

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0940452	(X3) Date Survey Completed 08/02/2021
Name of Provider or Supplier Satya P Kastuar Md	Street Address, City, State 2480 Route 27, North Brunswick, NJ	
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 Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the calendar years 2019 and 2020. The LD confirmed on 8/2/21 at 10:00 am that the laboratory did not perform BA for Histopathology testing twice in 2019 and 2020.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from 1/23/19 to the date of survey. The LD confirmed on 8/2/21 at 10:00 am that a BA procedure was not established.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p>

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from January 2019 to the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 2500 patient slides. 3. The LD confirmed on 8/2/21 at 10:15 am that the laboratory did not document H&E QC stain reaction.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to ensure BA was performed accurately in the calendar years 2019 and 2020. The findings include: 1. There was no evaluation of the LD to ensure accuracy. 2. The LD confirmed on 8/2/21 at 10:00 am that BA was not performed.