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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D1022232 | (X3) Date Survey Completed 07/01/2019 |
| Name of Provider or Supplier Southeast Michigan Surgical Hospital | Street Address, City, State 21230 Dequindre, Warren, MI | |
| 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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined that the laboratory failed to successfully participate in a CMS approved proficiency testing program for the routine chemistry analytes pH blood gas, PO2 blood gas, and PCO2 blood gas. Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for three of five proficiency testing events for the routine chemistry analytes: pH blood gas, PO2 blood gas, and PCO2 blood gas. Refer to D2089 and D2096</p> |

D2089

ROUTINE CHEMISTRY

CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the routine chemistry analytes pH blood gas, PO2 blood gas, and PCO2 blood gas. Findings include: Unsatisfactory performance and results in a score of 0 for two consecutive proficiency testing events for routine chemistry: Routine Chemistry PT event Score 3rd event 2018 0% 1st event 2019 0% pH Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0% PO2 Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0% PCO2 Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0%

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in 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 CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the routine chemistry analytes pH blood gas, PO2 blood gas, and PCO2 blood gas. Findings include: Unsatisfactory performance for two of three consecutive proficiency testing events constituting unsuccessful performance for routine chemistry: Routine Chemistry PT event Score 3rd event 2018 0% 1st event 2019 0% pH Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0% PO2 Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0% PCO2 Blood Gas PT event Score 3rd event 2018 0% 1st event 2019 0%