

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0688318	(X3) Date Survey Completed 01/08/2018
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to perform the testing of proficiency testing samples the same way patient samples are tested for 6 of 6 proficiency testing events reviewed (2016 & 2017). The findings include: The 1/8/18 record review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) events for 2016 and 2017 showed the following: 1. The 2016 1st event for Hematology samples AT-01, AT-02, AT-03, AT-04, AT-05 were tested multiple times. AT-01: 2/26/16 at 11:51 and 12:06. AT-02: 2/26/16 at 11:53 and 12:08. AT-03: 2/26/16 at 11:55 and 12:09. AT-04: 2/26/16 at 11:57 and 12:11. AT-05: 2/26/16 at 11:59 and 12:16. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Lymphocytes, Monocytes, Granulocytes. 2. The 2016 2nd event for Hematology samples AT-06, AT-07, AT-08, AT-09, AT-10 were tested multiple dates and times. AT-06: 6/15/16 at 12:04 and on 6/16/16 at 7:53. AT-07: 6/15/16 at 12:07 and on 6/16/16 at 7:56. AT-08: 6/15/16 at 12:08 and on 6/16/16 at 7:59. AT-09: 6/15/16 at 12:11 and on 6/16/16 at 8:01. AT-10: 6/15/16 at 12:13 and on 6/16/16 at 8:02. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Lymphocytes, Monocytes, Granulocytes. 3. The 2016 3rd event for Hematology samples AT-11, AT-12, AT-13, AT-14, AT-15 were tested multiple dates and times. AT-11: 9/22/16 at 9:56 and on 9/23/16 at 7:42. AT-12: 9/22/16 at 9:58 and on 9/23/16 at 7:44. AT-13: 9/22/16 at 10:01 and on 9/23/16 at 7:47. AT-14: 9/22/16 at 10:09 and on 9/23/16 at 7:48. AT-15: 9/22/16 at 10:13 and on 9/23/16 at 7:50. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV),</p>

Lymphocytes, Monocytes, Granulocytes. 4. The 2017 1st event for Hematology samples AT-01, AT-02, AT-03, AT-04, AT-5 were tested multiple dates and times. AT-01: 2/24/17 at 11:06 and on 2/28/17 at 13:43. AT-02: 2/24/17 at 11:09 and on 2/28/17 at 13:46. AT-03: 2/24/17 at 11:11 and on 2/28/17 at 13:50. AT-04: 2/24/17 at 11:14 and on 2/28/17 at 13:54. AT-05: 2/24/17 at 11:16 and on 2/28/17 at 13:56.. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Lymphocytes, Monocytes, Granulocytes. 5. The 2017 2nd event for Hematology samples AT-06, AT-07, AT-08, AT-09, AT-10 were tested multiple dates and times. AT-06: 6/14/17 at 14:42 and on 6/16/17 at 7:36. AT-07: 6/14/17 at 14:44 and on 6/16/17 at 7:38. AT-08: 6/14/17 at 14:48 and on 6/16/17 at 7:43. AT-09: 6/14/17 at 14:50 and on 6/16/17 at 8:10. AT-10: 6/14/17 at 14:52 and on 6/16/17 at 8:00. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Lymphocytes, Monocytes, Granulocytes. 6. The 2017 3rd event for Hematology samples AT-11, AT-12, AT-13, AT-14, AT-15 were tested multiple dates and times. AT-11: 9/20/17 at 14:48 and on 9/21/17 at 7:30. AT-12: 9/20/17 at 14:52 and on 9/21/17 at 7:31. AT-13: 9/20/17 at 14:54 and on 9/21/17 at 7:33. AT-14: 9/20/17 at 15:02 and on 9/21/17 at 7:35. AT-15: 9/20/17 at 15:04 and on 9/21/17 at 7:37. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Lymphocytes, Monocytes, Granulocytes. During interview on 1/8/18 at 11:15, the testing personnel #1 confirmed the proficiency samples were tested in duplicate, which is not how patient samples are normally tested. .

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure the laboratory testing conducted on patient samples for lipid profile testing met the applicable manufacturer's instructions. The findings include: The record review on 1/8/18 of the test menu showed the laboratory performs lipid testing on the Alere Cholestech LDX instrument. The manufacturer instructions for the lipid profile cassette pulled from the current lot in use showed the instructions were last updated on July 2013. The instructions stated, "The Alere Cholestech LDX System is CLIA waived for fingerstick or venous whole blood unprocessed samples only". The laboratory testing person stated on 1/8/18 at 10:00am that the facility uses patient serum for lipid testing. The testing person provided manufacturer instruction documentation from an unknown date that stated, "The Alere Cholestech LDX System is CLIA waived for fingerstick or venous whole blood unprocessed samples only. If you run serum or plasma on the Alere Cholestech LDX System you will have to comply with the regulations for moderate complexity". At 12:33pm on 1/8/18, the

surveyor contacted Alere Technical Support and spoke with a consultant that confirmed the Alere Cholestech LDX system when used with the Lipid Profile cassette is CLIA waived only and that using serum is not an acceptable specimen for patient testing.