

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2203110	(X3) Date Survey Completed 03/07/2023
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with technical supervisor #2 (TS) (CMS-209 personnel #5), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 technical consultants (TC) and 1 of 2 technical supervisors (TS) for their supervisory responsibilities from 03/18/2021 to the date of the survey. Findings include: 1. On the day of survey, 03/07/2023 at 11:31 am, the laboratory could not provide a competency assessment policy to assess the competency of 1 of 2 TC (CMS-209 personnel #5) and 1 of 2 TS (CMS-209 personnel #5) for their supervisory responsibilities from 03/18/2021 to 03/07/2023. 2. The laboratory could not provide documentation for the delegation of duties for the TC and TS (CMS-209 form, personnel #5). 3. TS #2 confirmed the findings above on 03/07/2023 around 12:00 pm.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the technical supervisor #2 (TS) (CMS-209 personnel #5), the laboratory failed to evaluate twice annually the relationship between automated blood differentials (Sysmex XS1000iC) and manual blood differentials from 03/18/2021 to the date of the survey. Findings include: 1. On the day of survey, 03/07/2023 at 01:27 pm, the laboratory could not provide documentation of the comparison of test results performed between automated blood differentials (Sysmex XS1000iC) and manual blood differentials from 03/18/2021 to 03/07/2023. 2. The laboratory performed 225,243 hematology tests in 2022 (annual volume listed on CMS 116 form). 3. TS #2 confirmed the findings above on 03/07/2023 around 02:15 pm.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on lack of Quality Assurance (QA) documentation and interview with the technical supervisor #2 (TS) (CMS-209 personnel #5), the Laboratory Director (LD) failed to ensure a QA program was maintained and documented to ensure the quality of services provided by the laboratory from 03/18/2021 to the date of the survey. Findings include: 1. On the date of the survey, 03/07/2023 at 01:02 pm, the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 03/18/2021 to 03/07/2023. 2. The laboratory performed 249,843 non waived tests in 2022 (annual volume listed on CMS 116 form). 3. TS #2 confirmed the findings above on 03/07/2023 around 02:00 pm.

D8103

BASIC INSPECTION REQUIREMENTS
CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with technical supervisor #2 (TS) (CMS-209 personnel #5), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 03/07/2023. Findings include: 1. On the day of survey, 03/07/2023 at 01:27 pm, the laboratory could not provide the following records upon request: - 2021 American Proficiency Institute (API) proficiency testing results and attestation documentation for hematology and chemistry. - Patient test reports from 03/18/2021 to 09/06/2022. - Test requisitions from 03/18/2021 to 09/06/2022. - Temperature records from 03/18/2021 to 12/31/2021 (refrigerator/freezer/room temperature). 2. TS #2 confirmed the findings above on 03/07/2023 around 02:15 pm.