| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D0232508 | 10/08/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Family Physicians Of Marion | 1020 Terrace Drive - Suite 200, Marion, VA | |

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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Family Physicians of Marion on October 8, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows: |
| **D2014** | TESTING OF PROFICIENCY TESTING SAMPLES<br><br>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, quality assurance check list, PT manufacturer's instructions, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the testing personnel (TP) for four (4) of five (5) events reviewed (survey timeframe of December 13, 2023 to October 8, 2025). Findings include: 1. Review of the CMS 209 personnel form revealed that the Laboratory Director (LD) identified two TP as responsible for performing non-waived hematology Complete Blood Count (CBC) during the review timeframe of 12/13/23-10/08/25. 2. Review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) hematology PT documentation (2024 Events 1-3, 2025 Events 1-2), a total of 5 events, revealed no signed TP attestation statements for the following Hematology modules: 2024 Event 2, 2024 Event 3, 2025 Event 1, 2025 Event 2. 3. Review of the laboratory's PT Event |

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| | quality assurance checklist forms for each of the events outlined above revealed instructions: "Answer Yes or No for the following prompts". The inspector noted that prompt "All testing personnel and lab director have signed the attestation sheet?" was marked as "Yes" for all events. 4. Review of AAB-MLE PT instructions for each of the events outlined above revealed the following instructions, "Be sure to keep the attestation statements printed from your online reporting form. The attestation statements must be signed for each analyte by the analyst performing the procedures and kept in your files for your inspection purposes." 5. The inspector requested to review TP attestation signatures for the 4 events listed above. The documentation was not available for review. 6. An exit interview with the laboratory's two TP on 10/8/25 at 2:00 PM confirmed the above findings. |
| **D2127** | HEMATOLOGY<br>CFR(s): 493.851(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records, and interviews, the laboratory failed to submit hematology PT results resulting in unsatisfactory scores for one (1) of five (5) events reviewed (timeframe of survey: December 13, 2023 through October 8, 2025). Findings include: 1. During a pre-survey review, the CMS CASPER Report 0096D revealed zero percent (0%) scores were reported on 2024 Event 2 for the following speciality and six (6) analytes: 0760 HEMATOLOGY 0765 CELL ID- Automated Diff 0775 RBC - Red Blood Cell Count 0785 HCT - Hematocrit 0795 HGB - Hemoglobin 0805 WBC -White Blood Cell Count 0815 PLT - Platelets 2. Review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT hematology module event results (2024 Events 1-3, 2025 Event 1-2), a total of 5 events, revealed unsatisfactory scores for the following event 2024 Hematology Event 2: PT challenge samples HD 06 through HD10 received 0% scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. AAB-MLE reported "results not submitted to API resulting in score of zero". 3. The inspector inquired regarding corrective action for the event outlined above. The two testing personnel (TP) both stated on 10/08/25 at 12:30 PM, "We were short staffed during the time of that event"; "We failed to get the results submitted on time." The inspector requested to review self grading for the event. No documentation was available for review. 4. An exit interview with the laboratory's two TP on 10/8/25 at 2:00 PM confirmed the above findings. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<br><br>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a pre-survey review of the Center for Medicaid and Medicare Services Survey Summary 0096D report, review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed ensure corrective action/self grade was documented when unsatisfactory PT performance was reported by American Association of Bioanalysts Medical Laboratory Evaluation for one of five hematology events as reviewed during the recertification inspection on 10 /8/25 (survey timeframe 12/13/23 through 10/08/25). Refer to D2127. |