

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2277396	(X3) Date Survey Completed 08/31/2023
Name of Provider or Supplier Southern Immediate Care Hoover	Street Address, City, State 1575 Montgomery Hwy, Hoover, 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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on the entrance tour, a review of the CMS-209 Laboratory Personnel Report and interviews with Testing Personnel #2 and the Laboratory Supervisor in Heflin, the Laboratory Director failed to ensure a qualified individual was employed to fill the position of Technical Consultant after moderate-complexity patient testing began on 7/6/2023 until the day of the survey on 8/31/2023. The findings include: 1. During the entrance tour on 8/31/2023 at 8:45 AM, Testing Personnel #2 stated the laboratory performed Complete Blood Counts (CBC's) on the Beckman Coulter DxH 560 Hematology analyzer. A review of the patient log revealed CBC testing began on 7/6/2023. 2. A review of CMS-209 Laboratory Personnel Report revealed the laboratory failed to list an individual in the Technical Consultant position. 3. During an interview on 8/31/2023 at 9:20 AM, the surveyor noted there was no Technical Consultant listed on the CMS-209, and asked if a qualified individual had been hired to perform technical reviews of the laboratory records. Testing Personnel #2 stated they did not have a Technical Consultant, and "did not know it was required". 4. During a phone interview on 8/31/2023 at 10:00 AM the Laboratory Supervisor in Heflin also confirmed the laboratory did not have a Technical Consultant. .</p>

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 Beckman Coulter (B-C) DxH 560 Hematology analyzer, and an interview with the Testing Personnel #2, the Laboratory Director failed to document review and approval of the procedures as verification of the manufacturer's performance specifications before patient testing began on 7/06/2023. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of the validation records for the B-C DxH 560 revealed the Laboratory Director failed to document review and approval (via his signature and date) of the procedures verifying the manufacturer's performance specifications until 8/30/2023. Patient CBC (Complete Blood Count) testing began on 7/06/2023. 2. During the exit summation, in an interview on 8/31/2023 at 12:05 PM, the surveyor reviewed the records with the Testing Personnel #2, and confirmed the above noted findings. .

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on the entrance tour, a review of the CMS-209 Laboratory Personnel Report and interviews with Testing Personnel #2 and the Laboratory Supervisor in Heflin, the laboratory failed to fill the position of Technical Consultant after moderate-complexity patient testing began on 7/6/2023 until the day of the survey on 8/31/2023. The findings include: 1. Refer to D6036. .

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 the entrance tour, a review of the CMS-209 Laboratory Personnel Report and interviews with Testing Personnel #2 and the Laboratory Supervisor in Heflin, the laboratory failed to fill the position of Technical Consultant after moderate-complexity patient testing began on 7/6/2023 until the day of the survey on 8/31/2023.

The findings include: 1. During the entrance tour on 8/31/2023 at 8:45 AM, Testing Personnel #2 stated the laboratory performed Complete Blood Counts (CBC's) on the Beckman Coulter DxH 560 Hematology analyzer. A review of the patient log revealed CBC testing began on 7/6/2023. 2. A review of CMS-209 Laboratory Personnel Report revealed the laboratory failed to list an individual in the Technical Consultant position. 3. During an interview on 8/31/2023 at 9:20 AM, the surveyor noted there was no Technical Consultant listed on the CMS-209, and asked if a qualified individual had been hired to perform technical reviews of the laboratory records. Testing Personnel #2 stated they did not have a Technical Consultant, and "did not know it was required". 4. During a phone interview on 8/31/2023 at 10:00 AM the Laboratory Supervisor in Heflin also confirmed the laboratory did not have a Technical Consultant. SURVEYOR ID#32558 Licensure and Certification Surveyor