3. In an interview on 10/16/2019 at 4:05 PM, Testing Personnel #1 reviewed and confirmed the above noted findings. 4. This is a repeat deficiency. .
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: Based on a lack of Hematology quality control documentation and an interview with Testing Personnel #1, the laboratory failed to implement and document a mechanism to monitor quality control (QC) shifts and trends over time. The findings include: 1. A review of the QC records for the Beckman Coulter AcT diff Hematology analyzer revealed only the daily QC printouts were available for review. The laboratory had no mechanism to monitor QC shifts and trends over time. (Examples include printing Levi-Jennings (L-J) charts periodically or submitting data to Coulter's Interlaboratory Quality Assurance Program [IQAP]). 2. During an interview on 10/16/2019 at 2:30 PM the surveyor asked Testing Personnel #1 if the laboratory printed the Hematology QC Levi-Jenning charts. Testing Personnel #1 stated the testing personnel were supposed to print the L-J charts, however they sometimes forgot to perform this task. The surveyor then asked if results for each QC lot number were submitted to the Coulter IQAP for analysis; Testing Personnel #1 stated they did, however the reports had not been printed. [No documentation was provided during the survey.] Thus the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor