Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386471	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cross Medical Laboratories Llp	321 E Market Street, Suite 102, Iowa City, IA	

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
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, record review and interview, it was determined that the laboratory failed to establish written policies and procedures to prevent cross-contamination of nongynecologic specimens having a high potential for cross-contamination (refer to D5619); failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic specimens (refer to D5629); failed to establish individual workload limits for five of five Technical Supervisors (refer to D5633); failed to establish written policies and procedures to reassess workload limits every six months (refer to D5637); failed to establish written policies and procedures to prorate workload limits for five of five Technical Supervisors (refer to D5641); and failed to establish written policies and procedures for the documentation of workload limits for five of five Technical Supervisors. 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 subspecialty of Cytology.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following

	staining. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to prevent cross-contamination of nongynecologic specimen slides with a high potential for cross-contamination. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prevent cross-contamination of nongynecologic specimens with a high potential for cross-contamination with other nongynecologic specimens. 2. Technical Supervisor #2 confirmed during an interview with the Survey Team at 1:50 PM on January 15, 2019 that the laboratory did not have a procedure to prevent cross-contamination of nongynecologic specimens. .
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedure and interview, it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic cytology specimens in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. Technical Supervisor #2 confirmed during an interview with the Survey Team at 1:50 PM on January 15, 2019 that the laboratory did not have a procedure for an annual statistical evaluation of three required statistics.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor #1, for five of five Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that a maximum individual workload limit was established by Laboratory Director/Technical Supervisor #1 for the five Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide an individual workload limit for each of the five Technical Supervisors for 2017, 2018 and to the date of the survey in 2019. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 3. Technical Supervisor #2 confirmed during an interview with the Survey Team at 1:50 PM on January 15, 2019 that the laboratory did not have a procedure for establishing a maximum individual workload limit for each of the five Technical Supervisors.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for five of five Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2018, and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the workload limit for five of five Technical Supervisors would be reassessed at least every six months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit five of five Technical Supervisors for 2018 and to the date of the survey in 2019. 3. Technical Supervisor #3 confirmed during an interview with the Survey Team at 8:30 AM on January 15, 2019 that the laboratory did not have written policies and procedures for or record of a six month reassessment of workload records.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for five of five Technical Supervisors was prorated in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for the five Technical Supervisors, when examining slides in less than an 8-hour workday or with activities other than primary examinations of cytology slides. 2. Technical Supervisor #3 confirmed during an interview with the Survey Team at 8:30 AM on January 15, 2019 that the laboratory did not have a written procedure for prorating the workload limits.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Cross refer to D5633 Based on the review of laboratory policies and procedures and interviews, it was determined that the laboratory failed to establish a written policy and procedure to ensure that records were available to document the workload limit for five of five Technical Supervisors for the years 2017, 2018 and 2019 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for five of five Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 2. Technical Supervisor #3 confirmed during an interview with the Survey Team at 8:30 AM on January 15, 2019 that the laboratory did not have a written procedure for documenting the individual workload limits for the five Technical Supervisors.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview, it was determined that the Laboratory Director/Technical Supervisor #1 failed to establish individual workload limits in 2017, 2018 and to the date of the survey in 2019 for five of five Technical Supervisors. Cross Refer to D5633
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This

	information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.