

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D2272556	<b>(X3) Date Survey Completed</b> 04/08/2024
<b>Name of Provider or Supplier</b> Women's Health Center Of Southern Oregon	<b>Street Address, City, State</b> 595 N Main St, Ste 1, Ashland, 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 American Proficiency Institute (API) proficiency testing failure summary 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) testing events for the specialty bacteriology. Refer to D2028.</p>
<b>D2028</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</p>

Failure to achieve an overall testing event score of satisfactory performance 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 American Proficiency Institute (API) proficiency testing failure summary 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) testing events for the specialty bacteriology. Findings include: 1. Review of the API failures summary revealed, a) Bacteriology 2nd event 2023 = 60% b) Bacteriology 1st event 2024 = 0% 2. Casper reports 0155D revealed, a) Bacteriology 2nd event 2023 = 60% b) Bacteriology 1st event 2024 = 0% 3. Telephone interview with the TS on 04/08/2024 at 14:00 pm confirmed, the laboratory failed 2 out of 3 testing events in bacteriology.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on proficiency testing (PT) desk review of the American Proficiency Institute (API) proficiency testing failures summary results, review of the CASPER Report 0155D, and phone conversation with the technical supervisor (TS), the laboratory director (LD) failed to provide overall management and direction to the laboratory. Refer to D6018.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) desk review of the American Proficiency Institute (API) proficiency testing failure summary results, review of the CASPER Report 0155D, and phone conversation with the technical supervisor (TS) revealed the laboratory director failed to provide proper guidance that resulted in unsuccessful participation for two (2) out of three (3) testing events for the specialty bacteriology. Findings include: 1. Review of the API failures summary revealed, a) Bacteriology 2nd event 2023 = 60% b) Bacteriology 1st event 2024 = 0% 2. Casper reports 0155D

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3. Telephone interview with the TS on 04/08/2024 at 14:00 pm confirmed, the laboratory failed 2 out of 3 testing events in bacteriology.