

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0992000	(X3) Date Survey Completed 09/03/2019
Name of Provider or Supplier Dublin Hematology & Oncology Care Pc	Street Address, City, State 207 Fairview Park Drive - Dublin, Dublin, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on September 3, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute(API) Proficiency testing (PT) documents for Hematology, and staff interview, the laboratory failed to provide signed attestation statements signed by the Laboratory Director (LD). Findings: 1. A review of the API PT documents for 2018 and 2019 Hematology revealed that the LD did not sign attestation statements for the first or second events in 2018. The first and second events for 2019 also failed to include the signature by the laboratory director. 2. Interview with the office manager and staff # 4 (CMS form 209) on September 3, 2019 at approximately 4 pm in the Laboratory, confirmed that the aforementioned attestation documents were not signed by the LD.</p>

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency testing (PT) documents for Hematology, and staff interview the LD failed to sign review statements for PT events in 2018 and 2019. Findings: 1. A review of the 2018 and 2019 API PT documents for Hematology, revealed that the LD did not sign the review statements for the first, second, or third events in 2018 . The laboratory director also failed to sign the review statements in 2019 for the first and second events. 2. An interview with the office manager and staff #4(CMS form 209), on September 3, 2019, at approximately 4 pm in the Laboratory, confirmed that the aforementioned PT review documents were not signed by the LD.