Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2189459	01/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Concierge Care, Llc	3535 S Jefferson Ave Suite 104, Saint Louis, MO	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedure manual, quality control program and interviews, the laboratory failed to include step-by-step procedures (refer to D5403) and failed to have control procedures that monitor the accuracy and precision of the complete analytic process (refer to D5441).
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 the procedure manual and interview with testing personnel (TP) #1, the laboratory failed to have step-by-step procedures for urine microscopy, white blood cell (WBC) manual differentials, corrective actions, calibration and control processes for the Sysmex XN-430. Findings: 1. The laboratory failed to have a procedure for performing moderate complex urine microscopy 2. Review of the procedure manual for the Sysmex XN-430 hematology analyzer showed a lack of procedures for control and calibration processes and WBC manual differentials. 3. The laboratory failed to have a procedure for corrective actions. 4. Interview with TP #1 on January 5, 2021 at 11:00 AM confirmed the laboratory failed to have have step-by step procedures for urine microscopy, white blood cell manual differentials, corrective actions, calibration and control processes for the Sysmex XN-430.
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 temperature logs and interview with testing personnel (TP) #1, the laboratory failed to document room temperature from July 20, 2020 to date January 5, 2021. Findings: 1. Review of temperature logs showed a lack of documentation for room temperature from July 20, 2020 to date January 5, 2021. 2. Interview with TP #1 on January 5, 2020 at 10:45 AM confirmed the laboratory failed to document room temperature.
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 Sysmex XN 430 hematology instrument, quality control (QC) package insert, and interview with the testing personnel (TP) #1, the laboratory failed to establish a control procedure that monitored the accuracy and precision of the complete analytic process. Findings: 1. Review of QC ranges in the Sysmex XN 430 hematology instrument showed: lot # 02131401 level one QC ranges: RBC: 2.17-2.43 HGB: 5.7-6.3 HCT: 16.1-18.5 PLT: 35-82 lot # 02131402 level two QC ranges: RBC: 3.92-4.32 HGB: 11.6-12.6 HCT: 31.6-36 PLT: 192-276 lot # 02131403 level three QC ranges: RBC: 4.56-5.02 HGB: 14.7-15.9 HCT: 39.6-44.6 PLT: 444-567 2. Review of the Sysmex XN QC package insert showed: Lot # 02131401 level one QC ranges: RBC: 2.20-2.43 HGB: 5.8-6.4 HCT: 16.4-18.9 PLT: 37-92 Lot #02131402 level two QC ranges: RBC: 3.98-4.31 HGB: 12.0-13.0 HCT: 33.1-37.3 PLT: 213-265 Lot #02131403 level three QC ranges: RBC: 4.74-5.13 HGB: 15.1-16.4 HCT: 41.1-46.4 PLT: 469-562 3. Interview with TP #1 stated, "it was her understanding that they were using the package insert ranges and that the Sysmex representative said when we put the new lot # in the Sysmex the QC ranges would automatically change." 4. Interview on January 5, 2021 at 10:30 AM with TP #1 confirmed, the laboratory failed to establish a control procedure that monitored the accuracy and precision of the complete analytic process.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the verification procedures, quality assessment program, testing personnel training, procedure manuals, and interviews, the laboratory director failed to ensure that verification procedures used are adequate (refer to D6086); failed to ensure that the quality assessment programs are established (refer to D6094); ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training (refer to D6102) and ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process (refer to D6106).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 Sysmex XN-430 verification procedures and interview with the clinical consultant (CC) and testing personnel (TP) #1, the laboratory director (LD) failed to ensure manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. Findings: 1. Review of Sysmex XN-430 verification procedures showed no documentation for verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes; white blood cell, red blood cell, hemoglobin, hematocrit and platelets. 2. Interview with the CC and TP #1 on January 5, 2021 at 10: 30 AM confirmed the LD failed to ensure the Sysmex verification procedures included manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the testing personnel (TP) #1, the laboratory director failed to ensure a quality assessment program was established to assure the quality of laboratory services. Findings: 1. No quality assessment program was available for review. 2. Interview with the TP #1 on January 5, 2021 at 11:00 AM confirmed the LD failed to ensure a quality assessment program was established to identify failures.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 lack of testing personnel (TP) training documentation and interview with the clinical consultant (CC) and testing personnel (TP) #1, the laboratory director (LD) failed to ensure one of one TP received the appropriate training for the type and complexity of laboratory testing prior to patient testing. Findings: 1. Review of training documentation showed lack of training documentation for TP #1. 2. Interview with the CC and TP #1 on January 5, 2021 at 10:30 AM confirmed the LD failed to ensure TP #1 received appropriate training.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the Sysmex XN-430 hematology procedure manual for complete

	blood cell counts and interview with the testing personnel (TP) #1 and the clinical consultant (CC), the laboratory director (LD) failed to have an approved manual available for testing personnel. Findings: 1. Review of the Sysmex XN-430 procedure manual for CBC showed no approval by the LD. 2. Interview with the TP #1 and CC on January 5, 2021 at 11:00 AM confirmed the LD failed to ensure an approved procedure manual was available to all testing personnel.