

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0687538	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Dothan Hematology And Oncology Pc	Street Address, City, State 287 Healthwest Drive, Dothan, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxH 520 Operator's Manual, and interviews with Testing Personnel #1, the surveyor determined the Laboratory Director failed to document his review and approval (as indicated by signature and date) for one of one new procedures used by the testing personnel on the new Hematology instruments. The findings include: 1. A review of the Beckman Coulter DxH 520 Operator's Manual, "Instructions for Use" revealed no signature and date on the procedures to indicate the the Laboratory Director's review and approval. 2. A review of new laboratory instrumentation revealed two new Beckman Coulter (B-C) DxH-520 Hematology analyzers: A) The "Top" analyzer (SN BD060566) was installed 12/15/2020; patient CBC (Complete Blood Count) testing began 3/19/2021. B) The "Bottom" analyzer (SN BD070624) was installed 4/19/2021; patient CBC testing began 4/19/2021. 3. During an interview and review of the manual on 9/13 /2022 5:15 PM, Testing Personnel #1 confirmed the above findings. .</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:
 Based on a review of comparison data between the two Beckman Coulter (B-C) DxH-520 Hematology analyzers and an interview with Testing Personnel #1, the laboratory failed to ensure the differences in results between the two instruments did not exceed acceptable performance limits on five out of six studies between 6/29/2021 and 6/9/2022. The findings include: 1. A review of records comparing results between the two B-C DxH-520 Hematology analyzers revealed the laboratory ran two samples on both instruments semi-annually, documented the results and calculated the CV (Coefficient of Variation) to demonstrate precision. The chart specified the CV Limits for all CBC (Complete Blood Count) parameters, with the question, "Acceptable?" on the bottom line. 2. A further review of the comparison charts revealed the laboratory had answered "yes" to the "Acceptable?" question on all the charts, however the surveyor noted the following: A) 6/29/2021 Sample #1: One of nine parameters unacceptable B) 6/29/2021 Sample #2: Three of nine parameters unacceptable C) 12/28/2021 Sample #1: Two of nine parameters unacceptable D) 6/09/2022 Sample #1: Eight of nine parameters unacceptable E) 6/09/2022 Sample #2: Three of nine parameters unacceptable The surveyor noted there was no evidence of review of the comparison studies, and the laboratory further failed to implement an investigation and corrective actions to determine the cause of the unacceptable CV limits. 3. During an interview and review of the records on 9/13/2022 at 5:10 PM, Testing Personnel #1 confirmed the above findings, and stated the other testing personnel may have entered the data incorrectly. .

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 the installation and validation records for the two Beckman Coulter (BC) DxH520 Hematology analyzers, and an interview with Testing Personnel #1, the surveyor determined the Laboratory Director failed to document review and approval of the installation procedures as verification of the manufacturer's performance specifications before patient testing began. This affected two of two new instruments performing moderate-complexity testing. The findings include: 1. A review of the validation records for the two BC DxH520 Hematology analyzers (SN BD070624 [Bottom] and SN BD060566 [Top]) revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. Patient CBC (Complete Blood Count) testing on the Top analyzer began 3/19/2021 and patient testing on the Bottom analyzer began 4/19/2021. 2. During an interview on 9/13/2022 at 1:12 PM, the surveyor reviewed the records with Testing Personnel #1, who stated the Laboratory Director had "looked" at the validation data, but he had not signed his approval. .

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 Hematology records and personnel files, and interviews with Testing Personnel #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to document provision of technical and scientific oversight of the laboratory since the previous survey on 1/6/2021. The findings include: 1. A review of Hematology records and personnel files revealed no documentation of the Technical Consultant's reviews and scientific oversight in the following areas: A) No evidence of review of the comparison studies, with investigation to determine the cause of the unacceptable CV (Coefficient of Variation) limits, and implement corrective actions, if needed. (Refer to D5775.) B) No documentation of review and approval of the installation procedures for the two new Beckman Coulter DxH520 Hematology analyzers to ensure the manufacturer's performance specifications were verified before patient testing began. (Refer to D6013.) C) No technical supervision to ensure training was performed and documented before testing personnel began moderate-complexity CBC (Complete Blood Count) testing on patients using the new Beckman Coulter DxH520 Hematology analyzers. (Refer to D6045.) 2. During the exit summation interview with Testing Personnel #1 on 9/13/2022 at 5:20 PM, the surveyor reviewed and confirmed the above findings. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on reviews of personnel files, the Hematology analyzer validation records, and an interview with Testing Personnel #1, the Technical Consultant (also the Laboratory Director), failed to provide technical supervision and ensure training was performed and documented as per CLIA requirements before testing personnel began moderate-complexity CBC (Complete Blood Count) testing on patients using the new analyzers. This affected two of two testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of new laboratory instrumentation revealed two new Beckman Coulter (B-C) DxH-520 Hematology analyzers: A) The "Top" analyzer (SN BD060566) was installed 12/15/2020; patient CBC (Complete Blood Count) testing began 3/19/2021. B) The "Bottom" analyzer (SN BD070624) was installed 4/19/2021; patient CBC testing began 4/19/2021. 2. A review of personnel records revealed no documentation of training on the new B-C DxH-520 analyzers for Testing Personnel #1 or #2. 3. During an interview on 9/13 /2022 at 1:09 PM, the surveyor reviewed the above records with Testing Personnel #1, who stated the Beckman Coulter Technician trained the testing personnel during the installation procedures, but the training was not documented. SURVEYOR ID #32558
Licensure and Certification Surveyor