Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0680612	04/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Legacy Community Health Services - Southwest	6441 High Star Dr, Houston, 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 at the entrance and exit conferences. The facility representative was 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.
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 review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer, review of patient test results, and staff interview, it was revealed the laboratory failed to ensure the verification studies were complete. The findings were: 1. A review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer in March 2018 revealed the laboratory failed to

	have documentation of performing the required accuracy studies and verification of patient normal ranges. 2. A review of the laboratory's records revealed the following patient normal ranges were utilized by the facility: a) Newborn WBC 9.1 - 34.0 RBC 4.1- 6.7 HGB 15.0 - 24.0 HCT 44 - 70 MCV 102 - 115 MCH 33 - 39 MCHC 32 - 36 RDW 13.0 - 18.0 Platelet 150 - 450 NEU 6.0 - 23.5 LYM 2.5 - 10.5 b) 1 - 23 Months WBC 6.0-14.0 RBC 3.8 - 5.4 HGB 10.5 - 14.0 HCT 32 - 42 MCV 72 - 88 MCH 24 - 30 MCHC 32 - 36 RDW 11.5 - 16.0 Platelet 150 - 450 NEU 1.1 - 6.6 LYM 1.8 - 9.0 c) 2 - 9 years WBC 4.0 - 12.0 RBC 4.0 - 5.3 HGB 11.5 - 14.5 HCT 33 - 43 MCV 76 - 90 MCH 25 - 31 MCHC 32 - 36 RDW 11.5 - 15.0 Platelet 150 - 450 NEU 1.4 - 6.6 LYM 1.0 - 5.5 d) 10 - 17 years (male) WBC 4.0 - 10.5 RBC 4.2 - 5.6 HGB 12.5 - 16.1 HCT 36 - 47 MCV 78 - 95 MCH 26 - 32 MCHC 32 - 36 RDW 11.5 - 14.0 Platelet 150 - 450 NEU 1.5 - 6.6 LYM 1.3 - 6.0 e) 10 - 17 years (female) WBC 4.0 - 10.5 RBC 4.1 - 5.3 HGB 12.0 - 15.0 HCT 35 - 45 MCV 78 - 95 MCH 26 - 32 MCHC 32 - 36 RDW 11.5 - 14.0 Platelet 150 - 450 NEU 1.5 - 6.6 LYM 1.3 - 6.0 f) 18+ years (male) WBC 4.0 - 10.5 RBC 4.7 - 6.0 HGB 13.5 - 18.0 HCT 42 - 52 MCV 78 - 100 MCH 27 - 31 MCHC 32 - 36 RDW 11.5 - 14.0 Platelet 150 - 450 NEU 1.5 - 6.6 LYM 1.3 - 6.0 g) 18+ years (female) WBC 4.0 - 10.5 RBC 4.2 - 5.4 HGB 12.5 - 16.0 HCT 37 - 47 MCV 78 - 100 MCH 27 - 31 MCHC 32 - 36 RDW 11.5 - 14.0 Platelet 150 - 450 NEU 1.5 - 6.6 LYM 1.3 - 6.0 3. The laboratory was asked to provide documentation of the missing verification studies. No documentation was provided. 4. An interview with the director of laboratory services on 04/19/2018 at 1215 hours in the conference room - after is review of the records - confirmed the findings. Key WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW - red cell distribution width NEU - neutrophils LYM - lymphocytes
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the

	laboratory failed to have documentation of performing calibration verification every six months as required for bilirubin testing performed on the Reichert Unistat analyzer in 2016 and 2017. The findings were: 1. A review of the laboratory's records for bilirubin testing on the Reichert Unistat analyzer revealed the laboratory utilized 2 calibrators and 2 levels of control material and thus, it required calibration verification every 6 months. 2. The laboratory was asked to provide documentation of performing calibration verifications in 2016 and 2017. No documentation was provided. 3. An interview with the director of laboratory services on 04/19/2018 at 1445 hours in the conference room revealed the laboratory did not perform calibration verification. This confirmed the findings.
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 hematology quality control records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of monitoring control values overtime to detect shifts and trends. The findings were: 1. A review of the laboratory's hematology quality control records from 2016 and 2017 revealed the laboratory failed to have documentation of monitoring quality control values overtime for 24 of 24 months. 2. The laboratory was asked to provide documentation of monitoring hematology control values over time. No documentation was provided. 3. An interview with the director of laboratory services on 04/19/2018 at 1440 hours in the conference room revealed the laboratory did not monitor the control values as required. This confirmed the findings.
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 manufacturer's instructions for the BioRad Liquichek Pediatric Control Levels 1 and 2, review of the laboratory's quality control records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of establishing its own ranges as required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the BioRad Liquichek Pediatric Control Levels 1 and 2 (2016-08, 3680-00) under the section titled "Assignment of Values" revealed: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only an guides." 2. A review of the laboratory's bilirubin quality control records from 2017 revealed the laboratory utilized the manufacturer-provided means and ranges to access quality control results. 3. Further review of the laboratory's quality control records revealed the laboratory used the following lots of controls in 2017: a) Lot 21640 in use: 01/01/2017 to 07/06/2017 b) Lot: 21670 in use: 07/07/2017 to present 4. The laboratory was asked to provide documentation of establishing its own ranges for the identified lots. No documentation was provided. 5. An interview with the director of laboratory services on 04/19/2018 at 1330 hours in the conference room revealed the laboratory used the manufacturer's ranges and was unaware of the laboratory's need to establish their own ranges. This confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and staff interview, it was revealed the laboratory failed to have documentation of the laboratory's address on patient reports. The findings were: 1. A review of patient test reports for hematology testing performed on the Sysmex XP-300 hematology analyzer from March 29, 2018 to April 19, 2018 revealed the laboratory performed testing on 5 patients. 2. Further review of the identified 5 patient reports revealed the reports failed to have the laboratory's address printed on each of the 5 reports. 3. The laboratory was asked to provide documentation of the laboratory's address being included on patient test reports. No documentation was provided. 4. An interview with the director of laboratory services on 04/19/2018 at 1230 hours in conference room - after his review of the records-confirmed the findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have a policy which defined the laboratory's panic values and the required notification of providers. The findings were: 1. A review of the laboratory's policies revealed the laboratory failed to have a policy with defined panic values and provided instructions for the notification of providers of panic values. 2. The laboratory was asked to provide documentation of a policy. No documentation was provided. 3. An interview with the director of laboratory services on 04/19/2018 at 1545 hours in conference room revealed the laboratory did not have any define panic values and did not have a policy to ensure the notification of providers of life-threatening values. This confirmed the findings.
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 review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer and staff interview, it was revealed the laboratory director failed to ensure the verification studies were complete (refer to D5421).
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 the laboratory's quality control records, and staff interview it was revealed the laboratory director failed to ensure a quality control plan was established and followed. The findings were: 1. The laboratory director failed to ensure the laboratory monitored quality control values for hematology over time to detect shifts and trends (refer to D5441). 2. The laboratory director failed to ensure the laboratory established its own ranges for controls (refer to D5469).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer and staff interview, it was revealed the technical consultant failed to ensure the verification studies were complete (refer to D5421).