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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 38D0933088 | (X3) Date Survey Completed 12/30/2024 |
| Name of Provider or Supplier Umpqua Medical Pc | Street Address, City, State 1813 W Harvard Ave Suite 436, Roseburg, 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 results, review of the Casper Report 0155D , and phone interview with the front office manager revealed the laboratory had unsuccessful participation for two consecutive testing event for the specialty hematology. Refer to D2127 and D2130.</p> |
| D2127 | <p>HEMATOLOGY CFR(s): 493.851(d)</p> |

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) reports, and Casper Report 0155D, and phone interview with the front office manager, the laboratory failed to run and submit proficiency testing (PT) that resulted to a zero score for the 2nd event of 2024 in hematology. Findings include: 1. API 2nd event 2024. a) Platelet = 0% 2. Casper Report 0155D. a) Platelet = 0% 3. Phone interview with the front office manager on 01/08/2024 @ 12:36 PM confirmed that the laboratory failed to run PT samples and unable to submit the PT results to the PT provider.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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) results, review of the Casper report 0155D, and phone interview with the front office manager, the laboratory had unsuccessful performance in two (2) consecutive testing events for the following analyte in hematology in 2024. Findings include. 1. API 2nd event 2024 a) Platelet = 0% 2. API 3rd event 2024 a) Platelet = 60% 3. Casper Report 1055D 2nd event 2024 a) Platelet = 0% 4. Casper Report 0155D 3rd event 2024 a) Platelet = 60% 5. Phone interview with the front office manager on 01/08/2024 @ 12:36 PM confirmed that the laboratory failed to run PT samples and unable to submit the PT results to the PT provider.

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 results, review of the Casper Report 0155D, and phone interview with the front office manager revealed the laboratory director (LD) failed to provide overall management and direction to the laboratory. Refer to D6017 & D6018.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

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

(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 American Proficiency Institute (API) proficiency testing reports, and Casper Report 0155D, and phone interview with the front office manager, the laboratory director failed to ensure that PT results were run and submitted on time to the PT providers. Findings includes: 1. API 2nd event 2024. a) Platelet = 0%. 2. Casper Report 0155D 2nd event 2024. a) Platelet = 0% 3. Phone interview with the front office manager on 01/08/2024 @ 12:36 PM confirmed that the laboratory director failed ensure that PT samples were run and results were submitted on time to the PT provider.

D6018

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

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) desk review of the American Proficiency Institute (API) performance summary results, review of the Casper Report 0155D, and phone interview with the front office manager, the laboratory director failed to evaluate the laboratory's PT performance and failed to identify any problems that require corrective action which resulted to having unsuccessful performance in two (2) consecutive testing events for the analyte in hematology in 2024. Finding includes: 1. API 2nd event 2024. a) Platelets = 0% 2. AP 3rd event 2024. a) Platelets = 60% 3. Casper Report 0155D 2nd event 2024. a) Platelets = 0% 4. Casper Report 0155D 3rd event 2024. a) Platelets = 60% 5. Phone interview with the front office manager on 01/08/2024 @ 12:36 PM confirmed that the laboratory director failed to evaluate the laboratory's PT that require corrective actions.