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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D0310629 | (X3) Date Survey Completed 09/17/2021 |
| Name of Provider or Supplier State Of Franklin Healthcare | Street Address, City, State 215 East Springbrook Drive, Johnson City, TN | |
| 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: ===== Virology: The laboratory failed to maintain satisfactory participation in two out of three events for the Herpes Simplex Virus (HSV) analyte resulting in the initial unsuccessful proficiency testing (PT) occurrence for HSV. (Refer to D2064) =====</p> |
| D2064 | <p>VIROLOGY CFR(s): 493.831(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 a desk review of the CMS CASPER Report 0155D and the laboratory's 2020/2021 Proficiency Testing (PT) performance summary records from the American Proficiency Institute(API) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the Herpes Simplex Virus (HSV) analyte in the 3rd event 2020 and 2nd event 2021, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed unsatisfactory HSV analyte scores of 50% for the 3rd event of 2020 and 0% for the 2nd event of 2021. 2. A review of the laboratory's API Proficiency Testing records revealed the 2020 3rd event had unacceptable performance for HSV resulting in a 50% score. 3. A review of the laboratory's API Proficiency Testing records revealed the 2021 2nd event had unacceptable performance for HSV resulting in a 0% score, resulting in the initial unsuccessful PT occurrence. =====