

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521144	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier St Mary's Health	Street Address, City, State 701 Lewiston St, Cottonwood, ID	
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
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 Proficiency Testing (PT) desk review of graded PT results from the American Proficiency Institute (API) and an interview with the laboratory manager on 12/6/2022, the laboratory failed to successfully participate in PT for the analyte digoxin for one event in 2019 and two (2) consecutive testing events in 2020 and 2022. See D2118</p>
D2118	<p>TOXICOLOGY CFR(s): 493.845(f)</p>

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 a proficiency testing (PT) desk review of graded PT results from the American Proficiency Institute (API) and an interview with the laboratory manager on 12/6/2022, the laboratory failed to achieve an overall score of satisfactory performance for two (2) consecutive testing events for the analyte digoxin in 2022. The findings include: 1. A PT desk review of graded PT results from API identified that the laboratory failed to achieve satisfactory results for the following analyte: Analyte Year Event Score Digoxin 2019 3 40% Digoxin 2020 1 0% Digoxin 2020 2 60% Digoxin 2022 2 40% Digoxin 2022 3 20%. 2. A rolling review of the laboratory's graded PT results from API identified the subsequent occurrence of unsuccessful PT participation for the analyte digoxin in 2019 event three (40%), and in 2020 for events one (0%) and two (60%) for which the laboratory submitted an allegation of compliance (AOC) on 8/30/2020 which resulted in the reinstatement of testing of the analyte digoxin on 3/31/2021. 3. A PT desk review performed on 1/24/2023 identified the additional subsequent occurrence of unsuccessful PT participation for the analyte digoxin in 2022 for event two (40%) and event three (20%). 4. An interview with the laboratory manager on 12/6/2022 at 2:30 pm confirmed the PT failures for digoxin in 2019, 2020 and 2022.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on a Proficiency Testing (PT) desk review of graded PT results from the American Proficiency Institute (API), the subsequent occurrence of unsuccessful participation for the analyte digoxin (event 3 in 2019, event 1 and 2 in 2020), the corresponding allegation of compliance (AOC) and evidence of compliance (EOC) which provided the basis for reinstatement of testing on 3/31/2021 for the analyte digoxin, the laboratory director failed to ensure the plan of remedial action, training, or technical assistance was successful from previous proficiency testing failures and sanction for the analyte digoxin to ensure that the laboratory maintained successful participation for the analyte digoxin for two (2) consecutive proficiency testing events in 2022. See D6092

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on a Proficiency Testing (PT) desk review of graded PT results from the

American Proficiency Institute (API) and the previous limitation on testing for the analyte digoxin for the subsequent occurrence of unsuccessful participation dated 8/31/2020, the laboratory director failed to ensure that the laboratory maintained successful PT participation for the analyte digoxin. The findings include: 1. A rolling review of the laboratory's graded PT results from API identified that the laboratory director failed to ensure that the laboratory maintained successful PT participation for the analyte digoxin for event three in 2019, events one and two in 2020 and events two and three in 2022. 2. The laboratory submitted an allegation of compliance (AOC) for the subsequent unsuccessful PT participation for digoxin (event three in 2019 and events one and two in 2020) on 8/30/2020 which was accepted on 8/31/2020 and resulted in the reinstatement of testing of the analyte digoxin on 3/31/2021. 3. A PT desk review on 1/24/2023 revealed the additional subsequent occurrence of unsuccessful PT participation for the analyte digoxin in 2022 for event two (40%) and event three (20%) which identified that laboratory director failed to ensure that the plan of remedial action, training, or technical assistance was successful from the previous proficiency testing failures for the analyte digoxin in 2022. 4. An interview with the laboratory manager on 12/6/2022 at 2:30 pm confirmed the failure to achieve a satisfactory score for the analyte digoxin for event three in 2019, events one and two in 2020 and events two and three in 2022.