

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1082211	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Michael A Antony Md Pc	Street Address, City, State 1840 Willamsbridge Road, Bronx, NY	
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 surveyor review of the proficiency test verification records and an interview with the laboratory director on the day of the survey, the laboratory failed to verify the accuracy of the interpretation of FISH testing. Findings Include: On January 11, 2018 at approximately 11:10 am and confirmed by the laboratory director, the laboratory failed to perform twice annual verification for FISH testing from the date of the last survey January 26, 2016 through the date of this survey. Approximately 29 patient specimens were tested and reported for FISH testing during this time.</p>
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) stain records for histopathology, and an interview with the laboratory director at the time of the survey, the laboratory failed to document the QC test results for the FISH images. Findings Include: The laboratory director confirmed on January 11, 2018 at approximately 11:00 am that the laboratory failed to perform and document the stain quality for the FISH images read from the</p>

last survey of January 26, 2016 through the date of this survey. Approximately 29 patient specimens were tested and reported for FISH testing during that time.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of QC records and confirmed in an interview with the laboratory director at the time of the survey, the director failed to ensure that the QC program for histopathology was followed to assure the quality of laboratory services. Refer to D5475

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of records and confirmed in an interview with the laboratory director at the time of the survey, the director failed to perform twice annual verification for FISH testing. Refer to D5217