

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0899866	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier Pfizer Global R & D Clinical Pathology Laboratory	Street Address, City, State 100 Eastern Point Rd Bldg 274 Lab 1722, Groton, CT	
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 laboratory failed to perform proficiency testing (PT) samples in the same manner and/or the same number of times times as routine patient samples. Findings include: 1. Record review of the 2018-Event 3 PT records for CGL-C dated 9/7/18 from College of American Pathologists (CAP) for coagulation tests on 1/10/19 revealed five PT samples (CGL-11 through 15) were tested using Diagnostica Stago Compact instrument (SN# 1049173). The same samples were tested twice again on 9/7/18 using Diagnostica Stago Evolution instrument (SN#94055492) before results were submitted to CAP for evaluation. 2. Record review of the 2018-Event 2 PT records for CGL-B dated 6/1/18 from CAP for coagulation tests on 1/10/19 revealed five PT samples (CGL-6 through 10) were tested twice using Diagnostica Stago Evolution instrument (SN#94055492) before results were submitted to CAP for evaluation. 3. Record review of the 2018-Event 2 PT records for CGE-B dated 10/19/18 from CAP for coagulation tests on 1/10/19 revealed two PT samples (CGE-3 and 4) were tested twice using Diagnostica Stago Evolution instrument (SN#94055492) before results were submitted to CAP for evaluation. 4. Record review of the 2018-Event 1 PT records for CGE-A dated 4/12 /18 from CAP for coagulation tests on 1/10/19 revealed two PT samples (CGE-1 and 2) were tested twice using Diagnostica Stago Evolution instrument (SN#94055492) before results were submitted to CAP for evaluation. 5. Record review of the 2018-Event 3 PT records for FH4-C dated 10/5/18 from CAP for complete blood count (CBC) tests on 1/10/19 revealed five PT samples (FH4-11 through 15) were tested using Advia instrument (SN# 34800346). The same samples were also tested on 10/5</p>

/18 using Advia instrument (SN# IR1161829). The same samples were tested again on 10/12/18 using Advia instrument (SN# 34800346) before CBC results from 10/12/18 were submitted to CAP for evaluation. 6. Record review of the 2018-Event 2 PT records for FH4-B dated 6/13/18 from CAP for CBC tests on 1/10/19 revealed five PT samples (FH4-6 through 10) were tested twice using Advia instrument (SN# 34800346) before submitting for evaluation. 7. Record review of the 2018-Event 1 PT records for FH4-A dated 2/7/18 from CAP for CBC tests on 1/10/19 revealed five PT samples (FH4-1 through 5) were tested using Advia instrument (SN# 34800346) and Advia instrument (SN# IR1161829) before submitting for evaluation. 8. Record review of the laboratory's policy for PT (Document# LAB-01-GR-07-SD01: Section 14.1) on 1/10/19 revealed PT samples are to be tested the same number of times as routine patient samples. 9. Staff interview with the laboratory's general supervisor (GS) on 1/10/19 at 11:30 AM confirmed the above findings. The GS further stated only patient samples flagged by the instrument are to be repeated. 10. The laboratory performs 1093 tests annually in the specialty of Hematology.