Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0959698	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clear Lake Pediatric Clinic, Pa	16 Professional Park Dr, Webster, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the laboratory's American Proficiency Institute's results and staff interview, it was revealed the laboratory failed to attain a score of at least 80 percent for the analyte Lymphocytes for the 2017 Hematology/Coagulation- 3rd Event. Findings include: 1. A review of the laboratory's American Proficiency Institute's 2017 Hematology/Coagulation- 3rd Event revealed the laboratory received a grade of unacceptable for 2 out of 5 samples, resulting in a 60 percent for the analyte Lymphocytes. The following results were submitted: Sample Reported Result Expected Results HEM-11 6.2 26.0-29.7 HEM-12 31.5 25.0-29.4 HEM-13 13.4 12.3-

	15.1 HEM-14 10.7 9.6-12.2 HEM-15 54.8 50.6-57.6 2. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2 /19) on 7/9/19 at 10:00 in the emergency room confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Beckman Coulter 4C-ES Cell Controls, the CLPC Medical Lab Maintenance Logs from 2019, surveyor observation of reagents stored in the laboratory's refrigerator, and staff interview, it was revealed the laboratory failed to ensure reagents were stored at temperatures required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the Beckman Coulter 4C-ES Cell Controls revealed the manufacturer required the controls to be stored at a temperature range of 2 - 8C. 2. A review of the laboratory's temperature records for the CLPC Medical Lab Maintenance logs from 2019 revealed the laboratory documented unacceptable temperature ranges for the 'Fridge Temp' on the following dates: 3/7/19 Temperature reading 1.9 3/8/19 Temperature reading 1.9 3/28/19 Temperature reading 1.0 4/16/19 Temperature reading 1.9 4/17/19 Temperature reading 1.9 4/18/19 Temperature reading 1.6 5/1/19 Temperature reading 1.2 6/14/19 Temperature reading 1.0 3. Surveyor observation of quality control material stored in the laboratory's refrigerator 11:50 on 7/9/19 revealed the following controls stored in the refrigerator with the thermometer reading of 1.3C: Coulter 4C-ES Cell Controls Normal lot # 077800 Abnormal low lot # 067800 Abnormal high lot # 087800 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9/19 at 11:55 in the laboratory confirmed that the refrigerator temperature was too low for storing the quality controls according to the manufacturer's instructions. This confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
I. Based on review of the Operator's guide for the Beckman Coulter Act Diff 2 hematology analyzer, the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer from 2017 to 2019, review of the laboratory's CLPC Medical Lab Maintenance Logs, and staff interview, it was revealed the laboratory failed have documentation of performing the manufacturer's required 'pre-calibration checks' for 4 of 4 calibrations. Findings include: 1. A review of the Operator's guide for the Beckman Couldter Act Diff 2 hematology analyzer states the following must be performed prior to calibrating the analyzer: Precalibration Checks: - Do the Clean the Baths procedure in Chapter 6 of this manual. - Calibrate only when the ambient temperature is within the system's operating range (20 - 35C). 2. A review of the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer revealed the anlayzer was calibrated on the following dates: 12/28/17 6/28 /18 12/20/18 6/22/19 3. A review of the laboratory's Communication Logs from 2017 to 2019 revealed the laboratory failed to Clean the Baths on the days when the laboratory calibrated the analyzer. Further review of the laboratory's Communication Logs revealed the Clean the Baths procedure was performed on 2/3/18, no calibration was performed after this procedure was performed. 4. A review of the laboratory's CLPC Medical Lab Maintenance Logs from 2017 to 2019 revealed the laboratory failed to calibrate only when the ambient temperature is within the system's operating range of (20-35C). The laboratory's room temperature was recorded at the following temperatures on the days the calibration was performed on the Beckman Coulter Act Diff 2: 6/28/18 Temperature reading 19C 12/20/18 Temperature reading 19C 6/22/19 Temperature reading 19C 5. An interview with testing personnel #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9/19 at 10:55 in the emergency room confirmed the above findings. II. Based on review of the Operator's guide for the Beckman Coulter Act Diff 2 hematology analyzer, the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer from 2017 to 2019, and staff interview, it was revealed the laboratory failed have documentation of verify the calibration by running quality controls after the calibration for 3 of 4 calibrations Findings include: 1. A review of the Operator's guide for the Beckman Couldter Act Diff 2 hematology analyzer states the following must be performed after calibrating the analyzer: -Verify calibration by running 4C Cell Control 2. A review of the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer revealed the anlayzer was calibrated on the following dates: 12/28/17 6/28/18 12/20/18 6/22/19 3. A review of the laboratory's quality control records for 2017 to 2019 revealed the laboratory failed to verify the calibration by running the 4C Cell Controls after calibrating the Beckman Coulter Act Diff 2 analyzer 3 of 4 times. 12/28/17- quality controls run after calibration 6/28/18- quality controls not run after calibration- no patients run/resulted after calibration was performed 12/20/18- quality controls not run after calibration- 1 patient run/resulted after calibration was performed (patient ID000042401) 6/22/19- quality controls not run after calibration- no patient run/resulted after calibration was performed 4. An interview with testing personnel #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9/19 at 10:55 in the emergency room confirmed the above findings. III. Based on review of the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer from 2017 to 2019, review of the laboratory's Communication Log, and staff interview, it was revealed the laboratory failed to have documentation of calibrations when calibration factors had changed. 1. A review of the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer from 2017 to 2019 revealed calibrations were performed on the following days: A. 3/8/17 New calibration factors WBC: 1.145 RBC: 1.157 HGB:

	1.098 MCV: 0.9060 PLT: 1.040 MPV: 1.108 B. 12/28/17 In use calibration factors WBC: 1.103 RBC: 1.157 HGB: 1.118 MCV: 0.9256 PLT: 1.109 MPV: 1.108 There was no documentation of a calibration to document when and why the calibration factors for WBC, HGB, MCV, and PLT, had changed since the calibration on 3/8/17. No change in calibration factors needed as a result of this calibration. C. The calibration performed on 6/28/18 needed no change in calibration factors. D. 12/20/18 New calibration factors WBC: 1.067 RBC: 1.157 HGB: 1.118 MCV: 0.9256 PLT: 1.109 MPV: 1.108 E. 6/22/19 In use calibration factors WBC: 1.067 RBC: 1.143 HGB: 1.118 MCV: 0.9095 PLT: 1.109 MPV: 1.108 There was no documentation of a calibration to document when and why the calibration factors for RBC and MCV had changed since the calibration on 12/20/18. 2. An interview with testing personnel #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9 /19 at 10:55 in the emergency room explained that the technical support specialist from Beckman Coulter "adjusted the numbers"on the analyzer. This confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin MCV - mean corpuscular volume PLT- platelet MPV - mean platelet volume
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the Beckman Coulter Act Diff 2 quality control records, and staff interview, it was revealed the laboratory failed to verify the criteria for acceptability of all control materials. Findings include: 1. A review of the laboratory's policy titled 'C.L.P.C. Medical Laboratory General Policies' stated the following, "Quality Control Policy: All new lot numbers of reagent, control material, test kits or media are verified for quality as detailed in the quality control manual before use in the laboratory." 2. A random review of the Beckman Coulter Act Diff 2 quality control reports from 2019 revealed the following quality control lot numbers were placed into service and the laboratory failed to cross-check the new quality control lot against the old quality control lot: Lot # 079500 Lot # 077800 Lot # 088900 Lot # 089500 Lot # 068900 3. An interview with testing person #1 (as listed on the CMS 209 form) on 7/9/19 at 12:00 in the emergency room revealed the laboratory failed to have documentation of new quality control lots being cross-checked against old quality control lots, verifying the criteria for acceptability of the control material. This confirmed the above findings.
D5479	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Beckman Coulter 4C-ES Cell Controls and staff interview, it was revealed the laboratory failed to have a mechanism in place to follow the manufacturer's instructions for performing quality control testing. Findings include: 1. A review of the manufacturer's instructions for the Beckman Coulter 4C-ES Cell Controls under the Table of Expected Results states: **Assumes that the Instruction Section of the package insert is performed a maximum of 20 times within 35 days. 3. The laboratory was asked to provide documentation of performing quality control testing as required. No documentation was provided. 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9/19 at 11:15 in the emergency room revealed "the quality control is good for 30 days". After showing testing person #1 the manufacturer's instructions for the controls, it was confirmed that the laboratory did not have a mechanism in place for performing quality control testing according to the manufacturer's instructions.
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 quality control policy, manufacturer's instructions for the Beckman Coulter 4C-ES Cell Control, review of the laboratory's quality control records from 2018, and staff interview, it was revealed the laboratory failed to ensure control results were acceptable prior to reporting patient results. Findings include: 1. Based on review of the laboratory's policy titled 'C.L.P.C Medical Laboratory General Policies' (signed by the laboratory director on 10/27/2017) revealed: A. Quality control samples are analyzed each day (as outlined in the technical procedure manual), and must be within acceptable limits before patient samples may be analyzed. B. Any controls which are outside acceptable limits are addressed and corrected before patient samples tested. 2. Review of the manufacturer's instructions for the Beckman Coulter 4C-ES Cell Control- Abnormal High control stated: A. "*" flags for platelet, MONO% and MONO # parameters confirm that distribution criteria are not met. 2. A random review of the laboratory's quality control records from 2019 revealed the following days where the Abnormal High control was receiving "*" flags for MONO% and MONO#, however the laboratory failed to perform remedial action to correct the problem: -Abnormal High Lot # 089400 Lot in use with flags present from 6/1/18 to 6/29/18 -Abnormal High Lot # 087500 Lot in use with flags present from 6/30/18 to 8/31/18 -Abnormal High Lot # 088200 Lot in use with flags present from 9/1/18 to 10/1/18 4. An interview with testing person #1 (as indicated on the CMS 209 form signed by the laboratory

	director on 7/2/19) on 7/9/19 at 11:30 in the emergency room revealed the manufacturer told the laboratory that flags on the MONO# and MONO% were normal and it was ok to accept this quality control as acceptable. The laboratory was asked to provide documentation of the manufacturer's claims, no documentation was provided. This confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based review of manufacturer's instructions, review of laboratory records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. 3. The laboratory's quality assessment program failed to identify the laboratory failed follow its own policy for new reagent lot confirmation and acceptability (refer to D5401). 2. The laboratory's quality assessment program failed to identify the laboratory failed to ensure reagents were stored at temperatures as required (refer to D5413). 3. The laboratory's quality assessment program failed to identify the laboratory failed to perform and document calibration procedures as required (refer to D5437). 4. The laboratory's quality assessment program failed to identify the laboratory failed to perform quality control testing as required by the naurfacturer's instructions (refer to D5479). 5. The laboratory's quality assessment program failed to identify the laboratory failed to ensure quality control results were acceptable prior to reporting patient results (refer to D5481),
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 a review of the laboratory's policies, the laboratory's quality assessment records, and staff interview, it was revealed that the laboratory director failed to ensure that a quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings include: 1. A review of the laboratory's policies revealed the laboratory's Table of Contents identified there was a 'Quality Assessment Plan' written policy. The 'Quality Assessment Plan' written policy could not be found in the policy binder. The laboratory was asked to provide documentation of a quality assessment policy. No documentation was provided. 2. The laboratory had documentation of 'Semi annual Quality Assurance check list' performed by the laboratory director on the following dates: 3/7/18 1/4/19 6/21/19 3.

	An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/2/19) on 7/9/19 at 12:05 in the emergency room revealed there was not a quality assessment policy. This confirmed the above findings.
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 the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that 4 of 4 testing personnel had documentation of training on the Beckman Coulter Act Diff 2 hematology analyzer prior to performing patient testing (refer to D6066).
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's CMS 209 form, personnel records, the laboratory's 'Laboratory Competency Review' form and staff interview, it was revealed the laboratory failed to fully evaluate the competency for 4 of 4 testing personnel. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 7/2/19) revealed the laboratory identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed competency assessments for 4 of 4 testing personnel were completed by the technical consultant. 3. Further review of the 'Laboratory Competency Review' form revealed the assessment did not contain all of the required elements needed to evaluate the competency of testing personnel. The 'Laboratory Competency Review'' form was missing the following elements: - direct observation of testing procedure 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 7/9/19 at 10:05 in the emergency room confirmed the above findings.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's CMS 209 form, personnel records, the laboratory's 'Laboratory Competency Review' form and staff interview, it was revealed the laboratory failed to fully evaluate the competency for 4 of 4 testing personnel. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 7/2/19) revealed the laboratory identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed competency assessments for 4 of 4 testing personnel were completed by the technical consultant. 3. Further review of the 'Laboratory Competency Review' form revealed the assessment did not contain all of the required elements needed to evaluate the competency of testing personnel. The 'Laboratory Competency Review" form was missing the following elements: - assessment of problem solving skills 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 7/9/19 at 10:05 in the emergency room confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed that 4 of 4 testing personnel failed to have documentation of training on the Beckman Coulter Act Diff 2 hematology analyzer prior to performing patient testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/2 /19) revealed the laboratory identified 4 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that 4 of the 4 testing personnel listed did not have documentation of training on the Beckman Coulter Act Diff 2 hematology analyzer prior to performing patient testing. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 7/2/19 at 09: 30 in the emergency room revealed the laboratory did not have documentation of the training for each of the 4 testing personnel. This confirmed the above findings.