

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0688318	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Millennium Physician Group	Street Address, City, State 11513 N Main St, Jacksonville, FL	
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
D0000	At the time of the announced, onsite recertification survey, Millennium Physician Group was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory failed to review proficiency test scores for 5 of 6 testing events in 2020 and 2021. Findings include: Review of American Proficiency Institute (API) proficiency test records showed the Laboratory Director or designee failed to document review of the 1st and 2nd Hematology testing events in 2020. The Laboratory Director or designee failed to document review of the 1st, 2nd, and 3rd Hematology testing events in 2021. During interview on 2/1/22 at 11:15am, Technical Consultant A confirmed the laboratory did not document review of proficiency test scores for the events listed above. .</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for</p>

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete verification for Complete Blood Count testing on the Medonic hematology analyzer. The findings include: Review of the laboratory's records for performance verification for Complete Blood Counts (CBCs) on the Medonic analyzer showed that the laboratory had not completed the correlation studies. During an interview on 2/1/22 at 10:41 AM, Technical Consultant A confirmed that the laboratory had not performed correlation studies. .

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform calibrations every 6 months on the Medonic Hematology analyzer since the instrument was put in use (October 2020). The findings include: Review of calibration records for the Medonic analyzer showed a calibration was performed on 3/4/21. During an interview on 2/1/22 at 11:40am with Technical Consultant A, it was confirmed the every 6 month calibrations were not performed. .