

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0294583	(X3) Date Survey Completed 04/11/2018
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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not have documentation to indicate that they checked the physical characteristics of each batch of media or that they checked each batch of media with control organisms. Findings include: Review of quality control records for fungal cultures on 04/11/18 revealed that there was no documentation that indicated that the physical characteristics of the media were not compromised or that a positive and a negative organism was used for each lot number to check it's ability to support growth and to produce the correct biochemical response. During an interview with the director at 10: 40 a.m. on 04/11/18, he confirmed that that information was not documented.</p>