Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2057241	07/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Loving Care Group, Llc	2275 Westpark Ct Suite 101, Euless, 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	An announced recertification survey was conducted on 07/17/19 at Loving Care Group LLC DBA Pediatric Palace of DFW. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 5:00 PM on 07/17/19. The laboratory failed to validate instruments prior to patient testing and failed to run quality control every day of patient testing (See D5400). The following Conditions were not met: D5400 Analytic Systems 493.1250 D6000 Moderate Complex Laboratory Director 493.1403
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager and Testing Person #B the laboratory failed to verify the accuracy of Influenza A+B, Strep complete assay, and RSV (Respiratory syncytial virus) testing since 01/17/2018 and CRP (C-reactive protein) testing since 04/05/2017 at least twice a year. Findings Included: Review of the manufacturer's instructions for Solana Influenza A+B Assay revealed that the test is Moderately complex in the subspecialty of Virology. There was no verification of accuracy of testing twice a year since testing began in 01/17/2018. Review of the manufacturer's instructions for Solana Strep Complete Assay revealed that the test is Moderately complex in the subspecialty of Bacteriology. There was no verification of accuracy of testing twice a year since testing began in 01/17/2018. Review of the manufacturer's instructions for Solana RSV revealed that the test is Moderately complex in the subspecialty of Virology. There was no verification of accuracy of testing twice a year since testing began in 001/17/2018. Interview on 07/17/19 at 10: 00 AM Testing Person #B confirmed that testing on the Solana began on 01/17/2018.

	Review of the manufacturer's instruction for the CRP testing performed on the Piccolo instrument revealed that the test is Moderately complex in the subspecialty of General Immunology. There was no verification of accuracy of testing twice a year since 04/05 /2017. Interview on 07/17/19 at 11:30 AM the Office Manager confirmed that verification of accuracy at least twice a year was not performed for Influenza A+B, Strep, RSV, or CRP testing.
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 record review and staff interviews the laboratory failed to validate the Piccolo Xpress and Solana instruments prior to patient testing (See D5421) and failed to perform daily QC or have an IQCP plan for testing on the Piccolo Xpress and Solana instruments (See D5448).
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 record review and interview with Testing Person #B the laboratory failed to perform a validation on the Solana instrument since received on 01/17/2018. Finding Included: Review of revealed that the instrument Solana started patient testing 01/17 /18 for Influenza A+B, Strep Complete Assay, and RSV (Respiratory Syncytial Virus). No validation of the Solana instrument was performed prior to patient testing. The annual volume of patient tests for Strep was 2,110. The annual volume of patient tests for Influenza was 423. The annual volume of patients tests for RSV was 168. Interview on 07/17/19 at 10:00 AM the Testing Person #B confirmed that there was no validation performed on the Solana instruments.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified

	in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #B the laboratory failed to perform daily QC (quality control) or follow manufacturers' instructions for testing on the Piccolo Xpress (C-reactive protein testing) and Solana (Influenza A+B, Strep, and Respriatory Syncytial Virus testing) for 2 (2017-2019) out of 2 years reviewed. Findings Included: Review of Manufacturer's instructions for the Piccolo Xpress revealed that QC (low level and high level) should be ran: "1. Every 30 days 2. Whenever lab conditions change 3. When training or retraining of personnel 4. When test results do not match patient symptoms 5. With EACH new lot number of reagent discs". Review of QC performed on the Piccolo Xpress revealed that CRP (C-reactive protein) controls were performed: 06/14/19, 04/26/19, 02/26/19, 01/14/19, 03/22/18, 03/20/17, and 02/23/17. Interview on 07/17/19 at 12:30 PM Testing Person #B confirmed that QC was not done everyday testing of patient specimens, confirmed that there was no other QC performed, confirmed QC was not done at least every 30 days, and that no IQCP was performed. Annual test volume for CRP is 122. Review of QC performed on the Solana for Influenza A+B, Strep, and RSV (Respiratory Syncytial Virus) testing revealed that QC was being performed on every lot change per the Manufacturers' instructions, however there was no IQCP performed to allow for QC not being performed each day of testing. No additional QC was provided. Interview on 07/17/19 at 12 :30 PM Testing Person #B confirmed that QC was not performed each day of testing and no IQCP was performed. Annual test volume for Influenza A+B is 423, RSV is 168, and Strep is 2110.
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 record review and interview with the Office Manager the laboratory failed to have the correct address since 03/2018. Findings Included: Review of patient reports from 07/17/19 revealed that the address was not where the laboratory was currently located. Interview on 07/17/19 at 11:07 AM the Office Manager confirmed that the address on the report was the previous address and the laboratory moved in 03 /2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview the Laboratory Director failed to have oversight of the laboratory for 2 out of 2 (2017-2019) years reviewed (See D6004).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interviews the Laboratory Director failed to have oversight of the laboratory for 2 out of 2 years reviewed (2017-2019). Findings Included: The laboratory failed to validate the Piccolo Xpress and Solana instruments prior to patient testing (See D5421). The laboratory failed to perform daily QC or have an IQCP plan for testing on the Piccolo Xpress and Solana instruments (See D5448).