

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>05D1067205</p>	<p>(X3) Date Survey Completed</p> <p>08/28/2024</p>
<p>Name of Provider or Supplier</p> <p>Palo Alto Medical Foundation For Health,</p>	<p>Street Address, City, State</p> <p>701 E El Camino Real, 2nd Fl, Mountain View, CA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D2020</p>	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: . Based on review of patients tests results, proficiency testing reports for Event 3, 2023, from CMS/CLIA (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists, report VS-C 2023 Vaginitis Screen), and interview with Technical Consultant-2, it was determined the laboratory had unsatisfactory testing in Microbiology by failing to attain an overall testing event score of at least 80%. Findings included: a. The laboratory utilized the BD Affirm VPIII test system for Candida, Gardnerella, and Trichomonas and reported patients results, as follows: Date ID Result reported ----- 9/01/23 F1199102 Neg 9/02/23 S7224130 Neg 9/13/23 W1268733 Pos: Gardnerella 9/20/23 W1311094 Pos: Gardnerella and Candida 9/25/23 M1288297 Pos: Gardnerella 10/06/23 F1381224 Neg b. For Event 3, 2023: CMS and CAP reported the unsatisfactory score of 33% for testing in Microbiology due to the laboratory's 4 out of 5 results for Gardnerella graded as Unacceptable (*), as follows: PT Sample Laboratory CAP ID Reported Intended ----- VS-11PositivePositive VS-12Positive*.....Negative VS-13Positive*.....Negative VS-14 Positive*.....Negative VS-15Positive*.....Negative c. Technical Consultant-2 affirmed (8/28/24 at 5:00 PM) the aforementioned findings. d. And thus, the laboratory's testing for Gardnerella was unsatisfactory. The reliability and quality of results reported for the aforementioned patients could not be assured by the proficiency testing. e. The laboratory tested 970 patients specimens in the timeframe September 2023 to October 2023. The reliability and quality of results reported could not be assured. .</p>

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on observation of the equipment, review of laboratory documents, proficiency test reports, and patients test reports; and interview with Technical Consultant-2, it was determined the laboratory failed to verify the accuracy of testing for Platelet Function, GGT (Gamma Glutamyl Transferase), and Semen Analysis. Findings included: a. The laboratory reported testing for Platelet Function, GGT, and Semen Analysis (CMS116 CLIA Application, 8/14/24; LAB144A, Laboratory Testing Declaration, 8/14/24). b. The laboratory chose to enroll in proficiency testing with CAP as the means to fulfill the requirement to at least twice annually verify the accuracy of testing for Platelet Function and GGT. 1. The laboratory performed the Platelet Function Assay by utilizing Siemens PFA100 analyzer (serial number 3883). i. For Event 2, 2021: PF-1-B 2021 Platelet Function (Kit mailed 11/6/23; original evaluation 12/05/23), CAP reported the laboratory's results as "Code 11, Unable to analyze". ii. The laboratory was unable to provide for this CLIA survey records documenting alternate means of verifying the accuracy of the PFA at least one other time in 2021. iii. Technical Consultant-2 affirmed (8/28/24 at 4:00 PM) the aforementioned findings; and thus, the laboratory's failure to verify the accuracy of the PFA at least twice in 2021. iv. The laboratory tested and reported results for patients specimen in 2021, including the following selected at random for this CLIA survey. The reliability and quality of results reported could not be assured in the absence of proficiency testing at least twice annually: Date Accession number ----- 3/16/21 T6099935 4/06/21 T6217244 5/03/21 M6689088 6/01/21 T6507269 7/02/21 F6795513 v. The reliability and quality of results reported for PFA in 2021 likewise could not be assured. The total number of specimen tested and reported were 77. 2. The laboratory tested for GGT by using Siemens Dimension Vista 500 (serial number DV370402) and Siemens Dimension Vista 1500 (serial number DV350328). i. For Event 2, 2024: C-A 2024 General Chemistry, the laboratory reported 2 Unacceptable results (*) out of 5 for GGT, as follows: PT Sample ID Reported Acceptable range ----- CHM-02 332 * 299 - 327 CHM-05 257 * 231 - 255 ii. Technical Consultant-2 affirmed (8/28/24 at 4:00 PM) the aforementioned findings; and thus, the accuracy of testing for GGT in this first event for 2024 failed to be verified. iii. The laboratory reported results for the following patients specimen selected at random for this survey. The reliability and quality of results reported could not be assured by the unsatisfactory proficiency test: Date Accession number ----- 12/13/23 W1771345 1/12/24 F1928526 2/22/24 H2105366 3/05/24 T2243243 4/20/24 S8057628 iv. The reliability and quality of 268 results reported for GGT during this timeframe, December 2023 until the next Event in April 2024, could not be assured. c. The laboratory chose to enroll in Semen Analysis proficiency testing by AAB/MLE (American Association of Bioanalysts/Medical Laboratory Evaluation) as the means to fulfill the requirement to verify the accuracy of testing. 1. The laboratory tested for Sperm Count and Motility using the automated IVOS II system. i. For Event 1, 2024: AAB/MLE documented the following laboratory reported results as incorrect (*) : Reported Grading range ----- Sperm Count Specimen 248*17.0 - 32.0 Sperm Motility Specimen 149* 4.0 - 2.8 Specimen 2.....31* 3.0 -

2.7 ii. Technical Consultant-2 affirmed (8/28/24 at 4:00 PM) the aforementioned findings; and thus, the accuracy of Semen Analysis, Sperm Count and Motility, in this first event for 2024 failed to be verified. iii. The laboratory reported results for the following patients specimen, which were selected at random for this survey. The reliability and quality of results reported could not be assured by the proficiency testing. Date Accession number ----- 12/04/23
M1679423 1/26/24 F2003510 2/01/24 H1966963 3/16/24 S7940256 4/25/24
H2466981 iv. The reliability and quality of results reported for Sperm Count and Motility during this timeframe until the next Event in April 2024, could not be assured. The laboratory reported Sperm Count and Motility for 198 patients specimen.

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