

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382707	(X3) Date Survey Completed 04/14/2023
Name of Provider or Supplier Wayne County Hospital	Street Address, City, State 417 South East Street, Corydon, IA	
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 review of proficiency records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 4/14/2023, the laboratory failed to successfully participate in a proficiency testing program for the analyte, albumin for two consecutive proficiency testing events: 2022 event 3 and 2023 event 1 (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 proficiency records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 4/14/2023, the laboratory failed to achieve satisfactory performance for the analyte, albumin, for two consecutive testing events for unsuccessful participation. The laboratory received unsatisfactory performance scores of 60% for 2022 testing event 3 and 2023 testing event 1.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of coagulation quality control (QC) records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 4/14/2023, the laboratory failed to document corrective action when the coagulation controls fell outside the established ranges for seven out of 32 time periods from 11/1/2022 - 11/29/2022. The findings include: 1. Testing personnel identifier #1 confirmed the laboratory performed coagulation QC every 8 hours that the laboratory performed Prothrombin time (PT) and/or Partial Thromboplastin Time (PTT) testing. 2. The laboratory established the following coagulation ranges: *PT control level 1: 9.5 - 11.6 seconds *PTT control level 1: 23.9 - 28.0 seconds *PT control level 3: 42.1 - 51.2 seconds *PTT control level 3: 52.0 - 60.0 seconds 3. At the time of the survey, the laboratory had the following QC outside of the established ranges and did not document corrective action: *11/5/22 at 0700 am: PT control level 1 - 11.8 seconds; PTT control level 3 - 51.9 seconds *11/5/22 at 1636 pm: PTT control level 3 - 51.9 seconds *11/12/22 at 530 am: PT control level 1 - 11.8 seconds *11/12/22 at 2200 pm: PT control level 1 - 12.4 seconds; PTT control level 1 - 29.0 seconds; and PTT control level 3 - 51.2 seconds *11/13/22 at 1900 pm: PT control level 1 - 12.7 seconds *11/21/22 at 0915 am: PTT control level 3 - 51.4 seconds *11/28/22 at 1915 pm: PT control level 3 - 52.5 seconds 4. A total of eight patients had PT and/or PTT testing performed when the controls fell outside the established ranges.