

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628274	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Summit Health City Md	Street Address, City, State 1501 Ne Medical Center Dr, Bend, 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 comparative evaluation results, review of the CASPER Report 0155D, and phone conversation with the technical supervisor (TS) revealed the laboratory had unsuccessful participation for three (3) out of four (4) testing events for the specialty toxicology for the analyte digoxin. Refer to D2118.</p>
D2118	<p>TOXICOLOGY CFR(s): 493.845(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 comparative evaluation results, review of the CASPER Report 0155D, and phone conversation with the technical supervisor (TS) revealed the laboratory had unsuccessful participation for three (3) out of four (4) testing events for the analyte digoxin. Findings include. 1. Review of the API comparative evaluation results revealed a) 1st event 2023 digoxin 60% , b) 3rd event 2023 digoxin 60% c) 1st event 2024 digoxin 60% 2. Review of the Casper Report 0155D a) 1st event 2023 digoxin 60% b) 3rd event 2023 digoxin 60% c) 1st event 2024 digoxin 60% 3. Phone conversation with the TS confirmed these findings on 03/07/2024 at 3:13 PM.

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 comparative evaluation 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 which resulted to three (3) out four (4) PT event failures. 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 phone conversation with the technical supervisor (TS), the laboratory director (LD) failed to implement an approved corrective action plan to the laboratory which resulted in unsuccessful participation for three (3) out of four (4) testing events for the analyte digoxin. Findings include. 1. Review of the API comparative evaluation results revealed a) 1st event 2023 digoxin 60% , b) 3rd event 2023 digoxin 60% c) 1st event 2024 digoxin 60% 2. Review of the Casper Report

0155D a) 1st event 2023 digoxin 60% b) 3rd event 2023 digoxin 60% c) 1st event 2024 digoxin 60% 3. Phone conversation with the TS confirmed these findings on 03/07/2024 at 3:13 PM.