

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0141801	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Gastrointestinal Associates Of Rockland	Street Address, City, State 500 New Hempstead Road, Suite A, New City, 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 histotechnician, the laboratory failed to verify the accuracy of the interpretation of immunohistochemistry (IHC) slides. Findings Include: On February 21, 2018, at approximately 1:30 AM and confirmed by the histotechnician, the laboratory failed to perform twice annual verification for IHC slides processed at Pathline laboratory's from February 2016, through the date of this survey. Approximately 500 patient slides were read and results reported for IHC testing during that 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 histotechnician, the laboratory failed to document the QC test results for IHC slides. Findings Include: The histotechnician confirmed during the interview on February 21, 2018, at approximately 1:30 PM that the laboratory failed</p>

to document the QC test results for IHC slides that were processed by Pathline, the technical component laboratory from February 2016 through the date of this survey. Approximately 500 patient slides were read and results reported for IHC 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 by the histotechnician during an interview on February 21 2018 at approximately 1:30 PM, 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 laboratory records, surveyor's observation and an interview with the histotechnician on February 21, 2018 at approximately 1:30 PM, the laboratory director failed to ensure that the QA program for histology pathology testing was maintained to ensure quality laboratory services. Refer to: D5217