

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2029867	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Vaughn Family Care Llc	Street Address, City, State 9540 Wynlakes Place, Montgomery, 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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the new Abbott Cell Dyn Emerald Hematology analyzer and an interview with the Laboratory Manager (also Testing Personnel #1), 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 new Abbott Cell Dyn Emerald's installation documentation (Serial number 030817-007292) revealed no review and approval by the Laboratory Director on the initial verification procedures performed on 2/19/2019. Use of this analyzer for patient CBC (Complete Blood Count) testing began in February 2019. 2. During an interview and review of these records on 10/17/2019 at 12:38 PM, the Laboratory Manager was unable to find any documentation of review and approval of the validation data by the Laboratory Director (as indicated by a signature and date). At 12:50 the Manager stated the Director had "looked" at the installation data, however he had not signed it because the previous analyzer had also been an Abbott Cell Dyn Emerald. Thus the above noted findings were confirmed. .</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the Quality Assurance (QA) Program procedure and other laboratory records, the surveyor determined the Laboratory Director failed to follow the QA policy in the overseeing the plan and documenting routine QA reviews. The findings include: 1. A review of the Quality Assurance Program procedure revealed the following: "The Laboratory Director oversees the implementation of our plan and helps identify and correct problems as they occur. ...". 2. A review of laboratory processes revealed no documentation of the Laboratory Director's QA reviews of Hematology calibrations, maintenance, quality control records, corrective action logs, environmental logs, or initial validation procedures for the new Abbott Cell Dyn Hematology analyzer. 3. During an interview on 10/17/2019 at 3:50 PM, the TP #1 was unable to provide documentation of Laboratory Director's periodic reviews, thus the above noted findings were confirmed. .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on reviews of the Abbott Cell Dyn Hematology analyzer installation and validation records, quality control (QC) and calibration records, a lack of quality assurance reviews and interviews with the Laboratory Manager (also Testing Personnel #1), the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide and document technical and scientific oversight of the laboratory. The findings include: 1. A review of laboratory processes revealed no documentation of the Technical Consultant's (also the Laboratory Director) technical and scientific oversight in the following areas: A) No documentation of review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the new Abbott Cell Dyn Hematology analyzer, before patient testing began. (Refer to D6013.) B) No documentation of reviews of Hematology calibrations, or maintenance and QC records. [The surveyor's review of the QC records and the corrective action logs revealed numerous problems with the previous Cell Dyn analyzer, including continuing problems with the platelet QC, and / or the Red Blood Cell (RBC), Hemoglobin and Hematocrit QC. The Testing Personnel documented the problems and the corrective actions, however there was no documentation of the Laboratory Director / Technical Consultant's oversight and reviews.] 2. During an interview on 10/17/2019 at 3:50 PM, the surveyor requested quality assurance records or other documentation of the Laboratory Director / Technical Consultant's periodic review of the laboratory processes and procedures. The Laboratory Manager (also Testing Personnel [TP] #1) stated she performed the monthly reviews. The surveyor then confirmed TP #1 has a High School Diploma.

During the previous CLIA survey on 9/15/2017 the surveyor (the current CLIA Supervisor) had told TP #1 she was acting outside the scope of her responsibilities in performing reviews. This oversight should be provided by the Laboratory Director or a qualified Technical Consultant with a minimum of a Bachelor in Science. The surveyor explained lack of laboratory oversight by a qualified individual has the potential to affect the quality of testing and patient care. TP #1 was unable to provide documentation of the Laboratory Director / Technical Consultant's periodic reviews, thus the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor