Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2172639	12/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
1st Choice Healthcare Services, Llc	123 E Main Street, Hookerton, NC	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 monthly QA (quality assessment) forms, random review of patient requisitions and test reports (accession #6416, #6419, #6459, #6466, #6590, #6870), and interview with the owner and TS (technical supervisor) 12/6/22, the laboratory's quality assessment program failed to identify problems identified during the survey in the preanalytic systems. Review of the "SLP 13 ... : Specimen Collection and Handling" procedure revealed " ... Specimen Transport ... Note: Every patient sample must have two identifiers and be properly packaged with the correct patient information. All writing on the requisition form and sample must be legible and complete. The following needs to be on the requisition form: Date of collection Collector's initials Two proper identifiers ... The sample must match the clinical ID /requisition form ... Sample Processing: Accessioning and Order Entry ... Accession the sample. Check the specimen and accompanying documents again to ensure patient identifiers (see EasyTox User Manual) match. ... If a discrepancy is found, the specimen will be placed aside for further investigation. ... Specimen Rejection Criteria If it is determined that the specimen is unlabeled or mislabeled (For example - no sample collection date, missing patient identifiers and/or mismatching information with test requisition), the specimen must be discarded and recollected. ...". Review of the "General Laboratory Systems Quality Management Policy" revealed "... Specimen Identification and Integrity Specimens are collected and handled according to manufacturer's specifications. ... Specimens that do not meet acceptable criteria are rejected according to our specimen rejection policy. ... These issues are maintained

	and reviewed on our monthly QA form. ... Patient Test Management All CLIA required information is obtained on the requisition as specified in the patient test management policy. ...". Review of monthly QA forms revealed no problems noted during 2020, 2021, and 2022. Review of random patient requisitions and test reports revealed missing information on requisitions and information on requisitions that did not match information on test reports. Examples: a. Accession #6416 - date of collection not legible, time of collection missing b. Accession #6419 - missing date and time of collection c. Accession #6459 - collection date of 10/6/22 on requisition, test report lists collection date as 10/11/22 d. Accession #6466 - missing date and time of collection, collector initials e. Accession #6590 - missing date and time of collection, collector initials f. Accession #6870 - missing date of collection During interview at approximately 2:30 p.m., the owner and TS stated that specimens would not be rejected if some of the information was missing from the requisition. They stated that specimen collectors are supposed to ensure all information is present on requisitions and personnel who accession the specimens should try to obtain any missing information overlooked by the collector.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals, review of laboratory quality control (QC) and calibration procedures, review of manufacturers' instructions and interviews with laboratory director (LD) and liquid chromatography and mass spectrometry device (LCMS) management consultant 12/6/22, the laboratory has duplicate procedures, and the laboratory QC and calibration procedures for the Diatron Pictus 700 and LCMS analyzers fail to specify the type and levels of QC and /or calibration reagents used by the laboratory. Findings: 1. The laboratory has duplicate procedures. Findings: Review of laboratory records revealed 2 procedure manuals. Procedure manual #1 was signed and implemented by the LD on 12/18/19 when the laboratory was only performing drug screen testing on the Diatron Pictus 700 analyzer. Procedure manual #2 was signed and implemented by the LD on 7/5/20 when the laboratory began toxicology confirmation testing on the LCMS analyzer under a LCMS management company. Review of laboratory procedure manuals #1

	and #2 revealed duplicate procedures and it was unclear which procedures were discontinued and which procedures were current for the laboratory testing performed. For example: a. 2 procedures for QC, "Quality Control and Calibrations Procedure", signed by LD 12/18/19 and "SLP 26 ...: Quality Control", signed by LD 7/5/20. b. 2 procedures for competency assessment, "Personnel Competency Assessment", signed by LD 12/18/19 and "SLP 8...: Competency", signed by LD 7/5/20. c. 2 procedures for reference and/or referral of specimens, "Reference Laboratory Testing Policy", signed by LD 12/18/19 and SLP 11...:Referral of Specimens to Outside Labs", signed by LD 7/5/20. During interview with LCMS management consultant at approximately 12:00 p.m., the consultant stated they do not manage the testing on the Diatron Pictus 700 and the procedures in procedure manual #2 only apply to the LCMS testing. During exit interview with LD at approximately 3:30 p.m., the LD confirmed the laboratory had 2 procedure manuals with duplicate procedures. He stated they were trying to work with the LCMS management company to combine procedures that were specific to his laboratory. 2. Review of laboratory procedures revealed the QC and calibration procedures for the drug screen testing performed on the Diatron Pictus failed to define the type and levels of QC and calibration reagents used. Findings: Review of laboratory procedure "Quality Control and Calibrations Procedure General Laboratory Policy...All quality control materials utilized are recommended by the instrument, system and method manufacturers and/or established assayed values for the methods performed.". The procedure fails to include the type and levels of QC and calibration reagents used on the Diatron Pictus. Review of manufacturer's instructions (MI) for the drug screen reagents revealed the MI's fail to include the type and levels of QC and Calibration reagents used by the laboratory. For example: a. "DRI Ethyl Alcohol Assay...Quality Control and Calibration...Good laboratory practices suggest the use of controls to ensure proper assay performance. Both 50 mg/dL and 300 mg /dL ethyl alcohol controls are available...establish the acceptable control ranges for your own laboratory. Both negative and 100 mg/dL alcohol calibrators should be used to calibrate the assay.". b. "DRI Cannabinoid Assay...Good laboratory practice suggests the use of control specimens...Use controls near the cutoff calibrator to validate the calibration...Qualitative analysis...use the 20ng/mL., or 50 ng/mL, or 100 ng/mL...as a cutoff level.". c. "DRI Oxycodone Assay...Quality Control and Calibration...For qualitative analysis of samples, use either the Oxycodone 100 Calibrator, or the Oxycodone 300 calibrator, as a cutoff level.". 3. Review of laboratory procedures and QC package insert revealed the procedures and QC package insert failed to correctly identify the type and/or level of QC used for the drug confirmation testing performed on the LCMS analyzer. Findings: Review of laboratory procedure "SLP 26...:Quality Control...6.2 LCMS...Data analyst...Daily verify that control values are within allowable tolerance ranges (see instrument specific SLPs and manufacturer's instructions and/or inserts).". The procedure fails to state the type and levels of QC reagent used on the LCMS analyzer. Review of laboratory procedure "SLP...Sample Preparation...4.5.2.1.2....Quality Controls... Positive control level 2...Positive control level 4...Positive control level 6...". Review of QC package insert "One Shot Urine Quality Control (unconjugated)" revealed the 3 levels of positive QC used by the laboratory as "...Low QC...Mid QC...High QC...". Interview with LCMS management consultant at approximately 12:00 p.m. confirmed the procedures failed to correctly identify the type and/or levels of QC reagent used on the LCMS analyzer. She stated the QC reagents are labeled positive control level 2, positive control level 4 and positive control level 6, but are referred as Low QC, Mid QC and High QC in the package insert. She also confirmed both laboratory procedures failed to include the type "name" of QC reagent used for testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with laboratory owner 12/6/22, the laboratory failed to discard quality control (QC) reagent that had exceeded its expiration date. Findings: At approximately 2:00 p.m. surveyor observed one bottle urine QC reagent, DRI THC 60 ng/mL - Lot # 74236571 - expiration 6/30/22, in a clear plastic tray on the second shelf of the laboratory refrigerator. Interview with laboratory owner at 2:00 p.m. confirmed the urine QC reagent was expired. The owner promptly disposed of the QC reagent.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the Federal Drug Administration (FDA) medical device database, review of verification of performance specification records for the Diatron Pictus 700 analyzer and interview with LD 12/6/22, the laboratory failed to perform specimen stability studies for the drug screen testing performed. Findings: The laboratory performs drug screen testing on the Diatron Pictus 700 analyzer for the following analytes; Amphetamines (AMPH)Cannaboids (THC), Cocaine (COC), Ethyl Alcohol (ETOH), Oxycodone (OXY) and Opiates (OPI) using Thermo Scientific DRI reagents. Review of FDA medical device database revealed the Thermo Scientific DRI reagents are not approved by the FDA for use on the Diatron Pictus 700 analyzer. Review of performance specification records for the testing performed on the Diatron Pictus 700 revealed no documentation of specimen stability studies. During exit interview with LD at approximately 3:30 p.m., the LD confirmed the laboratory had not performed specimen stability studies for the testing performed on the Diatron Pictus 700. He stated they were unaware that specimen stability studies should be performed.
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 interview with the TS (technical supervisor) and review of a random patient test report (accession #UR22-6416) 12/6/22, the laboratory's patient test reports failed to include the name and address of the laboratory where the urine toxicology confirmation testing was interpreted. Findings: During interview at approximately 11: 20 a.m., the TS stated that urine toxicology confirmation results from the LCMS analyzer are not interpreted by the laboratory. He stated they are sent to another laboratory for interpretation. Review of a random patient test report (accession #UR22-6416) revealed only the laboratory's name and address. The test report did not include the name and address of the laboratory located in another city where the urine toxicology confirmation test results were interpreted.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 AAB (American Association of Bioanalysts) and CAP (College of American Pathologists) proficiency testing records 12/6/22, the laboratory failed to ensure all proficiency testing results were reviewed by appropriate staff to evaluate the laboratory's performance and identify any problems requiring corrective action. Findings: Review of the "Proficiency Testing Policy" revealed "... When proficiency testing results are returned, these will be evaluated. ... The lab director must review and sign all results.". Review of the "General Laboratory Systems Quality Management Policy" revealed "... Proficiency Testing ... PT results are reviewed with the laboratory director upon receipt and retained for a period of two years. ...". Review of 2020, 2021, and 2022 proficiency testing results revealed the results were not signed and dated by the laboratory director for the following events: a. AAB 2020 Q3 b. AAB 2022 Q1 c. AAB 2022 Q2 (printed during survey).