

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>36D2157641             | <b>(X3) Date Survey Completed</b><br><br>03/18/2019 |
| <b>Name of Provider or Supplier</b><br><br>Consultants In Laboratory Medicine  | <b>Street Address, City, State</b><br><br>2130 W Central Avenue, Suite 300, Toledo, OH |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D5601</b>              | <p><b>HISTOPATHOLOGY</b><br/>CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review, and interview with the Laboratory Director (LD), the laboratory failed to document all control procedures performed at this location, to include the reactions and observations of the control slides, for the differential stain Hematoxylin and Eosin (H&amp;E). All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the procedure manual found a policy for H&amp;E quality control, for each day of patient testing, which complied with the regulation. 2. Review of documentation failed to find documentation of H&amp;E quality control each day of patient testing, per the procedure manual. 3. An interview with the LD, on 3/18/19 at 1:45 pm, confirmed that H&amp;E quality control testing was not performed at this testing location, as required; thus the H&amp;E quality control documentation for each day of testing could not be produced.</p> |