Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0302095	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jerry Harrison Family Practice	904 26th Street, Haleyville, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the 2016-2018 API (American Proficiency Institute) Hematology Proficiency Testing records and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure attestation statements for four of seven surveys were signed by the Laboratory Director. The findings include: 1. A review of the API Hematology Proficiency Testing (PT) records revealed no signature of the Laboratory Director on attestation statements for three of three 2017 surveys, and the Event #1-2018 survey. Testing Personnel #1 had signed the documents instead of the Laboratory Director. 2. A review of page 2 of the Proficiency Testing procedure in the laboratory Procedure Manual revealed, "The Laboratory Director and all staff performing the testing should sign the attestation spaces provided on the data sheet." 3. During the exit interview on 4/3/2018 at approximately 3:45 PM, TP #1 was asked if the Laboratory Director had changed the above procedure, and had delegated the signing of the attestation statements to TP #1 in writing. TP #1 stated there was no delegation of this responsibility from the Director in writing. Thus, the above noted findings were confirmed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the 2017 API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing results were submitted within the timeframes established by the PT program. This was noted on one of three of the 2017 surveys reviewed. The findings include: 1. A review of the 2017 API PT records revealed the Event #2 Hematology survey received a score of 0% due to "Failure to participate". The results for this survey were not submitted before the established deadline. The facility performed the testing, however they failed to perform an internal evaluation once the results were available from API to ensure the accuracy of their results. 2. During an interview on 4/3/2018 at 1:25 PM, Testing Personnel (TP) #1 stated she had entered the results on the API website. However during the process, TP #1 stated she was interrupted, and failed to hit the submit button afterwards. Thus the above noted findings were confirmed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Abbott Cell Dyn 1800 Hematology analyzer quality control (QC) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure at least two levels of Hematology QC were run and were within acceptable limits before patient testing began. This was noted on one day of patient CBC (Complete Blood Count) testing in 2016. The findings include: 1. A review of the 2016 Hematology cumulative QC report revealed three levels of QC were outside of acceptable ranges on 4/15/2016. A review of the cumulative monthly patient data log revealed three patient CBC's were performed on this date. 2. During the exit interview on 4/3/2018 at approximately 3:45 PM, the above noted findings were reviewed and confirmed with Testing Personnel #1. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor