

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2203110	(X3) Date Survey Completed 10/23/2024
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 1311 Bristol Pike, Bensalem, PA	
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
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 review of laboratory records, lack of documentation and interview with the Quality Director (QD), the laboratory director (LD) failed to ensure that quality assessment programs were maintained to ensure the quality of laboratory services provided from March 2023 to December 2023. Findings include: 1. On the day of survey, 10/23/2024, the laboratory could not provide the following 9 of 10 Quality Assessment reports titled "Dr. Shah's Monthly Director Visits" from March 2023 to December 2023: - March 2023, April 2023, May 2023, June 2023, July 2023, August 2023, September 2023, October 2023, and November 2023. 2. The QD confirmed the findings above on 10/23/2024 at 12:00 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> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's competency assessment records and interview with the quality director (QD), the technical consultant #1 (CMS 209 TC #1) failed to assess the competency of 1 of 4 testing personnel (TP) that performed chemistry, and hematology testing from 03/07/2023 to the date of the survey. Findings include: 1. Review of lab corp Competency Assessment records revealed that TP #3 (CMS 209 TP #3) completed initial training on 2/05/2023 for hematology and chemistry testing. 2. On the day of survey, 10/23/2024, review of the laboratory's competency assessment records revealed the TC failed to assess 1 of 4 TP (CMS 209 TP#3) that performed chemistry and hematology testing from 03/07/2023 to 10/23/2024: - 6 month competency. - 2024 annual competency. 3. The QD confirmed the findings on 10/23/2024 at 10:15 am.