

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2126621	(X3) Date Survey Completed 09/08/2023
Name of Provider or Supplier Mat-Su Urgent Care	Street Address, City, State 209 W Evergreen Ave, Ste B, Palmer, AK	
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 a review of the Proficiency Testing (PT) data report (CASPER report 155), graded results from the American Proficiency Institute (API), and an interview with the Technical Consultant, the laboratory failed to successfully participate in the White Blood Cell (WBC) Differential PT analytes which include Basophils, Eosinophils, Lymphocytes, Monocytes, and Neutrophils. The laboratory had unsatisfactory scores for the third event in 2022, the first event in 2023, and the second event in 2023. See D2130</p>
D2130	HEMATOLOGY

CFR(s): 493.851(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 a review of the Proficiency Testing (PT) data report (CASPER report 155), graded results from American Proficiency Institute (API), and an interview with the Technical Consultant (TC) on 09/06/2023, the laboratory failed to achieve an overall score of satisfactory performance for three consecutive tests events which include analytes Basophils, Eosinophils, Lymphocytes, Monocytes, and Neutrophils included in the White Blood Cell (WBC) Differential in 2023. Findings include: 1. A PT desk review of graded PT results from API identified that the laboratory failed to achieve satisfactory scores for the following tests: Test Year Event Score WBC Differential 2022 3 20% WBC Differential 2023 1 0% WBC Differential 2023 2 24% 2. Record review of the laboratory's graded PT scores from API identified the initial occurrence of unsuccessful PT participation for WBC differential 2022 event 3 (20%) and 2023 for event one (0%), for which the laboratory submitted an allegation of compliance (AOC) on 05/24/2023 which resulted in the reinstatement of testing of the WBC differential on 05/25/2023. Test Year Event Score WBC Differential 2022 3 20% WBC Differential 2023 1 0% 3. A Review of the laboratory's 2023 graded PT scores from API identified that the laboratory failed to achieve satisfactory results after the first unsuccessful performance resulting in a subsequent unsuccessful for the the WBC Differential 2023 event 2 (24%) Test Year Event Score WBC Differential 2023 2 24% 4. A phone interview with the TC on September 6, 2023, at 1:30 PM confirmed the laboratory failed to achieve a satisfactory score for the White Blood Cell (WBC) Differential for the third event in 2022 and events one and two in 2023.

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 the severity of the deficiency cited herein, the Condition: Laboratories Performing Moderate Complexity testing - Laboratory Director was not met, the laboratory director failed to ensure the plan of remedial action, training, or technical assistance was successful following initial occurrence of unsuccessful PT participation for the analytes Basophils, Eosinophils, Lymphocytes, Monocytes, and Neutrophils included in the White Blood Cell (WBC) Differential. See 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 a Proficiency Testing (PT) desk review of graded PT results from the American Proficiency Institute (API), the subsequent occurrence of unsuccessful participation for the analytes Basophils, Eosinophils, Lymphocytes, Monocytes, and Neutrophils included in the White Blood Cell Differential (WBC) (event 3 in 20202, events 1 and 2 in 2023), the corresponding allegation of compliance (AOC) and evidence of compliance (EOC) which provided the basis for reinstatement of testing on 05/24/2023 for the analytes in the WBC Differential, the laboratory director failed to ensure the plan of remedial action, training, or technical assistance was successful from previous proficiency testing failures and sanction for the analytes in the WBC differential to ensure that the laboratory maintained successful participation for the analytes in the WBC Differential for two (2) consecutive proficiency testing events in 2023. See 2130