

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0627519	(X3) Date Survey Completed 07/15/2024
Name of Provider or Supplier Oregon Medical Group Center For Women	Street Address, City, State 330 S Garden Way Suite 220, Eugene, 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 Wisconsin State Laboratory of Hygiene (WSLH) 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 consecutive testing event for the specialty endocrinology. Refer to D2107.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(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 proficiency testing(PT) desk review of the Wisconsin State Laboratory of Hygiene (WSLH) 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) consecutive events for the analyte human chorionic gonadotropin (HCG). Findings include. 1. Review of the WSLH PT revealed. a. 3rd Event 2023 HCG = 20% b. 1st Event 2024 HCG = 0% 2. Review of the Casper report 0155D revealed. a. 3rd event 2023 HCG = 20% b. 1st event 2024 HCG = 0% 3. Phone conversation with the TS on 07/16/2024 at 15:20 PM confirmed these findings

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 Wisconsin State Laboratory of Hygiene (WSLH) 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 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 Wisconsin State Laboratory of Hygiene (WSLH) 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) consecutive events for the analyte human chorionic gonadotropin (HCG). Findings include. 1. Review of the WSLH PT revealed. a. 3rd Event 2023 HCG = 20% b. 1st Event 2024 HCG = 0% 2. Review of the Casper report 0155D revealed. a. 3rd event 2023 HCG = 20% b. 1st event 2024 HCG = 0% 3. Phone conversation with the TS on 07/16/2024 at 15:20 PM confirmed these findings