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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 17D1068886 | (X3) Date Survey Completed 10/28/2021 |
| Name of Provider or Supplier Laboratory Corporation Of America Holdings | Street Address, City, State 12210 West 87th Street, Lenexa, KS | |
| 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 |
|---------------------------|---|
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the procedure "Proficiency Testing", proficiency testing (PT) submission forms, corrective action document and interview with the quality manager, the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, American Proficiency Institute (API). Findings: 1. Procedure states under Survey Review "As an onsite second check on the accuracy of the completed form, a second staff member should review the data for accuracy. Including the instrument codes and reagent codes. In the case of one tech sites, the results may be reviewed on a different day by the tech, thus allowing for a 'fresh eye' approach." 2. Action Report Form for evaluation of API PT results of Hematology 1st Event 2021, dated 5/28/21, revealed the following corrective action: "Will use a second party to review preliminary results before making final transmission." 3. Review of the submission forms for API 2021: a. Microbiology 2nd Event, dated 6/25/21, found no documentation of a review. b. Immunology/Immunoematology 2nd Event, dated 8/11/21, found no documentation of a review. c. Hematology /Coagulation 2nd Event, dated 7/19/21, found no documentation of a review. 4. Interview with the quality manager on 10/28/21 at 2:25 p.m. confirmed the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, American Proficiency Institute (API).</p> |