Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2189804	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cross Medical Laboratories Llp	515 Valley View Dr - Ste 201, Moline, 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 record review and interview, the laboratory failed to process patient specimens using separate (distinct) or unique identifiers in order to avoid mislabeling, specimen mix-ups, incorrect test request entry, and incorrect reporting of results for four out of four patients. Findings include: 1. The Cross Medical Laboratories (Moline) requisitions, frozen section diagnosis logs, patients' slides, and final reports were reviewed. 2. The frozen section log revealed the following: *The log listed the date, case number, patient's name; frozen section diagnosis, stain quality; time specimen received and time specimen reported. *The case numbers listed are the accession numbers from the referral laboratory. *The log failed to include the source of each frozen section and diagnosis, especially patients with multiple tissue submissions. 3. On 09/09/2021 at 10:00 am, the laboratory director (LD) explained the laboratory's frozen section process as follows: *The surgery tissue(s) from Plastic surgery associates along with the Cross medical laboratories Moline requisition were submitted to the Pathologist (laboratory director- LD) for frozen section processing and tissue readings. *The LD recorded the patient's name, date and time of receipt; diagnosis and time reported in the Frozen Section Diagnosis log, however the Case number section was left blank. *The LD then freezes and sections the tissue(s) onto labeled slide(s) for staining and interpretation. *At the end day, the LD takes the remaining tissue(s) and slides to the referral laboratory (Cross Medical laboratories in Iowa) for further tissue processing, staining, and interpretation. *The accession number given at Iowa-Cross Medical Laboratories is later added to the Frozen section

	log in Moline. 4. Four (4) cases provided by the LD revealed the patient's identification written by the LD on the frozen section slides had been covered by the referring laboratory's (Cross Medical in Iowa) slide label. 5. The laboratory failed to ensure the frozen section slides processed in the Moline location could be positively identified through all phases of testing and failed to process patient specimens using separate (distinct) or unique identifiers, especially patients with multiple tissue submissions. 6. On an Initial survey conducted on 09/09/2021 at 11:15 AM, the LD confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure test reports indicated the name of the laboratory where the tests were performed for four out of four patient final reports. Findings include: 1. The patients' requisitions from 09/18 /2020; 10/30/2020; 01/08/2021 and 04/16/2021, frozen section diagnosis logs, and final reports were reviewed. 2. The final reports of four out four patients listed the name of the testing laboratory as "Plastic Surgery Associates". 3. The requisitions and logs of the four patients showed their tissues and frozen sections were performed by Cross Medical Laboratories in Moline. 4. On an Initial survey conducted on 09/09 /2021 at 11:15 AM, the LD confirmed the above findings. .
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4) (ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to MEET the general requirements of the inspection process when it failed to have all records and data accessible and retrievable within a reasonable time frame, during the course of the inspection for 10 out of 10 surgery patients. Findings Include: 1. The laboratory manual, frozen section diagnosis logs from 07/02/2021 to 08/20/2021, and slides were reviewed. 2. The procedures manual revealed the following: *The laboratory performed frozen section procedures and Histopathology slide interpretations; and *Patients' frozen section slides were taken to Cross Medical Laboratories in Iowa for storage. 3. The surveyor selected 10 patients (PT1, PT2, PT3,....PT10) from the frozen section log for requisition, slides, quality control (QC), and final report review. The laboratory failed to be able to present the selected QC and patient slides for 10 out of 10 patients, during the survey. 4. On an Initial survey conducted on 09/09/2021 at 11: 15 AM, the LD confirmed the above findings.