Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2110360	12/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Complete Care Llc	6836 Bee Caves Rd Suite 112, Austin, 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 December 29, 2021. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2000 - 42 C.F.R. 493.801 Enrollment And Testing Of Samples
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of patient testing records, proficiency testing (PT) records and interview, the laboratory failed to enroll in proficiency testing for the Gastrointestinal Panel tested on the Biofire Film Array for five of five months reviewed. Findings follow. A. Testing records showed the laboratory started reporting patient testing for the Gastrointestinal Panel on the Biofire on July 24, 2021. B. Review of the American Pathology Institute PT records from the 3rd event of 2021 for Microbiology from October 2021, showed the Biofire Gastrointestinal Panel under the specialty of Microbiology was not enrolled. The Gastrointestinal Panel included the bacteria: Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio, Vibrio Cholerae, Yersinia enterocolitica, Enteroaggregative E. coli, Enteropathogenic E. coli, Enterotoxigenic E. coli, Shiga-like toxin-producing E. coli, E. coli O157; parasites: Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia; viruses: Adenovirus F 40/41, Astrovirus, Norovirus GI

	/GII, Rotavirus A, Sapovirus. C. Interview with the Technical Consultant on December 29, 2021 at 1200 in the office acknowledged they should have started PT and confirmed they were not enrolled. D. Review of patient testing records showed 39 patients were tested for the Gastrointestinal Panel between 07/24/2021 to 12/29/2021.
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 review of patient testing records, maintenance logs and interview, the laboratory failed to document the periodic maintenance on the Biofire Film Array used to test the Gastrointestinal Panel and Respiratory Panel for 13 of 13 months reviewed. Findings follow. A. Patient testing for the Respiratory Panel started November 2, 2020 and patient testing for the Gastrointestinal Panel started July 24, 2021. B. Review of maintenance logs from 11/02/2020 - 12/29/2021 showed the Biofire Periodic Maintenance Logs were not being utilized by the laboratory, and the laboratory was not documenting the exterior cleaning, pouch loading station decontamination, module decontamination, weekly shutdown and restart, and the monthly archive of results to a flash drive. C. Interview with the Technical Consultant on December 29, 2021 at 1545 hours in the office confirmed the log was not being utilized by the laboratory and the maintenance on the Biofire was not documented.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, patient testing records, and interview, the laboratory failed to run controls every day of patient testing for the Complete Blood Count (CBC) tested using the Sysmex XP-300 for one out of 58 days reviewed. Findings follow. A. Review of quality control records from 10/19/2021 - 12/16/2021 showed there was no QC run on 11/18/2021. B. Review of testing records showed 3 patients were tested on 11/18/2021 for the CBC. C. Interview with the Technical Consultant on December 29, 2021 at 1530 hours in the office confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, patient testing records, and interview, the laboratory failed to include a negative and positive control each day of patient testing (or perform a IQCP study) for the Respiratory Panel tested on the Biofire Film Array for seven out of 13 months reviewed. Findings follow. A. Review of quality control records from 11/02/2020 - 06/30/2021 showed QC was performed on the following date: 1. 11/02/2020. An IQCP study was then performed from 07/01/2021 - 07/26 /2021. B. Review of patient testing records showed the laboratory started reporting patient testing for the Respiratory Panel using the Biofire on 11/02/2020. From 11/3 /2020 - 06/30/2021 213 patient testing were reported: 1. 11/03/2020: 8 patients 2. 11 /04/2020: 3 patients 3. 11/05/2020: 2 patients 4. 11/06/2020: 3 patients 5. 11/07/2020: 2 patients 6. 11/08/2020: 2 patients 7. 11/09/2020: 1 patient 8. 11/10/2020: 9 patients 9. 11/12/2020: 2 patients 10. 11/13/2020: 4 patients 11. 11/14/2020: 3 patients 12. 11 /16/2020: 4 patients 13. 11/17/2020: 7 patients 14. 11/18/2020: 8 patients 15. 11/19 /2020: 2 patients 16. 11/20/2020: 4 patients 17. 11/21/2020: 1 patient 18. 11/24/2020: 5 patients 19. 11/25/2020: 5 patients 20. 11/28/2020: 1 patient 21. 11/30/2020: 1 patient 22. 12/01/2020: 5 patients 23. 12/02/2020: 1 patient 24. 12/02/2020: 1 patient 25. 12/04/2020: 1 patient 26. 12/06/2020: 1 patient 27. 12/07/2020: 1 patient 28. 12/09 /2020: 2 patients 29. 12/13/2020: 1 patient 30. 12/14/2020: 2 patients 31. 12/15/202: 2 patients 32. 12/16/2020: 1 patient 33. 12/20/2020: 1 patient 34. 12/22/2020: 1 patient 35. 12/23/2020: 1 patient 36. 12/26/2020: 1 patient 37. 12/29/2020: 4 patients 38. 12 /30/2020: 1 patient 39. 12/31/2020: 2 patients 40. 01/01/2021: 1 patient 41. 01/02 /2021: 1 patient 42. 01/04/2021 2 patients 43. 01/05/2021: 3 patients 44. 01/08/2021: 1 patient 45. 01/15/2021: 1 patient 46. 01/19/2021: 3 patients 47. 01/21/2021: 1 patient 48. 01/23/2021: 1 patient 49. 01/26/2021: 2 patients 50. 01/29/2021: 1 patient 51. 01/30/2021: 1 patient 52. 02/02/2021: 2 patients 53. 02/03/2021: 1 patient 54. 02 /07/2021: 1 patient 55. 02/09/2021 2 patients 56. 02/18/2021: 1 patient 57. 02/20 /2021: 1 patient 58. 02/23/2021: 1 patient 59. 03/08/2021: 1 patient 60. 03/11/2021: 1 patient 61. 03/13/2021: 1 patient 62. 03/17/2021: 2 patients 63. 03/22/2021: 2 patients 64. 03/23/2021: 1 patient 65. 03/26/2021: 2 patients 66. 04/01/2021: 1 patient 67. 04 /04/2021: 2 patients 68. 04/06/2021: 1 patient 69. 04/07/2021: 1 patient 70. 04/10 /2021: 1 patient 71. 04/11/2021: 2 patients 72. 04/13/2021: 1 patient 73. 04/14/2021: 1 patient 74. 04/15/0221: 2 patients 75. 04/19/2021: 2 patients 76. 04/21/2021: 1 patient 77. 04/22/2021: 1 patient 78. 04/23/2021: 1 patient 79. 04/26/2021: 1 patient 80. 04/27 /2021: 1 patient 81. 04/28/2021: 1 patient 82. 04/29/2021: 1 patient 83. 04/30/2021: 1 patient 84. 05/01/2021: 1 patient 85. 05/04/2021: 1 patient 86. 05/05/2021: 1 patient 87. 05/15/2021: 1 patient 88. 05/18/0221: 1 patient 89. 05/19/2021: 1 patient 90. 05/20 /2021: 1 patient 91. 05/22/2021: 1 patient 92. 05/27/2021: 1 patient 93. 05/29/2021: 1 patient 94. 05/30/2021: 1 patient 95. 06/01/2021: 1 patient 96. 06/03/2021: 6 patients 97. 06/04/2021: 2 patients 98. 06/05/2021: 1 patient 99. 06/06/2021: 3 patients 100. 06 /07/2021: 3 patients 101. 06/09/2021: 1 patient 102. 06/12/2021: 1 patient 103. 06/13 /2021: 2 patients 104. 06/14/2021: 3 patients 105. 06/15/2021: 4 patients 106. 06/18 /2021: 2 patients 107. 06/19/2021: 2 patients 108. 06/22/2021: 2 patients 109. 06/28 /2021: 1 patient 110. 06/29/2021: 1 patient 111. 06/30/2021: 1 patient C. Interview with the Technical Consultant on December 29, 2021 at 1400 hours in the laboratory confirmed the findings.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)

	(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of patient testing records, proficiency testing (PT) records and interview, the technical consultant failed to ensure the laboratory was enrolled in proficiency testing for the Gastrointestinal Panel tested on the Biofire Film Array (see D2000).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of quality control records, patient testing records, and interview, the technical consultant failed to ensure a quality control program was appropriate for the testing performed for the Respiratory Panel tested on the Biofire Film Array (see D5449).
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the competency evaluations and interview, the laboratory consultant failed to incorporate the direct observation of routine patient test performance for four of four test systems in the laboratory for six of six testing personnel for two of two years reviewed. Findings follow. A. Review of the 2020 and 2021 competency evaluations for testing personnel #one through six, on the CMS form 209, showed for the Complete Blood Count (CBC) performed on the Sysmex XP-300, Metlac 12 on the Piccolo, Cardiac Markers and D-Dimer on the Alere Triage, and the Respiratory and Gastrointestinal panels on the Biofire Film Array, the skill of "testing performed in accordance with manufacturer's instructions and lab policy" were accomplished by "B" and "C". B was defined as "Monitoring the recording and reporting of results" and C was defined as the "Review of records, Worksheets Maintenance records Proficiency results and QC records". "A," not included in the verification method for the test performance was defined as the "Direct observation of test performance". B. Interview with the Technical Consultant on December 29, 2021 at 1040 hours in the office acknowledged she watched some, but not everyone who performed testing.

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of training records, patient testing records, and interview, the laboratory failed to have documentation of training for four of four testing personnel using the Biofire Film Array for the Respiratory and Gastrointestinal Panels performed. Findings follow. A. Training records for the Biofire were requested on December 29, 2021 at 1040 hours but not provided. B. Patient testing for the Respiratory Panel started November 2, 2020 and patient testing for the Gastrointestinal Panel started July 24, 2021. C. Interview with the Technical Consultant on December 29, 2021 at 1040 hours in the office confirmed she was not able to locate any training records for the Biofire for any testing personnel. NOTE: The technical consultant replaced the previous Technical Consultant in July 2021.