

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0899072	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Mitchell Medical Center	Street Address, City, State 1209 10th Street, Port Huron, 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
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 record review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the chemistry analyte uric acid. Findings include: The laboratory failed to attain a score of at least 80% of acceptable responses for the chemistry analyte uric acid, which is unsatisfactory performance. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the chemistry analyte uric acid in 2 (2nd event of 2022 and 3rd event of 2020) of 2 consecutive testing events. Findings include: 1. A review of the CMS database and the API proficiency testing reports revealed the laboratory had unsatisfactory performance for 2 of 2 consecutive proficiency testing events constituting unsuccessful performance for the chemistry analyte uric acid: PT Event Score 2nd event 2020 60% 3rd event 2020 60%