

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2120851	(X3) Date Survey Completed 07/15/2024
Name of Provider or Supplier Complete Integrative Care	Street Address, City, State 3156 State Street, Medford, 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, review of the CASPER Report 0155D, and email from the laboratory director (LD) revealed the laboratory had unsuccessful participation for three (3) consecutive testing events for the specialty chemistry. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 American Proficiency Institute (API) proficiency testing, CASPER Report 0155D, and email from the laboratory director (LD,) revealed the laboratory had unsuccessful participation for three (3) consecutive testing events for the analyte sodium. Findings include: 1. Review of the API summary report PT revealed. a. 3rd event 2023 Sodium = 60% b. 1st event 2024 Sodium = 40% c. 2nd event 2024 Sodium = 40% 2. Review of the Casper Report 0155D revealed a. 3rd event 2023 Sodium = 60% b. 1st event 2024 Sodium = 40%. c. 2nd event 2024 Sodium = 40% 3. Email threads from the LD on 07/02/2024 at 4:47 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 American Proficiency Institute (API) proficiency testing failures summary results, review of the CASPER Report 0155D, and email from the laboratory director (LD) , the LD failed to provide overall management and direction to the laboratory. Refer to D6019.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on proficiency testing(PT) desk review of the American Proficiency Institute (API) proficiency testing comparative evaluation results, review of the Casper report 0155D, and email from the laboratory director(LD), the LD failed to implement an approve corrective action plan to the laboratory which resulted in unsuccessful participation for three(3) consecutive events for the analyte sodium. Findings include. 1. Review of the API comparative evaluation results revealed. a. 3rd event 2023 sodium = 60% b. 1st event 2024 sodium = 40% c. 2nd event 2024 sodium = 40% 2. Review of the Casper Report 0155D revealed. a. 3rd event 2023 sodium = 60% b. 1st event 2024 sodium = 40% c. 2nd event 2024 sodium = 40% 3. Email from the LD on 07/02/2024 at 4:47 PM confirmed these findings.