

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2038943	(X3) Date Survey Completed 11/11/2020
Name of Provider or Supplier Peninsula Medical Center For Women	Street Address, City, State 10758 A Jefferson Avenue, Newport News, 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 on-site CLIA recertification survey was conducted at Peninsula Medical Center for Women on November 10, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/5/2020, virtual record review conducted on 11/9/2020, and exit interview on 11/11/20. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 a review of the CASPER Survey Summary (Report 0096D), proficiency testing (PT) documentation, Centers for Medicare and Medicaid Services (CMS) 116 form, PT enrollment documents, and interviews, the laboratory failed to release proficiency testing results to the regulatory agencies of Centers for Medicare and Medicaid Services (CMS) and the Virginia Department of Health (VDH) for five (5) of 5 PT events reviewed. Findings include: 1. During pre-survey preparation, the inspector reviewed a Survey Summary (Report 0096D) in the CASPER program database for Peninsula Medical Center for Women, 49D2038943. Review of the Summary Report revealed no PT scores for calendar year 2019 and year to date 2020. 2. Review of the laboratory's American Proficiency Institute (API) immunohematology PT documentation (2019 Events 1-3, 2020 Events 1-2; a total of 5 events) during the facility's record review, on 11/9/20, revealed that API recorded the facility's CLIA ID as 49D0226811. The inspector inquired of the laboratory director (LD) regarding documentation of contact/enrollment with the API PT</p>

program and the discrepant CLIA ID on reporting. The LD stated on 11/9/20, at approximately 12 Noon, "I do not have an explanation but will need to look into this matter". 3. Review of the laboratory's CMS 116 form confirmed that the LD acknowledged that Peninsula Medical Center for Women CLIA number as 49D2038943 and physical address 10758 A Jefferson Avenue Newport News, Virginia 23601. 4. The inspector requested to review the laboratory's API enrollment forms for calendar year 2019 and 2020. Review of the API order enrollment confirmations revealed that the laboratory provided a CLIA number as 49D0226811 for Peninsula Medical Center for Women with shipping instructions as 10758 A Jefferson Avenue Newport News Virginia 23601. The LD stated on 11/11/20 at approximately 2:00 PM, "Yes, the proficiency test order for Peninsula and it does have our Richmond office's CLIA number in error". 5. In an exit interview with the LD, on 11/11/20 at approximately 2:30 PM, the above findings were confirmed.