Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2072399	04/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
1st Choice Pediatrics	1205 North 6th Street, Longview, 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	A recertification survey was performed on 4/7/2022-4/8/2022. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D3000 - 42 C.F.R. 493.1101 Condition: Facility Administration 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.
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 the review of the API proficiency testing records from 2020-2021, and confirmed in an interview found the laboratory failed to ensure the TP and/or LD documented attestation sheets to the routine integration of the samples into the patient workload using the laboratory's routine methods for five of six PT testing events. The findings were: 1. Review of the API proficiency testing records from 2020-2021 revealed no documentation of the TP and/or LD attestation for five of six test events. 2020 Hematology/Coagulation-1st event 2020 Hematology/Coagulation-2nd event 2021 Hematology/Coagulation-1st event 2021 Hematology/Coagulation-2nd event 2021 Hematology/Coagulation-3rd event 2. An interview with the manager on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute TP=Testing personnel LD=Laboratory director PT=Proficiency testing
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 review of the laboratory's API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to attain a score of at least 80 percent for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's API proficiency test results from 2020-2021 revealed the laboratory received scores of less than 80% for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. Regulated Analyte Score (%) Erythrocyte Count 40% Hematocrit 40% Hemoglobin 40% Leukocyte Count 40% Platelets 20% White Blood Cell Differential 60% 2. Further review of the API proficiency test results for the 2020 Hematology/Coagulation-1st event reveled the following proficiency samples received unacceptable performance for the above analytes. Erythrocyte Count (x 10E9/L) HSY-01 Reported Result: 4.32 Expected Results: 4.89-5.53 HSY-02 Reported Result: 2.34 Expected Results: 4.04-4.56 HSY-03 Reported Result: 6.21 Expected Results: 2.26-2.56 Hematocrit (%) HSY-01 Reported Result: 36 Expected Results: 41-47 HSY-02 Reported Result: 18 Expected Results: 32-37 HSY-03 Reported Result: 54 Expected Results: 16-19 Hemoglobin (g /dL) HSY-01 Reported Result: 12.4 Expected Results: 14.7-17.1 HSY-02 Reported Result: 6.1 Expected Results: 11.4-13.2 HSY-03 Reported Result: 19.1 Expected Results: 5.6-6.5 Leukocyte Count (x 10E9/L) HSY-01 Reported Result: 7.8 Expected Results: 15.1-20.6 HSY-02 Reported Result: 3.6 Expected Results: 6.0-8.3 HSY-04 Reported Result: 17.6 Expected Results: 10.6-14.3 Platelets (x 10E9/L) HSY-01 Reported Result: 226 Expected Results: 385-644 HSY-02 Reported Result: 53 Expected Results: 163-274 HSY-03 Reported Result: 119 Expected Results: 40-68 HSY-04 Reported Result: 483 Expected Results: 91-152 White Blood Cell Differential Lymphocytes (%) HSY-02 Reported Result: 25.6 Expected Results: 27.0-31.9 HSY-03 Reported Result: 38.3 Expected Results: 19.8-26.4 Neut/Gran (%) HSY-01 Reported Result: 57.0 Expected Results: 47.7-53.2 HSY-02 Reported Result: 64.0 Expected Results: 55.7-62.1 HSY-03 Reported Result: 48.1 Expected Results: 62.6-70.6 3. An interview with the manager on 4/7/22 at 10:40 am in the office confirmed the above findings. Key: API=American Proficiency Institute
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the review of the CASPER Report 155 report, the review of the laboratory's API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to attain an overall acceptable score of at least 80 percent for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the CASPER 155 report revealed the laboratory attained an overall unacceptable score of 40% in Hematology in 2020 Hematology/Coagulation-1st event. 2020 Hematology/Coagulation-1st event 40% 2. Review of the laboratory's API proficiency test results from 2020-2021 revealed the laboratory received scores of less than 80% for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. Regulated Analyte Score (%) Erythrocyte Count 40% Hematocrit 40%

	Hemoglobin 40% Leukocyte Count 40% Platelets 20% White Blood Cell Differential 60% 3. An interview with the manager on 4/7/22 at 10:40 am in the office confirmed the above findings. Key: CASPER=Certification and Survey Provider Enhanced Reporting API=American Proficiency Institute
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the surveyor's direct observation, IFU from FDA website, the review of the laboratory's COVID testing records from 2020-2022, and confirmed in an interview found the laboratory failed to report 71 positive Rapid SARS-CoV-2 Antigen test results as required by 42 CFR 493.41 and 493.1100(a) for 15 of 15 months reviewed from 12/2/2020 to 2/11/2022. The findings were: 1. Review BD Veritor system for Rapid Detection of SARS-CoV-2 with the BD Veritor Plus Analyzer IFU (REF: 256082; 2021-03; L012304(05)) under Conditions of Authorization for the Laboratory revealed "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review Quidel Sofia2 Flu+SARS Antigen IFU (RED: 20390) under Conditions of Authorization for the Laboratory and Patient Care Settings revealed "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the laboratory COVID testing log from December 2020 to May 2021 revealed the laboratory used BD Veritor rapid COVID device (SN#: 2010160JC9620) from December 2020 to May 2021. 4. Surveyor's direct observation revealed the laboratory performs rapid Flu+SARS antigen on two of two Quidel Sofia2 devices (SN#: 25020437 and SN#: 25004550) starting from January 2021 to current. 5. Review of the COVID testing records from 12/2/2020 to 2/11/2022 provided by the facility revealed 438 patients were tested for SARS-CoV-2. Refer to Patient alias List for 45D2072399 for Rapid COVID testing. 6. An interview with the manager on 4/7/2022 at 9:30 am in the office confirmed the above findings. The manager stated the facility reported to a local health authority in the beginning of pandemic via phone and the facility stopped reporting thinking it was not necessary. Key: IFU=Instruction for Use FDA=Food and Drug Administration
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's CBC QC records from 2020-2021 and confirmed in an interview found that the laboratory failed to retain 22 of 24 QC lots of Sysmex EIGHTCHECK-3WP X-TRA hematology control assay sheets for a minimum of 2 years. The findings were: 1. Review of the laboratory Sysmex EIGHTCHECK-3WP X-TRA hematology control assay sheets revealed the laboratory failed to retain assay sheets for 22 of 24 quality control assay sheets used in 2020 and 2021. The two hematology control assay sheets found were: Lot# 20260710 Exp 04-May-22 Lot# 03370710 Exp 03-Jan-21 2. An interview with the manager on 4/8/22 at 9:24 am in the office confirmed the laboratory did not retain the hematology control assay sheets for a minimum of 2 years. Key: CBC=Complete Blood Count QC=Quality Control
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 the review of the manufacturer's instructions for use, the laboratory's temperature and humidity logs from 2020-2021, and confirmed in an interview found the laboratory failed to document the operating room temperature and humidity as required by the manufacturer for 24 of 24 months on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in chapter 14. Technical Information 14.1 Specification revealed the operating environment in ambient temperature was 15C-30C and relative humidity was 30% to 85%. 2. Review of the laboratory's temperature and humidity logs from 2020-2021 revealed no documentation of the required operating temperature and humidity for 24 of 24 months. 3. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 4 An interview with the manager on 4/7/22 at 11:45 am in the office confirmed the above findings. The manager stated the facility did not have temperature and humidity logs. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on the review of the manufacturer's manual, the laboratory's maintenance records from 2020-2021, CMS 116 records, and confirmed in an interview found the laboratory failed to perform and document maintenance as defined by the manufacturer's instructions for 24 of 24 months for one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 12. Cleaning and Maintenance 12.1 Maintenance schedule revealed daily and weekly maintenance are scheduled for the XP-300 Hematology analyzer (SN#:A5008). Daily Clean TD chambers and diluted sample lines (Shutdown) Check trap chamber level and discard Weekly Clean SRV tray 2. Review of the laboratory's maintenance records from 2020-2021 revealed no documentation of daily and weekly maintenance from 2020-2021. 3. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 4 An interview with the manager on 4/7/22 at 11:50 am in the office confirmed the above findings. The manager stated the facility did not know the maintenance schedule. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director
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 the review of the laboratory's QC records from 2020-2021 and confirmed in an interview found the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for five of five analytes on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the laboratory's QC records from 2020-2021 revealed the laboratory not have a method in place to monitor quality control values over time to detect shifts and trends for five of five analytes on one of one Sysmex XP-300 hematology instrument (SN#: A5008). RBC HCT HGB WBC PLT 2. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 3. An interview with the manager on 4/7/22 at 12:28 pm in the office confirmed the above findings. Key: QC=Quality Control RBC=Red Blood Cell HCT=Hematocrit HGB=Hemoglobin WBC=White Blood Cell PLT=Platelets CMS=Center of Medicare and Medicaid Service LD=Laboratory Director
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's manual, the laboratory reagent replacement history logs from 9/11/20 to 3/31/22 and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on eight of 15 days reviewed on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 4. Reagents revealed two reagents were used in the XP-300 Hematology analyzer (SN#:A5008). Cellpack Stromatolyser-WH 2. Random review of the reagent replacement history logs from 9/11/20 to 3/31/22 revealed eight of 15 days reviewed with no documentation of the quality control run after the following reagent change on the Sysmex XP-300 (SN#A5008) hematology analyzer. 9/11/20 at 8:41 am Stromatolyser-WH Lot#Y0002 Exp 2/21/2021 10/12/21 at 9:56 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 10/19/21 at 10:56 am Cellpack Lot#Y1008 Exp 1/30/2023 11/16/21 at 10:06 am Cellpack Lot#Y1008 Exp 1/30/2023 12/27/21 at 9:38 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 01/14/22 at 10:01 am Cellpack Lot#Y1012 Exp 5/01/2023 3/04/22 at 9:27 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 3/09/22 at 10:14 am Cellpack Lot#Y2002 Exp 7/12/2023 3. Review of the patient test records for the above date revealed the laboratory performed eight patient testing after the reagent change above with no documentation of the quality control run. Refer to Patients alias after Reagnet Replacement. 4. An interview with the manager on 4/7/22 at 12:25 pm in the office confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the laboratory's QA records from 2020-2021, and confirmed in an interview found the laboratory failed to provide QA records for HHS or its designee review. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under D. Quality Assurance Records revealed " All quality assurance records will be maintained by the laboratory for a period of two years and will be made available for review by HHS or its designee." 2. Review of the laboratory's QA records from 2020-2021 revealed no documentation of QA check list for QA

	indicators from 2020-2021. 3. An interview with the manager on 4/7/22 at 12:00 pm in the office confimed the above findings. The manager could not provide any QA records for review. Key: QA=Quality Assurance
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's final reports and confirmed in an interview found the laboratory failed to provide the reference ranges or reference intervals to the authorized person who ordered the test for one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the laboratory's final reports revealed no reference ranges or reference intervals were provided to the authorized person who ordered the test for one of one Sysmex XP-300 hematology instrument (SN# A5008). 2. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 3. An interview with the manager on 4/8/22 at 10:00 am in the office confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document the evaluation and verification for one of six PT events in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under B. Quality Assurance Indicators 3. Proficiency Testing revealed "All proficiency test results will be reviewed and corrective actions will be taken for any failures. 2. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed no documentation of evaluation and verification by the LD for one of six PT events. 2020 Hematology/Coagulation-1st event 3. Review of the API proficiency test results for the 2020 Hematology/Coagulation-1st event reveled six of six regulated analytes received unacceptable performance in 2020 Hematology/Coagulation-1st event. (Refer to D2121) 4. An interview with RN on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute LD=Laboratory Director PT=Proficiency testing

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document of corrective actions for one of six PT events in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under B. Quality Assurance Indicators 3. Proficiency Testing revealed "All proficiency test results will be reviewed and corrective actions will be taken for any failures. 2. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed no documentation of corrective actions for the unacceptable performance of six of six regulated analytes by the LD for one of six PT events. 2020 Hematology/Coagulation-1st event 3. Review of the API proficiency test results for the 2020 Hematology /Coagulation-1st event reveled six of six regulated analytes received unacceptable performance in 2020 Hematology/Coagulation-1st event. Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count Platelets White Blood Cell Differential 4. An interview with RN on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute LD=Laboratory Director PT=Proficiency testing
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's training records and confirmed in an interview found the laboratory failed to document training records prior to perform and report patient test results for one of four TP on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the laboratory's training records revealed

	no documentation of training records prior to perform and report patient test results for one of four TP on one of one Sysmex XP-300 hematology instrument (SN#: A5008). TP#3 (based on CMS 209 signed by the LD on 3/30/22) Hired Date: 6/15 /2020 2. An interview with the manager and TP#3 on 4/7/22 at 9:55 am in the office confirmed the above findings. TP#3 confirmed to perform and report patient test results independently starting on February 2020. Key: TP=Testing personnel CMS=Center of Medicare and Medicare Service LD= Laboratory Director