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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D0995726 | (X3) Date Survey Completed 02/04/2019 |
| Name of Provider or Supplier Clinlab, Inc | Street Address, City, State 763 S New Ballas Road, Ste 160, Saint Louis, MO | |
| 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 |
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| D3011 | <p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of established written safety procedures, manufacturer's quality control (QC) package inserts, observation of specimen and QC materials handling and interview with the technical supervisor, testing personnel # 7 failed to observe procedures to ensure protection from biochemical and biohazardous materials. Findings: 1. The laboratory's universal precautions policy states, "Gloves will be worn when in contact with blood, mucous membranes, non-intact skin or potentially infectious materials is likely." Section B, "Personal Protective Equipment" states "employees are required to wear gloves when employees have potential for direct skin contact with blood, hazardous chemicals and other infectious materials." 2. The manufacturer's QC package insert for MAS liquid drugs of abuse controls showed the QC material may cause "allergic skin reaction." The package insert for the MAS Chemtrak control materials showed the QC material is a "biological risk." 3. Observation of specimen and QC materials handling on February 4, 2019 at 09:50 AM revealed testing personnel # 7 did not wear gloves when handling/pipetting MAS QC materials or when handling patient purple top tubes containing blood. 4. On February 4, 2019 at 09:55 AM, testing personnel #7 said she does not wear gloves when handling QC materials. Interview with the technical supervisor on February 4, 2019 at 11:00 AM confirmed safety procedures were not observed when handling biochemical or biohazard materials.</p> |