

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2022590	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Avamar Gastroenterology Inc	Street Address, City, State 9225 East Market Street, Warren, OH	
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
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 interviews with testing personnel (TP) #1 and the Sales Representative for the professional component (SR), the laboratory failed to blindly verify the accuracy of the tissue biopsy grossing procedures performed, that are not listed in Subpart I, at least twice annually. Findings Include: 1. Review of the laboratory's tissue biopsy policies and procedures, provided on the date of the inspection, did not find any instructions to blindly verify the tissue biopsy grossing procedures performed, at least twice annually. 2. The Surveyor requested the laboratory's 2016, 2017 and 2018 blind tissue biopsy grossing test accuracy verification (TAV) documentation from TP#1 and SR. TP#1 and SR stated the laboratory had a misunderstanding between proficiency testing and quality assurance and confirmed the laboratory did not conduct any blind TAV activities for the tissue biopsy grossing procedures performed in 2016, 2017 and 2018 to date, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/20/2018 at 2:28 PM.</p>