

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2049876	(X3) Date Survey Completed 03/05/2018
Name of Provider or Supplier Renuka H Bhatt Md Sc	Street Address, City, State 120 Batson Court, New Lenox, IL	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, patients' test records, quality control (QC) records and interview; the laboratory failed to establish and follow written policies and procedures for the following: *Specimen processing *Specimen referral Findings: 1. The laboratory's procedures manual did not include procedures for specimen processing and referral. Records show that dates of specimen processing was not recorded. The surveyor could not determine if QC of the H & E stain was performed with each group of patients' slides that were processed and stained. Testing personnel told the surveyor that this is because the laboratory batches their specimens. However, there was no procedure that states that this laboratory batches their specimens. When the surveyor asked if a QC slide was cut and sent with referral specimens, the surveyor was told that they did not send a QC slide with referral specimens. When the surveyor asked if this laboratory documents the QC of the stain for referral specimens, the surveyor was told, "No." There were no procedures that describe QC of the stain for referral specimens. 2. During survey date 03/05/18, the surveyor requested the following information for 6 patients records selected for review: records that included the patients' requisitions; patients' test records; final reports; QC records; and patients slides along with their corresponding tissue blocks. The review revealed the following information: a. Patient # 1 - Date of Service 07/05/16; Specimen received 07/06/16; No documentation to show when the gross</p>

description of patient's specimen was performed and recorded; no date to show QC performance of H & E staining procedures on 07/06/16. b. Patient # 2 - Date of Service 09/20/16; Specimen received 09/21/16; No documentation to show when the gross description of patient's specimen was performed and recorded; no date to show QC performance of H & E staining procedures on 09/21/16. c. Patient # 3 - Requisition from a laboratory located in the state of Ohio with a Surgery date 11/25/16; Specimen Received 11/26/16; no date to show QC performance of H & E staining procedures on 11/26/16. d. Patient # 4 - Date of Service 03/17/17; Specimen received date 03/20/17; No documentation to show when the gross description of patient's specimen was performed and recorded; no date to show QC performance of H & E staining procedures on 03/20/17. e. Patient # 5 - Date of Service 12/26/17; No specimen received date; Date specimen gross description recorded 12/27/17; no date to show QC performance of H & E staining procedures on 12/27/17. f. Patient # 6 - Requisition from a laboratory located in the state of Ohio with a Surgery date 01/10/18; No date of specimen receipt; no date to show QC performance of H & E staining procedures on 01/10/18; no specimen block retained. 3. During survey date 03/05/18, the Histology Tech confirmed the surveyor's findings.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(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 review of patients' test records and quality control (QC) records and interview; the laboratory failed to perform and document the staining of a slide of known reactivity with each slide or group of patient slides when it performed Hematoxylin and Eosin (H&E) staining procedures. Findings include: 1. During survey date 03/05/18, the surveyor selected 6 patients test records for review. Review of (QC) records revealed that the dates of the QC of the H&E stain did not match the date that the gross description of the patients' specimen was recorded. The surveyor could not determine if the QC of the H&E stain was performed with each individual patient's specimen or group of patients' specimens for 6 of 6 patients test records reviewed. 2. During survey date 03/05/18, the Histology Tech confirmed the surveyor's findings.

D5603

HISTOPATHOLOGY
CFR(s): 493.1273(b)(f)

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures manual, patients test records, slides and blocks and interview; the laboratory failed to retain specimen blocks in a manner that ensures proper preservation of the tissue specimens until microscopic examination. 1. Review of the laboratory's procedures manual revealed that this laboratory performs the grossing, processing, and microscopic examination of patients' tissue specimens, along with referral services in which the laboratory grosses and processes specimens for a Dermatopathology laboratory located in the state of Ohio. 2. Review of 6 patients' test records revealed that the laboratory only grossed, processed, and diagnosed 4 of 6 patients' tissue specimens. Two of 6 patients' specimens were only grossed and processed for the laboratory in Ohio. 3. Review of patients' slides and blocks revealed that there was no tissue block for 1 of 6 patients specimens reviewed. The Histology Tech stated that the laboratory sends their block along with the patients' slide to the out of state laboratory. This laboratory did not retain the tissue block. 4. During survey date 03/05/18, the Histology Tech confirmed the surveyor's findings.