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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D0648109 | (X3) Date Survey Completed 08/30/2019 |
| Name of Provider or Supplier State Hygienic Laboratory | Street Address, City, State University Of Iowa Research Park, Coralville, IA | |
| 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 |
|---------------------------|---|
| D5219 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by interview, the laboratory failed to verify the accuracy of the Zika Virus testing twice annually. Findings include: 1. Review of proficiency testing records for 2017, 2018, and 2019 revealed that the laboratory was only performing the CDC Arbovirus Panel, that included the Zika virus, that was sent to the laboratory once a year, for Zika Virus testing. 2. Interview with Technical Supervisor #6 (on CMS Form 209) on 8/28/2019 at approximately 3 pm, confirmed that only the CDC Arbovirus Panel was performed once a year for Zika Virus testing.</p> |