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|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>06D0518456 | <b>(X3) Date Survey Completed</b><br><br>09/28/2022 |
| <b>Name of Provider or Supplier</b><br><br>Southeast Colorado Hospital District                                            | <b>Street Address, City, State</b><br><br>373 E 10th Ave, Springfield, CO  |                                                     |
| 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<br/>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:<br/>Based on a routine desk review of the CMS-155 report for proficiency testing performance and an interview with the laboratory manager, the laboratory failed to achieve satisfactory performance scores for compatibility testing for two out of three events in 2022. Event 1 and Event 2). See D2181.</p> |
| D2181              | <p>COMPATIBILITY TESTING<br/>CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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 proficiency testing scores from the American Proficiency Institute (API) and an interview with the laboratory manager, the laboratory failed to achieve a score of 100% for compatibility testing for Events 1 and 2 in 2022. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 9/25/2022, at 1:00 PM, revealed the compatibility testing scores for 2022 Event 1 and 2 were both 80%. 2. An interview with laboratory manager on 09/23/2022, at 2:50 PM, confirmed two consecutive unsuccessful proficiency scores for compatibility testing due to clerical and laboratory errors.