

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1013293	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Cullman Oncology & Hematology	Street Address, City, State 1750 Alabama Hwy 157, Cullman, 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 API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1 and the Laboratory Director, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on one out of two testing personnel listed on the CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of API attestation statements revealed Testing Personnel #1 had performed all three events in 2021. 2. During an interview on 01/06/2022 at 11:20 AM, Testing Personnel #1 and the Laboratory Director confirmed the proficiency testing was not rotated to Testing Personnel #2 who had been performing patient testing since March 2021.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with Testing Personnel #1 and the Laboratory Director, the Technical Consultant (the Laboratory Director fills</p>

this role) failed to evaluate and document the performance of individuals at least semiannually during the first year of performing CBC's (Complete Blood Counts). This was noted on two out of two testing personnel listed on the CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of personnel records revealed that semiannual performance was not evaluated or documented for Testing Personnel #1 and #2. Testing Personnel #1 started running patient test in October 2019; the initial training and semiannual performance was not documented for the Sysmex 1000i (the CBC analyzer previously used until July 2020). Testing Personnel #2's initial training was performed on 03/20/21, and no semiannual performance was documented. 2. During an interview on 01/06/2022 at 11:20 AM, Testing Personnel #1 and the Laboratory Director confirmed semiannual performance was not evaluated or documented for Testing Personnel #1 and #2.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of personnel records and an interview with Testing Personnel #1 and the Laboratory Director, the Technical Consultant (the Laboratory Director fills this role) failed to evaluate and document the performance of individuals at least annually after the first year of performing CBC's (Complete Blood Counts). This was noted on one out of two testing personnel listed on the CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of personnel records revealed the annual evaluation was not evaluated or documented for Testing Personnel #1. Testing Personnel #1 started running patient test in October 2019; the initial training and semiannual performance was not documented for the Sysmex 1000i (the CBC analyzer previously used until July 2020). Initial training for the Sysmex XN-430 was performed and documented on 08-05-2020 for Testing Personnel #1, and no annual evaluation was documented. 2. During an interview on 01/06/2022 at 11:20 AM, Testing Personnel #1 and the Laboratory Director confirmed the annual evaluation for Testing Personnel #1 was not performed and documented.

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 records and an interview with Testing Personnel #1 and the Laboratory Director, the laboratory failed to have educational documentation on file for Testing Personnel #2. This was noted on one out of two testing personnel listed on the CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of personnel records revealed that Testing Personnel #2 had no educational records on file; Testing Personnel #2 had performed patient testing since March 2021. 2. During an interview on 01/06/2022 at 11:20 AM, Testing Personnel #1 and the Laboratory Director confirmed the above noted findings.