

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628651	(X3) Date Survey Completed 05/06/2024
Name of Provider or Supplier Blue Mountain Hospital	Street Address, City, State 170 Ford Rd, John Day, OR	
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 proficiency testing (PT) desk review of the American Proficiency Institute (API) proficiency testing failure summary results, a review of the CASPER Report 0155D, and a phone interview with the general supervisor/technical supervisor (GS /TS) revealed the laboratory had unsuccessful participation for two (2) out of three (3) testing events for the specialty hematology. Refer to D2127 and D2130.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p>

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) proficiency testing performance summary reports, Casper Report 0155D, and a phone interview with the technical supervisor/general supervisor (TS/GS), the laboratory failed to submit proficiency testing (PT) results on time, resulting in zero scores for the second event of 2023 in hematology. Findings include: 1. API 2nd event 2023. a) Cell ID or WBC Diff = 0% b) Red Blood Cell = 0% c) Hematocrit = 0% d) Hemoglobin = 0% e) White Blood Cell = 0% f) Platelets = 0% 2. Casper Report 0155D. a) Cell ID or WBC Diff = 0% b) Red Blood Cell = 0% c) Hematocrit = 0% d) Hemoglobin = 0% e) White Blood Cell = 0% f) Platelets = 0% 3. A phone interview with the TS/GS on 05/07/2024 @ 10:45 AM confirmed that the laboratory failed to submit the PT results on time to the PT provider.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on Proficiency Testing (PT) desk review of the American Proficiency Institute (API) performance summary results, a review of the Casper report 0155D, and a phone interview with the general supervisor/technical supervisor (GS/TS), the laboratory had unsuccessful performance in two (2) out of three (3) consecutive testing events for the following analytes in Hematology. Findings include. 1. API 2nd event 2023 a) Red Blood Cell - 0% b) Hematocrit- 0% c) Hemoglobin - 0% d) White Blood Cell - 0% e) Platelets - 0% 2. Casper Report 1055D 2nd event 2023 a) Red Blood Cell - 0% b) Hematocrit- 0% c) Hemoglobin - 0% d) White Blood Cell - 0% e) Platelets - 0% 3. API 1st event 2024 a) Red Blood Cell - 60% b) Hematocrit- 40% c) Hemoglobin - 60% d) White Blood Cell - 60% e) Platelets - 60% 4. Casper Report 0155D 1st event 2024 a) Red Blood Cell - 60% b) Hematocrit- 40% c) Hemoglobin - 60% d) White Blood Cell - 60% e) Platelets - 60% 5. A phone interview with the GS /TS on 05/07/2024 at 10:45 AM confirmed these findings.

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 the American Proficiency Institute (API) performance summary results, a review of the Casper report 0155D,

and a phone interview with the general supervisor/technical supervisor (GS/TS), the laboratory director failed to provide overall management and guidance to the laboratory staff, which resulted in multiple PT failures. Refer to D6090 and D6092.

D6090

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

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) proficiency testing performance summary reports, Casper Report 0155D, and a phone interview with the technical supervisor/general supervisor (TS/GS), the laboratory director failed to ensure that proficiency testing (PT) results were submitted on time to the PT provider. Findings include: 1. API 2nd event 2023. a) Cell ID or WBC Diff = 0% b) Red Blood Cell = 0% c) Hematocrit = 0% d) Hemoglobin = 0% e) White Blood Cell = 0% f) Platelets = 0% 2. Casper Report 0155D. a) Cell ID or WBC Diff = 0% b) Red Blood Cell = 0% c) Hematocrit = 0% d) Hemoglobin = 0% e) White Blood Cell = 0% f) Platelets = 0% 3. A phone interview with the TS/GS on 05/07/2024 @ 10:45 AM confirmed that the laboratory failed to submit the PT results on time to the PT provider.

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 review of the American Proficiency Institute (API) performance summary results, a review of the Casper report 0155D, and a phone interview with the general supervisor/technical supervisor (GS/TS), the laboratory director (LD) failed to ensure that an approved corrective action plan was followed. The laboratory director's lack of guidance contributed to unsuccessful performance in two (2) out of three (3) consecutive testing events for the following analytes in Hematology. Findings include. 1. API 2nd event 2023 a) Red Blood Cell - 0% b) Hematocrit- 0% c) Hemoglobin - 0% d) White Blood Cell - 0% e) Platelets - 0% 2. Casper Report 1055D 2nd event 2023 a) Red Blood Cell - 0% b) Hematocrit- 0% c) Hemoglobin - 0% d) White Blood Cell - 0% e) Platelets - 0% 3. API 1st event 2024 a) Red Blood Cell - 60% b) Hematocrit- 40% c) Hemoglobin - 60% d) White Blood Cell - 60% e) Platelets - 60% 4. Casper Report 0155D 1st event 2024 a) Red Blood Cell - 60% b) Hematocrit- 40% c) Hemoglobin - 60% d) White Blood Cell - 60% e) Platelets - 60% 5. A phone interview with the GS/TS on 05/07/2024 at 10:45 AM confirmed these findings.