Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2103325	05/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ramon Ramos, Md	412 Us Hwy 80, Pooler, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 7, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing (PT) records, laboratory PT records and staff interview, the laboratory failed to take corrective action when results of lymphocyte percent were unacceptable. Findings include: 1. Review of AAFP PT results revealed the laboratory failed percent Lymphocytes with the following scores: 2017 event 1 60% 2017 event 2 60 % 2018 event 1 40% 2018 event 2 60% 2018 event 3 60% 2019 event 1 60% 2. Review of the laboratory's PT records revealed no documentation of corrective action until the failed event in 2019. 3 Interview with testing personnel # 1 (see CMS 209) on May 7, 2019at 2 pm in the break room confirmed corrective action was not taken until May 2019 when results of event 1 of 2019 were received.
D5024	HEMATOLOGY CFR(s): 493.1215

	If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to review and staff interview, the laboratory failed to meet the requirement for testing complete blood counts (CBC) on the Emerald Cell-DYN in the speciality of Hematology. Findings include: Refer to: D 5441, D 5481, D 5783
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of records to review, review of the laboratory's Quality Assessment policy and staff interview, the laboratory failed to have a QA policy and failed to perform QA in 2018 and from January to March in 2019.. Findings include: 1. Review of the laboratory's current QA policy revealed it was signed by the laboratory director on March 27, 2019. No QA policy prior to March 2019 is available and no documentation of QA activity is available for 2018 and 2019 from January through March.. 2. Interview with testing personnel #1 (see CMS 209) confirmed the laboratory did not have a QA policy prior to March 27, 2019 and no documentation of QA activity is available in 2018 and 2019 prior to April 2019.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 quality control (QC) records for testing performed on the Emerald Cell-Dyn Hematology analyzer and staff interview, the laboratory failed to monitor over time, the accuracy and precision of test performance. Findings include: 1. Review of 2018 and 2019 QC records revealed no evidence of Levey-Jennings (LJ) charts or other means for reviewing control values to

	determine shifts or trends in September through December of 2018 and January, February and March of 2019. 2. Interview with testing personnel # 1 (see CMS 209) on May 7, 2019 at 2 pm in the break room confirmed LJ charts or cumulative data was not printed in the months listed above and controls were not reviewed for shifts or trends.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 QC records and staff interview, the laboratory reported patient results when results of controls fell outside the acceptable ranges. Findings include: 1. Review of the laboratory's QC records revealed the results of controls fell outside the acceptable ranges on the following: control lot number 7324: 2/15/18 normal & high controls were below the acceptable range for white blood cell count (WBC) No low control was run. 2/16/18 all three levels were below the acceptable range for WBC 2/19/18 all three levels were below the acceptable range for WBC 2/23/18 two of three levels (high & normal) were below the acceptable range for WBC 2/26/19 all three levels were below the acceptable range for WBC 2/27/18 all three levels were below the acceptable range for WBC 2/28 /18 two of three levels (high & normal) were below the acceptable range for WBC 3 /01/18 all three levels were below the acceptable range for WBC 3/02/18 two of three levels (high & normal) were below the acceptable range for WBC 4/24/19 results for platelet count showed error on all three levels 4/25/19 normal & high controls were above the acceptable range for red blood cell count (RBC) & hematocrit (HCT) 4/26 /19 normal & high controls were above the acceptable range for red blood cell count (RBC) & hematocrit (HCT) 4/29/19 high controls were above the acceptable range for red blood cell count (RBC), hematocrit (HCT) and platelets. No other controls were run. 5/02/19 normal & high controls were above the acceptable range for red blood cell count (RBC) & hematocrit (HCT) 5/03/19 high control was above the acceptable range for hematocrit (HCT) 2. Review of reports pulled by the office manager and interview with the office manager on May 7, 2019 at 2:45 pm in the reception area confirmed patient results were reported on days when controls were unacceptable. 3. Interview with testing personnel #1 (See CMS 209) on May 7, 2019 at 2:50 pm in the laboratory revealed she was not aware it was not acceptable to report patient results when controls were out of range until May 1, 2019 when an employee at the sister location informed her of this and she routinely reported patient results in 2018 and until May 2019 when control results were unacceptable.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of records to review and staff interview, the laboratory failed to take and document corrective action when results of controls fell outside the acceptable ranges. Finding include: 1. Review of QC records revealed multiple times that controls fell outside the acceptable ranges. Refer to D 5481 2. Review of laboratory records revealed no documenation of corrective action for the unacceptable control results. 3. Interview with TP #1 (see CMS 209) on May 7, 2019 at 2:50 pm in the laboratory confirmed corrective action is not documented for out of range controls in 2018 and until May 2019.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to provide overall management and direction to the laboratory. Findings include: Refer to D 6020, D 6021, D 6025 & D 6029
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and staff interview revealed the laboratory director (LD)failed to ensure the QC program was established and maintained. Findings include: 1. Review of QC records for September through December of 2018 and January, February and March of 2019 revealed no documentation of review by the LD. Also refer to: D 5441, D 5481 & D 5783
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of QA records and staff interview, the laboratory director failed to ensure a QA program was established and maintained in 2018 and until March 27, 2019. Findings include: Refer to D 5291
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to ensure patient tests results were not reported when the Emerald Cell DYN hematology analyzer was not functing properly. Findings include: Refer to: D 5481
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of testing personnel training & competency assessment records and staff interview, the laboratory director failed to ensure testing personnel had the appropriate training needed to report accurate results. Findings include: 1. Review of laboratory personnel records revealed no documentation of training to perform CBC testing on the Emerald Cell-DYN for testing personnel #1. 2. Review of TP #1's competency assessment records revealed no documentation of assessment until 5/2/19. This competency assessment was performed by a TP from a sister office who does not meet the requirements for technical consultant. 3. Interview with TP # 1 (see CMS 209) and the office manager on May 7, 2019 at 3:15 pm in the break room confirmed there is no documentation of training for TP #1, no documentation of competency assessment for TP #1 prior to May 12, 2019 and the competency assessment performed on May 2, 2019 was not performed by the technical consultant. Also refer to D 5481 & D 5783
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records and staff interview, the technical consultant/laboratory director failed to perform competency assessment in 2018 and 2019. Findings include: 1. Review of TP #1's competency assessment records revealed no documentation of assessment in 2018. Competency assessment was performed on May 2, 2019 by a TP from a sister office who does not meet the requirements for technical consultant. 3. Interview with TP # 1 (see CMS 209) and the office manager on May 7, 2019 at 3:15 pm in the break room confirmed there is no documentation of competency assessment for TP #1 prior to May 2, 2019 and the competency assessment performed on May 2, 2019 was not performed by the technical consultant.