

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405516	(X3) Date Survey Completed 04/01/2022
Name of Provider or Supplier Madison Healthcare Services	Street Address, City, State 900 2nd Ave, Madison, MN	
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 review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing (PT) in 2022 for Partial Pressure of Oxygen (PO2) under the specialty of Chemistry. Findings include: 1. The CASPER Report 0155D, reviewed on April 1, 2022, indicated the the laboratory failed to successfully participate in PO2 PT in 2022. Unsatisfactory PT performance in PO2 testing was obtained in the following events as verified with API proficiency testing</p>

reports. -2021 2nd event 60% -2022 1st event 60% See D2087. 2. The CASPER Report 0155D indicated the laboratory failed to obtain a PO2 PT score of at least 80 percent in two out of three consecutive testing events in 2021 and 2022. See D2096. .

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to attain satisfactory PT scores for Partial Pressure of Oxygen (PO2) testing. Findings are as follows: 1. The laboratory failed to attain PT scores for PO2 testing of at least 80 percent in one event in 2021 and one event in 2022. Scores less than 80 percent resulted in unsatisfactory performance for the analyte. 2. API PT reports listed the following unsatisfactory PO2 scores. - 2021 2nd event: 60% - 2022 1st event: 60% .

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 a review of Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to achieve successful PT performance for Partial Pressure of Oxygen (PO2) testing. Findings are as follows: 1. The laboratory failed to attain satisfactory PO2 PT scores in two out of three consecutive PT events. Two out of three consecutive unsatisfactory PT scores for the same analyte constituted unsuccessful performance. 2. API PT reports listed the following unsatisfactory PO2 scores. - 2021 2nd event: 60% - 2022 1st event: 60%