

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2244033	(X3) Date Survey Completed 07/12/2024
Name of Provider or Supplier American Health Ne, Llc	Street Address, City, State 171 Forbes Blvd, Suite 2000, Mansfield, MA	
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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the Laboratory Director (LD) and via telephone with a College of American Pathologist (CAP) representative the laboratory failed to authorize the proficiency testing (PT) program to release to HHS all data required to determine the laboratory's compliance with Subpart H - Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity or Both. Findings include: 1. Record review on 7/12/2024 of the 0096D CLIA Application and Survey Summary Report revealed the 0096D did not contain PT scores for the laboratory. 2. Record review on 7/12/2024 of the laboratory's 2023 and 2024 to date PT result reports revealed the PT result reports did not contain the laboratory's CLIA number. 3. Interview via telephone with a CAP representative on 7/12/2024 at 11:00 AM confirmed the laboratory did not authorize the proficiency testing program to release to HHS the laboratory's PT scores. 4. Staff interview on 7/12/2024 at 11:05 AM with the LD confirmed the above findings. 5. The laboratory performs 8,812 Microbiology, 2,728 Diagnostic Immunology, 684,493 Chemistry and 64,205 Hematology tests annually.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the</p>

laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) was tested using the laboratory's routine methods in the specialty of Hematology. Finding include: 1. Record review on 7/12/2024 of the laboratory's 2023 and 2024 to date College of American Pathologists Hematology FH13 survey PT records revealed,; a. 2023 Event A - 6 testing personnel performed the cell identification on all samples. b. 2023 Event B - 7 testing personnel performed the cell identification on all samples. c. 2023 Event C - 7 testing personnel performed the cell identification on all samples. d. 2024 Event A - 4 testing personnel performed the cell identification on all samples. e. 2024 Event B - 6 testing personnel performed the cell identification on all samples. 2. Record review on 7/12/2024 of the laboratory's 'Complete Blood Count' procedure revealed, the procedure does not say that cell identification is performed by all testing personnel on each patient sample. 3. During staff interview with the Technical Supervisor (TS) on 7/12/2024 at 11:03 AM confirmed the above findings. The TS stated, "All techs do the diff survey and turn results in to me. I take turns deciding which techs results to turn in." 4. The laboratory performs 64,205 tests annually in the specialty of Hematology.