

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0294583	(X3) Date Survey Completed 07/28/2020
Name of Provider or Supplier Stephen E Chiarello Md Pa	Street Address, City, State 3280 Tamiami Trl Ste 20, Port Charlotte, FL	
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 recertification survey was conducted on 7/28/20 at Stephen E. Chiarello MD Pa, a clinical laboratory in Port Charlotte, Florida. Stephen E. Chiarello MD Pa was not in compliance with 42 Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not verify the accuracy of potassium hydroxide (KOH) preps or scabies preps twice annually. The Findings included: Review of proficiency testing and quality assessment records for the last two years revealed that there was no documentation to indicate that any verification of accuracy was done for KOH or scabies preps. During an interview with the laboratory director at 10:45 a.m., on 7/28/20, he confirmed that proficiency testing had not been done for KOH or scabies preps over the past two years.</p>