Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2028847	12/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Great Lakes Medical Laboratories Inc	13530 Michigan Avenue Suite 248, Dearborn, MI	

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
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 procedure review, record review, and interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures to ensure workload limit for the Laboratory Director was reassessed at least every six months and adjusted when necessary for 2 (December 2107 to December 2019) of 2 years. Findings include: 1. "Policy for monitoring workload limit every 6 months" states,"Any time that a slide examination total number exceeds the limit will be investigated and the reason for that identified." 2. Record review revealed for 2 of 2 years 14 of 113 days of slide examination, the number of slides examined exceeded the number allowed for the 24 hour period and no investigation was performed and the reason for the overage was not identified as follows: a. 1/30/18 33 slides examined - 25 allowed b. 3/1/18 27 slides examined - 25 allowed c. 3/29/18 20 slides examined - 19 allowed d. 5/1/18 20 slides examined - 19 allowed e. 7/17/18 33 slides examined - 31 allowed f. 7/24/18 33 slides examined - 31 allowed g. 7/31/18 32 slides examined - 31 allowed g. 8/2/18 36 slides examined - 31 allowed h. 9/13/18 15 slides examined - 13 allowed i. 9/20/18 15 slides examined - 13 allowed j. 1/22/19 26 slides examined - 25 allowed k. 4/16/19 26 slides examined - 25 allowed l. 6/1/19 19 slides examined - 18 allowed m. 9/26/19 26 slides examined - 25 allowed 3. During an interview on 12 /10/19 at approximately 1:50 pm, the LD confirmed the 6 month slide monitoring did not include documentation of the investigation and the reason for the slide review overage. ***Repeat Deficiency from 7/18/17 and 1/4/18***
D5645	CYTOLOGY

	CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with the Laboratory Director (LD), the laboratory failed to follow their procedure for documentation of Non-GYN workload limits for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. Review of the procedure "Policy for weekly Non-Gyn Cytology workload limits" revealed the laboratory did not follow the policy to "ensure that number of non-GYN slide examination does not exceed 100 conventional or cytospin (Liquid based) slides in 24 hours period." 2. Record review revealed lack of documentation for the weekly workload limits for 2 (December 2018 to December 2019) of 2 years. 3. Record review revealed the laboratory started using a log on 1/4 /18 that included each day of testing, "# slides examined, # of hours, and allowed # of slides to examine" to be examined for Non-GYN cytology slides workload limit. The log did not include "conventional and cytospin" documentation which accounts for the "100 conventional or cytospin (Liquid based) slides in 24 hours period." 4. During the interview on 12/10/19 at approximately 1:30 pm, the LD confirmed the weekly Cytology workload limits were not being performed and documented as stated in the policy. ***Repeat Deficiency from 7/18/17, 1/4/18, and 1/23/18 surveys***
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to detect incorrect patient first names for 2 (GA18-188 and GC19-210) of 23 patient charts audited. Findings include: 1. Record review for 2 of 23 patient charts audited revealed the spelling of the patient's first name was spelled incorrectly from the spelling on the sample requisition as follows: a. Histology /surgical specimen - GS18-188 b. Cytology specimen - GC19-210 2. During the interview on December 10, 2019 at approximately 1:30 pm, the LD confirmed the spelling of the patient's first name on the final reports were spelled incorrectly.