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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D1099117 | (X3) Date Survey Completed 02/14/2019 |
| Name of Provider or Supplier Christopher B Kruse Md, Llc | Street Address, City, State 225 Nj-35, Red Bank, 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 |
|---------------------------|---|
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of the Competency Assessment (CA) records, review of the personnel files and interview with the Laboratory Director (LD), the laboratory failed to perform a CA on Testing Personnel (TP) # 2 and # 3 in the calendar year 2018. The LD confirmed on 2/14/19 at 11:00 pm that CA was not performed on TP.</p> |
| D5601 | <p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing personnel (TP), the laboratory failed to document QC for Biopsies slides reviewed from technical component laboratory from July 2018 to the date of the survey. The TP#1 on CMS form 209 confirmed on 2/14/19 at 1:00 pm that the laboratory failed to failed to document QC for Biopsies slides.</p> |

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the testing Personnel (TP), the Laboratory Director (LD) failed to specify in writing the list of job responsibilities for data entry from 4/18/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 2/14/18 at 12:30 pm that job responsibilities were not established for data entry.