

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0857041	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Andalusia Family Practice	Street Address, City, State 712 East Three Notch Street, Andalusia, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2021 AAFP (American Academy of Family Physicians) proficiency testing (PT) records, personnel records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed moderate complexity Hematology testing on patients. This was noted on eight of eight survey events reviewed. The findings include: 1. A review of AAFP attestation statements revealed the Technical Consultant had performed all the testing on the eight surveys performed from 10/15/2018 through 3/4/2021 (the most current survey). None of the PT testing had been performed by Testing Personnel (TP) #1 or #2. 2. A review of the personnel files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed TP #1 and #2 were full time, and had been qualified to perform moderate complexity Hematology testing since the previous survey (on 7/24/2018). TP #3 was a new employee. 3. During an interview on 5/4/2021 at 1:20 PM, the Technical Consultant confirmed she had performed all the Hematology proficiency testing because she was the primary testing personnel until she leaves the laboratory at 11:00 AM, then the "nurses" (TP #1, #2 and #3) performed the patient CBC's (Complete Blood Counts). The surveyor then explained all testing personnel listed on the CMS-Form 209 must periodically participate in the performance of proficiency testing. .</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p>

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on reviews of the installation and validation records for the Beckman Coulter DxH-520 Hematology analyzer, and interviews with Testing Personnel #1 and the Technical Consultant, the surveyor determined the Technical Consultant failed to document review and approval of the validation before patient testing began. This affected one of one Hematology analyzers. The findings include: 1. During the entrance tour on 5/4/2021 at approximately 10:40 AM Testing Personnel #1 stated the laboratory had one new analyzer, the Beckman Coulter DxH-520 Hematology analyzer, installed in January 2020, with patient CBC (Complete Blood Count) testing beginning on 1/21/2020. 2. A review of the January 2020 validation records for the Beckman Coulter DxH-520 revealed no documentation of the Technical Consultant's review and approval (as indicated by a signature and date). 3. During an interview on 5/4/2021 at 3:10 PM, the Technical Consultant confirmed the above noted findings. .

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of personnel files, and an interview with the Technical Consultant, the laboratory failed to ensure educational documentation was available for two of three Testing Personnel (TP) performing and reporting CBC's (Complete Blood Counts) on patient samples. The findings include: 1. A review of the personnel files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed TP #1 had been employed since the previous survey on 7/24/2018, performing and reporting CBC's (Complete Blood Counts) on patient samples when the Technical Consultant was not working, however there were no educational documents on file. 2. A review of the file for TP #3 revealed she was a new employee, with training in progress as of 4/22/2021, performing patient testing with supervision, however the laboratory had failed to request her educational documentation until the day of the survey. 3. During an interview on 5/4/2021 at 12:20 PM, the Technical Consultant confirmed the above noted findings. .

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel files, the installation records for the Beckman Coulter DxH-520 Hematology analyzer, and an interview with the Technical Consultant, the laboratory failed to document Testing Personnel training occurred before testing and reporting CBC's (Complete Blood Counts) on patient samples. The findings include:

1. A review of the personnel files of Testing Personnel (TP) listed on the Form CMS-209 (Laboratory Personnel Report) revealed TP #1 and #2 had been employed since the previous survey on 7/24/2018, and had been trained to perform moderate CBC testing on the Beckman Coulter DxH-520 on 4/29/2021. TP #3 was a new employee, and her training was in progress.
2. A review of the Beckman Coulter DxH-520 records revealed the analyzer was installed in January 2020, with patient CBC (Complete Blood Count) testing beginning on 1/21/2020.
3. During an interview on 5/4/2021 at 12:20 PM, the surveyor asked the Technical Consultant when training on the Beckman Coulter (B/C) DxH-520 occurred. The Technical Consultant (TC) explained she was trained by the B/C Technician during the installation. Afterward, the TC trained TP #1 and #2, and they began performing patient CBC's when the TC was off, however the TC had failed to document the testing personnel training. Then before the CLIA inspection, TP #1 realized the training documentation would be required; TP #1 and #2 signed the training record on 4/29/2021. SURVEYOR ID# 32558 Licensure and Certification Surveyor