Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0101367	02/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Greenwich Hospital Dept Of Pathology	5 Perryridge Rd, Greenwich, CT	

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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and staff interview, the histopathology laboratory failed to follow policies and procedures to prevent cross contamination for tissue specimen processing (refer to D5311); failed to establish and follow quality assurance procedures to monitor, assess cross contamination issues during tissue processing (refer to D5391); failed to maintain specimen identity and prevention of cross contamination throughout the testing process (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the sub-specialty histopathology.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory personnel failed to follow

	policies and procedures to prevent cross contamination during tissue specimen processing in the sub-specialty of histopathology. Findings include: 1. Record review on 1/29/2020 of an adverse event report (# 000045-20-1) dated 1/22/2020 reported to the Connecticut State Department of Public Health revealed a "wrong surgical or other procedure performed on a patient." 2. Staff interview with the laboratory director (LD) on 1/30/2020 at 10:00 AM revealed the following events: a. Patient #1 (P1) underwent an incision core biopsy of a sonographically abnormal left axillary lymph node on 12/27/19. This specimen was grossed on 12/27/19 and placed on the tissue processor for processing on 12/28/19. b. Patient #2 (P2) had a skin shave biopsy sample taken on 12/27/19 that was grossed on 12/28/19 and placed on the same tissue processor with P1 on 12/28/19. c. Both the above specimens from P1 and P2 were embedded, cut and stained on 12/29/19 by histotechnician (HT) #2. d. Histopathology slides from P2 were read and signed out by testing personnel/pathologist (TP) #2 on 12 /29/19 with a diagnosis of "Basal cell carcinoma, micronodular pattern." e. Histopathology slides from P1 were read and signed out by TP#1 on 12/30/19 with a diagnosis of "Needle lymph node biopsy showing detached fragment of basaloid neoplasm and fragments of lymphoid tissue" with recommendation of surgical excision of the lymph node. f. Based on the diagnosis listed in (e) above, P1 underwent a surgical procedure on 1/17/2020 and 5 lymph nodes were removed. g. The initial evaluation on 1/21/2020 of the 5 lymph nodes surgically removed on 1/17 /2020 from P1 revealed absence of malignant cells. Immunohistochemical studies of the lymph nodes confirmed all 5 were negative for malignancy. h. Laboratory ' s investigation to identify the reason for the misdiagnosis revealed, there was a cross contamination of the specimens from P2 to P1 during the embedding process due to lack of proper cleaning of forceps used to embed the specimens by HT#2. Residual tissue left on the forceps from P2's specimen was carried over to P1's specimen during embedding. i. A complete root cause analysis for the misdiagnosis is ongoing. 3. Record review on 1/30/2020 of the processor wheel photo revealed the position of all cassettes processed on 12/29/19. P2 and P1 cassettes were adjacent to each other. 4. Record review on 1/30/2020 of the laboratory's policy (HIST-061) for 'Embedding and Quality Control Guidelines' dated and approved by the LD on 5/22/17, revealed, "The embedding forceps should be wiped with gauze between blocks to avoid transfer of fragments of tissue from one tissue block to another." 5. Staff interview with HT#2 on 2/4/2020 at 12:44 PM confirmed: a. HT#2 was the only processing technician that processed and stained both P1 ' s and P2 ' s specimens. b. HT#2 stated skin biopsies are embedded first and then other biopsies. c. HT#2 examined the processor photo indicated in #3 above and confirmed P2's specimen preceded P1's. d. He/she is, "Pretty confident the cross contamination happened during the embedding process and not at cutting because HT#2 goes fast when embedding." P1's specimen was cross contaminated with P2's specimen due to the lack of cleaning of forceps between specimen blocks in the tissue embedding process. e. HT#2 further stated he/she had to rush to process the specimens that day as he/she was getting calls from TP#2 inquiring if the specimens were ready to be read.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) 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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to establish and follow policies and procedures to prevent cross contamination in tissue specimen processing and assure that correct diagnosis is provided on the appropriate patient samples in the sub-specialty of histopathology. Findings include: 1. Record review on 1/30/2020 of the laboratory's policy (HIST-061) for 'Embedding and Quality Control Guidelines' revealed, "The embedding forceps should be wiped with gauze between blocks to avoid transfer of fragments of tissue from one tissue block to another." 2. Record review on 1/30/2020 the histopathology policies and procedures revealed the laboratory did not have a policy for the "Detection and Handling of Floaters" (Policy # GAP4-4) prior to 1/23/2020. This policy was instituted only after the adverse event was reported. 3. Staff interview with the laboratory's histopathology administrative supervisor on 1/30/2020 at 10:30 AM confirmed: a. Each histotechnician must wipe the forceps with gauze between each specimen block. b. A detailed step by step procedure for cleaning the forceps was not in place on 12/29/19. c. Failure to follow the laboratory's procedure for cleaning the forceps by HT#2 resulted in cross contamination of the paraffin embedded blocks between P2 and P1. This resulted in an incorrect diagnosis of basaloid carcinoma for P1 for the specimen collected on 12 /27/19. 4. Staff interview with the laboratory director on 1/30/2020 at 10:40 AM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to establish policies to ensure specimen integrity is maintained throughout the tissue processing and interpretation, to identify cross contamination in the sub-specialty of histopathology. Findings include: 1. Record review on 1/30/2020 of the histopathology laboratory polices in effect on 12/30/19, revealed the laboratory did not have a policy for maintaining specimen identity and prevent cross contamination throughout the testing process. 2. Staff interview with the laboratory director on 1/30/2020 at 12:00 PM confirmed: a. The laboratory did not have a policy in place for quality assessment and to ensure specimen integrity on 12/30/19. b. Cross contamination of a specimen resulting in an incorrect diagnosis of basaloid carcinoma occurred. 3. Review of laboratory's policy (GAP 2-2 approved by the laboratory director (LD) on 6/11/19) for 'Internal Consultations' on 1/30/2020 revealed, "Available pathologists review newly diagnosed malignancies, unusual or uncertain infectious process, cases where pathologic diagnosis is controversial and rare or difficult cases." 4. Record review on 1 /30/2020 of the pathologists consensus record dated 12/30/19 revealed: a. 3 of 9 pathologists participated in the consensus meeting. b. Patient #1's (P1) specimen was reviewed and no irregularities were identified. 5. Staff interview on 2/4/2020 at 12:10 PM with testing personnel/pathologist #1 revealed, P1's case was discussed with another pathologist for possible floater contamination outside of the consensus meeting and determined it was not contaminated due to: a. P1's prior history of malignancy. b. Possibility of metastasis. c. After reviewing his/her remaining biopsies prior to and following the lymph node biopsy. 6. Staff interview with the LD on 2/4 /2020 at 1:30 PM confirmed: a. Possibility of floater contamination referenced in #5

	above was never brought up in the consensus meeting on 12/30/19. b. The laboratory did not have documentation of the meeting referenced in #5 above. c. Dermatopathologists do not attend the consensus meetings and skin biopsy results are not discussed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the sub-specialty of histopathology. Findings include: 1. The LD failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable test results. Refer to D6087. 2. The LD failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failure in quality as they occur. Refer to D6094. 3. The LD failed to ensure: a. Prior to testing patient specimens, all personnel received the appropriate training and have demonstrated that they can perform all testing operations reliably. b. Identify training needs, needs for remedial training or continuing education to improve skills. c. All personnel maintained competency for tissue specimen processing. Refer D6102 and D6103.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: The laboratory director (LD) failed to ensure all laboratory personnel follow the laboratory's policy (HIST-061) for 'Embedding and Quality Control Guidelines' dated and approved by the LD on 5/22/17. Refer to D5311.
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 record review laboratory director failed to establish and follow policies for

	specimen integrity and procedures to prevent cross contamination in tissue specimen processing and assure that correct diagnosis is provided throughout the testing process in the sub-specialty of histopathology. Refer to D5391 and D5791.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to ensure that all laboratory histology staff received adequate training and assessed for their competency throughout the testing process. Findings include: 1. Record review on 1/30/2020 of the 'Histology Staff Training' checklist in effect on 12/30/19, revealed the lack of assessment for cross-contamination techniques using forceps. 2. Telephone interview with histotechnician (HT) #6 on 2/5/2020 at 12:10 PM revealed: a. Adequate training for tissue specimen processing was not provided, only a "crash training" was provided before HT#6 started working independently with patient samples. b. Training was not provided for proper cleaning of forceps to avoid cross contamination. c. Lack of adequate staffing to handle the workload. d. The laboratory did not have enough forceps available for tissue processing prior to 1/29/2020. 3. Telephone interview with the LD on 2/5/2020 at 12:40 PM confirmed HT#6 will be provided with additional training.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure histology personnel were competent in the embedding process utilizing the tissue forceps in the sub-specialty of histopathology. Findings include: 1. Record review of the histopathology section staff 's 2018 and 2019 competency records on 1/30/2020 revealed the laboratory did not assess 6 of 6 histology personnel for the use and proper cleaning of tissue forceps to avoid cross contamination. 2. Staff interview with the histopathology administrative supervisor on 1/30/2020 at 11:45 AM confirmed the above finding.