

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0627519	(X3) Date Survey Completed 09/17/2024
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
D0000	A proficiency testing desk review was completed on September 17, 2024. At the time of review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies cited: D2016 - 42 CFR 493.803 Condition: Successful Participation D6000 - 42 CFR 493.1403 Condition: Moderate Complexity Laboratory Director
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 failure summary results, review of the CASPER</p>

	<p>Report 0155D, and phone conversation with the technical consultant (TC), revealed the laboratory had unsuccessful participation for three (3) consecutive testing events for the subspecialty of Endocrinology. Refer to D2100 & D2107.</p>
<p>D2100</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>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 consultant (TC), revealed the laboratory failed to participate in two (2) consecutive events resulting in zero score for the 1st and 2nd event of 2024 in subspecialty of Endocrinology. Findings includes: 1. Review of WSLH PT revealed 1st and 2nd events 2024. a. Endocrinology = 0% b. Human Chorionic gonadotropin (HCG) = 0% 2.. Review of Casper Report 0155D 1st and 2nd events 2024 a. Endocrinology = 0% b. HCG = 0% 3. Phone conversation with the TC on 09/17/2024 at 11:06 AM confirmed these findings.</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <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.</p> <p>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 consultant (TC), revealed the laboratory had unsuccessful participation for three (3) consecutive events for the analyte human chorionic gonadotropin (HCG) in subspecialty of Endocrinology. Findings include. 1. Review of the WSLH PT revealed. a. 3rd Event 2023 HCG = 20% b. 1st Event 2024 HCG = 0% c. 2nd event 2024 HCG = 0% 2. Review of the Casper report 0155D revealed. a. 3rd event 2023 HCG = 20% b. 1st event 2024 HCG = 0% c. 2nd event 2024 HCG = 0% 3. Phone conversation with the TC on 09/17/2024 at 11:06 AM confirmed these findings</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

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 consultant (TC), revealed the laboratory director failed to provide overall management and direction to the laboratory. Refer to D6016 & D6017.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

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 consultant (TC) revealed, the laboratory director (LD) failed to ensure the laboratory had successful participation in an HHS approved proficiency testing program on three (3) consecutive events for the analyte human chorionic gonadotropin (HCG) in subspecialty of Endocrinology. Findings include. 1. Review of the WSLH PT revealed. a. 3rd Event 2023 HCG = 20% b. 1st Event 2024 HCG = 0% c. 2nd event 2024 HCG = 0% 2. Review of the Casper report 0155D revealed. a. 3rd event 2023 HCG = 20% b. 1st event 2024 HCG = 0% c. 2nd event 2024 HCG = 0% 3. Phone conversation with the TC on 09/17/2024 at 11:06 AM confirmed the LD failed to ensure the laboratory had successful proficiency testing participation.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing performance summary reports, and Casper Report 0155D, and phone interview with the technical consultant (TC), the laboratory director (LD) failed to ensure the laboratory participated and submitted the proficiency testing (PT) results on time to the their proficiency testing provider which resulted in zero scores for the 1st and 2nd

event of 2024 in Endocrinology.. Findings include: 1. Review of WSLH PT revealed 1st and 2nd event 2024. a. Endocrinology = 0% b. Human Chorionic Gonadotropin(HCG) = 0% 2. Review of Casper Report 0155 D 1st and 2nd events 2024 a. Endocrinology = 0% b. HCG = 0% 3. Phone conversation with the TC on 09/17/2024 @ 11:06 AM confirmed that the laboratory director failed to ensure the laboratory participated and submitted the PT results on time to the PT provider.