Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0950186	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Med Care Of Gadsden	3206 West Meighan Blvd, Gadsden, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Cell Dyn Quick Reference Guide and an interview with Testing Personnel #2, the laboratory failed to ensure the Laboratory Director signed and dated his review and approval of the new procedure before use by the testing personnel for patient testing. The findings are: 1. A review of the Cell Dyn Quick Reference Guide had no signature to indicate the Director's review and approval for use by the testing personnel. CLIA regulations require the Laboratory Director's review and approval of all new procedures as indicated by his actual signature and the date. Patient testing on the new Cell Dyn Emerald began on 7/16/2016. 2. During an interview on 5/30/2018 at 12:20 PM, Testing Personnel (TP) #2 was asked if the Laboratory Director had reviewed, dated and signed his approval for the new analyzer procedures. TP #2 explained she had printed the new Reference Guide from the internet when they received the instrument, and had not realized the Laboratory Director needed to review and sign the procedures. 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 Emerald Hematology analyzer quality control (QC) records, patient logs, and an interview with Testing Personnel #2, 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 2017. The findings include: 1. A review of the 2017 Hematology cumulative QC reports revealed only the Low level QC was performed and within acceptable ranges on 4/11/2017. There were no results available for the Normal and High level QC on this date. 2. A review of the patient log revealed thirteen patient CBCs were performed on 4/11/2017. 3. During an interview on 5/30/2018 at 4:00 PM, the above noted findings were reviewed and confirmed with Testing Personnel #2. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the Abbott Cell Dyn Emerald Hematology analyzer and an interview with Testing Personnel #2, the Laboratory Director failed to document review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the Abbott Cell Dyn Emerald's installation documentation revealed no review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 4/13/2016. Patient CBC (Complete Blood Count) testing on this analyzer began on 7/16/2016. 2. During an interview and review of these records on 5/30/2018 at 12:20 PM, Testing Personnel #2 stated she was unable to find any documentation of review and approval of the validation data by the Laboratory Director (as indicated by his signature and date). Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor