

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652515	(X3) Date Survey Completed 10/21/2018
Name of Provider or Supplier Logan Health Shelby	Street Address, City, State 640 Park Ave, Shelby, MT	
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
D0000	Based on an off-site proficiency testing desk review conducted on 10/22/18, deficiencies were cited for Marias Medical Center in Shelby, MT.
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 routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for theophylline and an overall score for toxicology for two of three events (2018 event 1 and 2018 event 3), resulting in unsuccessful proficiency testing performance. See D2118 and D2119.</p>

D2118

TOXICOLOGY

CFR(s): 493.845(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 proficiency testing scores and interview, the laboratory failed to achieve a score of 80 percent for theophylline in two of three events in 2018, resulting in unsuccessful performance. The findings include: 1. On 10/8/18 at 3:24 p.m., the laboratory manager emailed regarding the failed submission of proficiency testing results. 2. During a review on 10/22/18 at 8:30 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Marias Medical Center with unsuccessful proficiency testing scores for theophylline. 3. During a review on 10/22/18 at 8:36 a.m. of the CMS-155 report, the American Proficiency Institute (API) theophylline score for event 1 of 2018 was 20%. 4. During a review on 10/22/18 at 8:36 a.m. of the CMS-155 report, the API theophylline score for event 3 of 2018 was 0%.

D2119

TOXICOLOGY

CFR(s): 493.845(g)

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 proficiency testing scores and interview, the laboratory failed to achieve a score of 80 percent for toxicology in two of three events in 2018, resulting in unsuccessful performance. The findings include: 1. On 10/8/18 at 3:24 p.m., the laboratory manager emailed regarding the failed submission of proficiency testing results. 2. During a review on 10/22/18 at 8:30 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Marias Medical Center with unsuccessful proficiency testing scores for toxicology. 3. During a review on 10/22/18 at 8:36 a.m. of the CMS-155 report, the API toxicology score for event 1 of 2018 was 73%. 4. During a review on 10/22/18 at 8:36 a.m. of the CMS-155 report, the API toxicology score for event 3 of 2018 was 0%.