

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0671650	<b>(X3) Date Survey Completed</b> 09/17/2024
<b>Name of Provider or Supplier</b> Good Shepherd Health Care System	<b>Street Address, City, State</b> 610 Nw 11th St, Hermiston, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 College of American Pathologists (CAP) proficiency testing results, review of the Casper Report 0155D , and phone conversation with the technical supervisor (TS) revealed the laboratory had unsuccessful participation for two (2) out of three (3) consecutive testing event for the specialty immunohematology. Refer to D2163.</p>
<b>D2163</b>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(g)</p>

Failure to achieve an overall testing event score of satisfactory 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 Proficiency Testing (PT) desk review of the College of American Pathologist (CAP) performance summary results, review of the Casper report 0155D, and phone interview with the technical supervisor (TS), the laboratory had unsuccessful performance in two (2) consecutive testing events for the following analytes in immunohematology in 2023 and 2024. Findings include. 1. CAP 2nd event 2023 ABO/RHO = 90% 2. CAP 2nd event 2024 ABO/RHO = 90% 3. Casper Report 1055D 2nd event 2023 ABO/RHO = 90% 4. Casper Report 0155D 2nd event 2024 ABO/RHO = 90% 5. Phone interview with the TS on 09/17/2024 at 10:30 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 proficiency testing(PT) desk review of the College of American Pathologist (CAP) proficiency testing results, review of the Casper Report 0155D, and phone conversation with the technical supervisor (TS) revealed the laboratory director failed to provide overall management and direction to the laboratory. Refer to D6092.

**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 Proficiency Testing (PT) desk review of the College of American Pathologist (CAP) performance summary results, review of the Casper report 0155D, and phone interview with the technical supervisor (TS), the laboratory director failed to provide guidance to the laboratory that resulted to having unsuccessful performance in two (2) consecutive testing events for the following analytes in immunohematology in 2023 and 2024. Findings include. 1. CAP 2nd event 2023 ABO/RHO = 90% 2. CAP 2nd event 2024 ABO/RHO = 90% 3. Casper Report 1055D 2nd event 2023 ABO/RHO = 90% 4. Casper Report 0155D 2nd event 2024 ABO/RHO = 90% 5. Phone interview with the TS on 09/17/2024 at 10:30 AM confirmed these findings.