Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0891640	**(X3) Date Survey Completed** 04/06/2021
Name of Provider or Supplier Amsurg Surgery - Pathology	**Street Address, City, State** 998 129th Infantry Dr, Joliet, 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**
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual; the specimen log; and interview with Mercy Hospital personnel, the laboratory failed to establish and follow written policies and procedures that ensure positive identification and optimum integrity of patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting results. Findings: 1. Review of the laboratory's procedures manual for "Frozen Sectioning" instructs the laboratory to do the following when it collected patients' specimens: a. Time stamp or document the receipt of the sample in the Gross Room. b. Each frozen section slide must be labeled with the patient's name and birth date. c. All frozen section or intraoperative smears must be labeled with the surgical pathology specimen number, stained, cover slipped, and retained with the rest of the slides on the case. 2. Review of specimen testing logs revealed that there was a total of one patient's specimen recorded in the specimen log from January 19, 2021 through April 6, 2021. There was no record of the patient's name; date of birth; and/or surgical pathology specimen documented on the specimen log. 3. On April 6, 2021 at 10:00 AM, Mercy Hospital personnel confirmed the surveyor's findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; Laboratory Personnel Report - CLIA (FORM 209); personnel records; and interview with Mercy Hospital personnel; the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings: 1. Review of the laboratory's procedures manual revealed that there were no procedures for how the lab assesses the competency of personnel who fulfill the duties and responsibilities for the following positions in the laboratory: a. Technical Supervisor c. General Supervisor d. Clinical Consultant. 2. Review of FORM 209 revealed that laboratory personnel were listed as follows on Form 209. a. Person #1 - Laboratory Director; Clinical Consultant; Technical Supervisor, and Testing Person b. Person #2 - Clinical Consultant and Testing Person c. Person #3 - Clinical Consultant and Testing Person 3. Review of personnel records revealed that there were no competency assessments based on the duties and responsibilities of the position in the laboratory for the following a. 3 of 3 Clinical Consultants in 2019, 2021, and January 2021 through March 2021 b. 3 of 3 Testing Persons in 2019 4. On April 6, 2021 at 10:30 AM, Persons form Mercy Hospital confirmed the surveyor's findings.
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 review of the laboratory's procedures manual; patient's testing logs; quality assessment records; and interview with personnel from Mercy Hospital, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services. Finding: 1. Review of the laboratory's procedures manual revealed the laboratory does have a quality assessment policy. It states, "the following activities are the responsibility of the Laboratory Medical Director: a. Review of monthly quality control data. b. Review of equipment quality control, maintenance, repair, and preventative maintenance records. c. Review of proficiency testing. d. Annual review of policies and procedures e. Reviews of staff training and competency f. Reviews of staff performance. g. Review of Quality Improvement data and recommendations. h. Review of quality reports of turnaround time, critical calls and productivity. i. Other matters as determined by the Department Medical Director. On the page 3 of 3 of the procedures it states, "Laboratory Mangers, Supervisors, and Coordinators may also perform the activities/responsibilities of the Laboratory Medical Director." 2. There was no documentation to show quality assessment performance from January 1, 2019 through April 6, 2021. 3. On April 6, 2021 at 11:00 AM, personnel from Mercy Hospital confirmed the surveyor's findings.
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 review of the laboratory's procedures manual; Laboratory Personnel Report (FORM 209); personnel records; and interview with Mercy Hospital personnel; the laboratory director failed to specify, in writing the duties and responsibilities of each consultant, each supervisor, and each testing person engaged in the testing process. Findings: 1. Review of the laboratory's procedures manual revealed that the laboratory director did not assign in writing persons to the following positions: a. Clinical Consultant b. Technical Supervisor c. General Supervisor e, Testing Person 2. Review of FORM 209 revealed that the following persons were listed on the form: a. Person #1 Laboratory Director listed as Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Person. b. Person #2 listed as Clinical Consultant and Testing Person. c. Person #3 listed as Clinical Consultant and Testing Person. 3. Review of personnel records revealed that the laboratory director did not assign a person to the following positions: a. Technical Supervisor b. Clinical Consultant c. General Supervisor d. Testing Personnel 4. On survey date April 6, 2020 at 10:30 AM, Mercy Hospital personnel confirmed the surveyor's findings.