

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1063929	(X3) Date Survey Completed 06/02/2023
Name of Provider or Supplier Edmund Rhett, Jr, Md, Pa	Street Address, City, State 1300 Hospital Drive, Suite 150, Mt Pleasant, SC	
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 Recertification Survey was initiated on 06/02/2023 and concluded on 06/02/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with one deficiency cited.
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 laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on document review, facility policy review, and interviews, it was determined that all personnel who routinely perform testing in the laboratory did not routinely process proficiency testing (PT) samples. Findings included: A review of proficiency testing (PT) records for 2022 and 2023 revealed that Testing Personnel (TP) #1 and TP #2 performed all the proficiency testing for the laboratory. This was noted for all American Proficiency Institute (API) events for microbiology for 2022 and 2023. Review of the facility's Standard Operating Procedure Manual "Tab 2: Proficiency Testing," approved by the Laboratory Director (LD) on 12/26/2017, revealed that it was the policy of the laboratory to "Rotate PT events amongst all personnel who test samples and report patient results." Review of the "Affirm VPIII Lab Testing [a molecular testing system for the detection of vaginitis] Log" for 2022 and 2023 revealed that TP #3, TP #4, and TP #5 routinely performed sample testing, as evidenced by their initials in the log. Interview with TP #1 and TP #2 at 11:30 AM on 06/02/2023 confirmed that TP #3, TP #4, and TP #5 routinely performed sample testing, but did not participate in proficiency testing.</p>