

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2028603	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Hoover Family Medicine	Street Address, City, State 774 Shades Mountain Plaza, 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
D0000	
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures manual and an interview with the Technical Consultant (TC), the Laboratory Director failed to establish and maintain a Quality Assessment program to assure the quality of laboratory services provided. This was noted from the date of the last survey, 12-202022 to the date of the current survey, 12-19-2024. The findings include: 1. A review of Policies and Procedures manual revealed a lack of a Quality Assessment program implemented to monitor and evaluate the laboratory's ability to perform quality testing and provide remedial action when failures are identified. 2. The TC confirmed the above findings during the exit conference on 12-19-2024 at 1:00 PM.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:
 Based on a review of the personnel records and an interview with the Technical Consultant(TC), the TC failed to ensure three of the three Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) had competency assessments which included the six minimal regulatory requirements. The surveyor noted six of the six requirements were missing on annual and semi-annual competencies. The findings include: 1. A review of the 2022 through 2024 personnel records revealed the TP competency assessment for Hematology specialty had no documentation of six of the six minimal regulatory requirements. The surveyor noted the missing six requirements were as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing, (2) Monitoring the recording and reporting of test results, (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem solving skills. 2. The TC confirmed the above findings during the exit conference on 12/19 /2024 at 1:00 PM.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
 Based on a review of the personnel records and an interview with the Technical Consultant (TC), the TC failed to ensure all Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had semi-annual competency assessments. The surveyor noted three of the three TP had no documentation of semi-annual competency assessment. The findings include: 1. A review of the personnel records revealed three of the three TP who performed Hematology testing did not have documentation of the semi-annual competency assessment. 2. The TC confirmed the above findings during the exit conference on 12 /19/2024 at 1:00 PM,

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 the personnel records and an interview with the Technical Consultant (TC), the TC failed to ensure all Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had annual competency assessments. The surveyor noted three of the three TP had no

documentation of annual competency assessment. The findings include: 1. A review of the personnel records revealed the TP who performed Hematology testing did not have annual competency assessment for 2022-2024. 2. The TC confirmed the above findings during the exit conference on 12/19/2024 at 1:00 PM,