

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2179632	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier O'sullivan Pathology, Pllc	Street Address, City, State 7384 Beulah Church Road, Mechanicsville, VA	
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	An announced CLIA initial survey was conducted at O'Sullivan Pathology, PLLC on May 20, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, patient test logs, three (3) randomly selected patient reports, and an interview, the laboratory failed to ensure that Flow Cytometry Analysis test reports include the correct performing laboratory name and address during the timeframe of March 1, 2021 to the date of the inspection on May 20, 2021. Findings include: 1. Review of the laboratory's CMS 116 form revealed a laboratory name and physical facility location as follows: O'Sullivan Pathology, PLLC 7384 Beulah Church Road Mechanicsville, Virginia 23111 2. Review of the patient test logs revealed eighty-eight (88) cases were reported from 3/1/21 to 5/11/21. The inspector requested to review the following Flow Cytometry Analysis results for Accession/Case Numbers: 3795933/FLT21-015481 dated 3/1/21, 3926465/FLT21-035721 dated 5/6/21, and 3935266/FLT-21037138 dated 5/11/21. The inspector's review of the 3 randomly</p>

selected patient reports revealed a performing laboratory name and testing location listed as: Hematology Oncology Associates of Fredericksburg 4501 Empire Court Fredericksburg, Virginia 22408 The laboratory director (LD) stated, on 5/20/21 at approximately 11 AM, that the laboratory name/address discrepancy was in the process of being corrected. 3. In an exit interview with the LD at approximately 12:30 PM, the above findings were confirmed.