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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2021686 | (X3) Date Survey Completed 04/03/2018 |
| Name of Provider or Supplier Perll Diagnostics Inc | Street Address, City, State 5010 Ritter Road, Mechanicsburg, 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 |
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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CASPER Report 155, and performance evaluations from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analyte: Susceptibility Testing, which is of the specialty Bacteriology. The laboratory had unsatisfactory scores for the 2nd event of 2017 and the 1st event of 2018. See D2028.</p> |
| D2028 | <p>BACTERIOLOGY CFR(s): 493.823(e)</p> |

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the Report (CASPER) 155 report and performance evaluations from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analyte: Susceptibility Testing, which is of the Bacteriology specialty. The laboratory had unsatisfactory scores for the 2017 2nd and 2018 1st events.

Findings: 1. API 2017 Event 2 for Susceptibility Testing the score was 50%. 2. API 2018 Event 1 for Susceptibility Testing the score was 55%.