Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0980753	**(X3) Date Survey Completed** 10/28/2020
Name of Provider or Supplier Columbiana Clinic Llc	**Street Address, City, State** 22266 Highway 25 Bypass, Columbiana, AL	
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**
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records for 2018 - 2020 and an interview with the Laboratory Director (who also serves as the Technical Consultant) and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the testing personnel performing the Provider-Performed Microscopy Procedures (PPMP) [urine sediment examinations, potassium hydroxide (KOH) and vaginal wet preparations] signed the attestestion statements for eight of eight Hematology testing events, reviewed by the surveyor. The Laboratory Director failed to sign the attestation statements for Hematology Event #1, 2018 and Event #2, 2020 and Core Chemistry Event #3, 2020. The findings include: 1. A review of the API proficiency testing records for Hematology Events #1, #2 and #3 of 2018 and 2019 and Events #1 and #2 of 2020 revealed the testing personnel (the physician) of the PPMP failed to sign the attestation statements. 2. In an interview on 10/28/2020 at 11:00 AM, the LD (also the Technical Consultant) and TP #1 confirmed the provider did perform the PPMP procedures but had not signed any of the attestation statements for 2018 through the second testing event of 2020. The LD confirmed she had not signed the attestation statement for Hematology Event #1, 2018.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty

	assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of 2018 - 2020 American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the laboratory failed to self-grade a platelet count (Hematology Event #1, 2019), which was not graded by API. This affected one of eight Hemtology testing events, reviewed by the surveyor. The findings include: 1. A review of Hematology PT Event #1, 2019 revealed the platelet count for specimen HEM 02 was not scored by API. The laboratory did not self-grade the result. 2. During an interview on 10/28/2020 at 12:19 PM, the LD reviewed the PT records and stated she could not remember what happened. The LD further confirmed the laboratory had not self-evaluated the results of the platelet count, when returned by API.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of 2018 - 2020 American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), who also serves as the technical consultant, the surveyor determined the laboratory failed to implement and document corrective actions for proficiency testing scores less than one hundred percent (100 %) for Chemistry Event #2, 2018. This affected one of twelve Chemistry PT evaluations reviewed. The findings include: 1. A review of the API records for Core Chemistry Event #2, 2018 revealed the laboratory scored 80 % for the Free T3 (free triiodothyronine) and CO2 (Carbon Dioxide). There was no corrective actions documented for these scores of less than 100 %. 2. During an interview on 10/28/2020 at 10:18 AM, the LD reviewed the PT records and quality assurance notes and confirmed there were no corrective actions documented.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the validation study for the Ace Axcel and an interview with the Laboratory Director (LD), the laboratory failed to evaluate and summarize the raw

	data for precision of the following analytes: alanine transaminase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, cholesterol (total), creatinine, glucose, high-density lipoproteins, lipase, magnesium, potassium, sodium, total protein, triglycerides, and uric acid. Lipase was discontinued prior to 2018; but was again implemented in September of 2019. This affected one instrument installation since the previous survey on March 8, 2018. The findings include: 1. A review of the validation for the Ace Axcel, installed September 2018, revealed there were at least ten runs of level 1 and level 2 quality controls for each analyte except lipase from 09/06/2018 to 09/17/2018, but the raw data was not evaluated and summarized for precision. 2. Lipase was implemented again in September of 2019, according to the LD on 10/28 /2020 at 4:15 PM. The precision was run by Testing Personnel (TP) #1 on 6/20/19 - 9 /26/19 by running two levels of quality control for ten days; however the raw data was not evaluated to determine the actual precision. Patient testing began immediately after the raw data was accumulated. 3. During an interview conducted on 10/28/2020 at 12:25 PM, the LD confirmed the data was not evaluated and summarized to determine actual precision of the analytes run on the instrument in 2018. During an interview at 4:15 PM, the LD stated she had not reviewed the data to determine precision, nor signed for the approval of the addition of the testing (the validation of Lipase) in the laboratory.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Access quality control records and an interview with Testing Personnel (TP) #1, the laboratory failed to document at least two levels of quality control material was analyzed for Vitamin D each day of patient testing. This was noted on 4 of 6 months, reviewed from April 2018 to July 2020. The findings include: 1. A review of the quality control records for the Access Chemistry analyzer revealed Vitamin D - Level 1 was documented, and Level 3 was not documented for 4 out of 6 months reviewed (August 2018, March 2019, October 2019, and February 2020). 2. During an interview conducted on 10/28/2020 at 1:55 PM, TP #1 confirmed the LabDaq (Laboratory Information System) control summary report being printed for quality control data for the Access was the only documentation retained from August 2018 to July 2020. TP #1 stated that Level 1 and Level 3 were run, but Level 3 did not show on the control summary report for Vitamin D due to it being a "greater than" (>) value. The laboratory staff had no other documents to provide to show at least two levels of quality control was run and documented during this time.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for the Cell-Dyn Emerald and the Ace Axcel, and interviews with the Laboratory Director (LD), the surveyor determined the LD failed to ensure the validations were reviewed and approved before patient testing started. This affected two of two new instruments installed, since the previous survey on March 8, 2018. The findings include: 1. During the initial tour of the laboratory on 10/28/2020 at approximately 9:30 AM, Testing Personnel (TP) #1 stated the Emerald and Ace Axcel were new instruments, since the previous survey. 2. A review of the validation records for the Cell-Dyn Emerald revealed the LD signed the validation on 04-15-19. 3. During an interview on 10/28/2020 at 10:35 AM, TP #1 confirmed patient testing started on 04-01-2019 on the Cell-Dyn Emerald, prior to the LD reviewing and signing the validation study. 4. A review of the validation records for the Ace Axcel Chemistry analyzer revealed the LD had not signed the validation study (included all analytes, except Lipase). During an interview conducted on 10/28 /2020 at 11:45 AM, the LD stated she signed the procedure manual as the procedure and validation for the Ace Axcel. The LD confirmed she gave the ok for patient testing to begin in September 2018 through text messages. The LD signed the validation of the Ace Axcel, during the current survey. 5. Lipase was installed on the Ace Axcel in September of 2019, according to the LD on 10/28/2020 at 4:15 PM. Patient testing began immediately after the raw data was accumulated. The raw data for precision had not been evaluated nor reviewed and signed by the LD. The method comparison, accuracy and reportable range studies had not been reviewed and approved of/signed by the LD.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of 2018 - 2020 American Proficiency Institute (API) Proficiency Testing records, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, and Testing Personnel (TP) #1, the surveyor determined the LD failed to ensure proficiency testing results were submitted to the provider within the established timeframes to ensure grading/scoring of the results. This affected two of fifteen PT events reviewed by the surveyor. The findings include: 1. A review of the API PT records revealed the laboratory was enrolled in proficiency testing for non-regulated analytes [Prostate Specific Antigen (PSA), Ferritin, vitamin D and vitamin B12], as well as the regulated analytes. 2. Further review of the PT records revealed the laboratory staff scored zero percent (0 %) for PSA, Ferritin, vitamin D and vitamin B12 for Miscellaneous Chemistry Event #2 of 2018, due to the

	laboratory's failure to submit the results within the estblished timeframe to ensure API scored the results. The laboratory self-graded the results. 3. During an interview on 10 /28/2020 at 12:11 PM, TP #1 stated both testing personnel were ill during this time. However, further explanation revealed the testing personnel were ill at separate times. The LD was present during this interview and confirmed the above noted findings. 4. A review of the PT records for the Core Chemistry Event #3, 2019 revealed the laboratory reported the instrument was down (API provided an artificial score of 100 %; and documents revealed the laboratory self-graded the results. 5. At 11:22 AM on 10/28/2020, the surveyor inquired of the circumstances, causing the laboratory to self-grade the results for Chemistry Event #3, 2019. The LD stated the instument went down just as the testing personnel was planning to analyze the specimens, which was near the end of the submission timeframe (the deadline for submission of results). The instrument was repaired and the specimens were analyzed, however not prior to the submission deadline. This caused the laboratory to self-grade the results.