Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0280554	09/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Finlay Clinical Laboratory Inc	330 Sw 27th Ave Ste 101, Miami, FL	

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 conducted on August 21 to September 27, 2023. Finlay Clinical Laboratory Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Condition was cited: D5400 Analytic Systems 493.1250
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observations, review of Material Safety Data Sheets (MSDS), and interview the laboratory failed to have exposure testing for Formalin and Xylene for 2 out of 2 years (2021-2023) reviewed. Findings Included: During a tour of the Histology and Cytology Departments on 08/22/2023 at 9:00 AM Formalin (Lot# 2317310 exp 06/26 /2025) and Xylene (Lot#2315131 exp 06/01/2027) were observed. Review of the MSDS for Formalin (revision date 10/29/2009) under "HAZARDOUS COMPONENTS AND EXPOSURE LIMITS" revealed the components of Formalin are Formaldehyde and Methanol. The exposure limit for Formaldehyde is 0.75 PPM (parts per million) and for Methanol is 200 PPM. Review of the MSDS for Xylene (revision 11/23/2009) under "HAZARDOUS COMPONENTS AND EXPOSURE LIMITS" revealed the exposure limit for Xylene is 100 PPM. Interview on 08/22 /2023 at 9:00 AM the Histotech confirmed that there was no exposure testing performed in 2021-2023.
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 observations, record review, and interviews the Laboratory failed to run negative controls for Giardia/Cryptosporidium and C. Diff testing (See D5441), failed to run quality control before Patients were ran (See D5481), and failed to have corrective action for freezer temperatures out of range (See D5781).
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 record review and interview the Laboratory failed to perform 2 levels of Quality Control (QC) on Giardia/Cryptosporidium and C. Diff testing for 2 out of 2 years (2021-2023) reviewed. Findings Included: Review of Tech Lab Manufacturer's instructions (last revised 06/2021) for C. Diff revealed that external controls should be ran to verify kit upon receipt using a "Positive Control and negative control (Diluent)." Review of ImmunoCard STAT! Giardia/Cryptosporidium Rapid Assay (Rev. B) revealed that a positive and negative control is to be run with each new kit lot or with each new untrained operator. Interview on 08/25/2023 at 3:40 PM the Laboratory Manager confirmed that there were no negative controls ran for Giardia /Cryptosporidium (54 Patients tested) or C. Diff testing (1560 Patients tested) in 2021 through 2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the instrument test results list and interview, the Laboratory failed to perform two levels quality controls prior to patient test samples on the Beckman

Coulter Immage 800 Immumochemistry analyzer and the DiaSorin Immunology analyzer for 2 of 2 months (July 2022, May 2023) reviewed. Findings include: The test results list contained patient results and QC results. Review of the test results list indicated the following: 1. For CRP (C-Reactive Protein) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/06/2022 - No controls were run and 16 of 16 Patients were tested prior to the controls. Patients were tested at 2:37 PM, 2:38 PM (2 Patients), 2:39 PM, 2:37 PM, 2:40 PM (2 Patients), 2:42 PM, 2:43 PM, 2:44 PM, 2:45 PM, 2:46 PM, 2:48 PM (2 Patients), and 2:50 PM (2 Patients). 07/11/2022 - Two levels of controls were run at 1:51 PM and 26 of 26 Patients were tested prior to the controls. Patients were tested at 1:18 PM (2 Patients), 1:19 PM , 1:20 PM (2 Patients), 1:21 PM, 1:23 PM, 1:24 PM, 1:25 PM (2 Patients), 1:26 PM, 1:27 PM, 1:28 PM (2 Patients), 1:29 PM, 1:30 PM (2 Patients), 1:31 PM, 1:32 PM (2 Patients), 1:33 PM, 1:34 PM(2 Patients), 1:35 PM , 1:36 PM, and 1:37 PM. 07/13/2022 - No controls were run and 1 Patient was tested at 1:05 PM. 7/14/2022 - Two levels of controls were run at 2:14 PM and 2:15 PM, and 4 of 21 Patients were tested prior to the controls. Patients were tested at 1:57 PM, 1:58 PM, and 1:59 PM (2 Patients), 07/17/2022 - No controls were run and 16 Patients were tested at 7:56 PM, 7:57 PM. 7:59 PM, 8:01 PM (2 Patients), 8:04 PM, 8:07 PM, 8:09 PM (2 Patients), 8:10 PM, 8:11 PM, 8:12 PM, 8:13 PM, 8:14 PM (2 Patients), and 8:18 PM 07/18/2022 - Two levels of controls were run at 8:25 PM and 8:26 PM, and 12 of 14 Patients were tested prior to the controls. Patients were tested at 7:55 PM, 7:56 PM(2 Patients), 7:57 PM, 7:58 PM (2 Patients), 7:59 PM, 8:00 PM (2 Patients), 8:01 PM, 8:02 PM, and 8:06 PM. 05/08 /2023 - Two levels of controls were run at 11:23 PM, and 31 of 31 Patients were tested prior to the controls. Patients were tested at 12:01 AM (2 Patients), 12:02 AM, 12:03 AM, 12:04 AM, 12:05 AM, 12:06 AM, 12:07 AM (2 Patients, 12:08 AM, 12:09 AM (2 Patients), 12:10 AM, 12:11 AM (2 Patients), 12:12 AM, 12:13 AM (2 Patients), 12:14 AM, 12:15 AM, 12:07 AM, 12:08 AM, 1:04 AM, 1:05 AM, 1:06 AM (2 Patients), 1:07 AM, 1:08 AM, 1:10 AM, 1:13 AM, and 1:14 AM. 05/10/2023 - Two levels of controls were run at 10:45 PM and 10:46 PM, and 1 of 1 Patients were tested prior to the controls at 12:56 AM. 05/13/2023 - No controls were run and 16 of 16 Patients were tested at 3:42 AM, 3:43 AM, 3:44 AM (2 Patients), 3:45 AM, 3:46 AM, 3:49 AM (2 Patients), 3:50 AM, 3:51 AM, 3:52 AM (2 Patients), 3:53 AM, 3:54 AM, 3:55 AM, 3:56 AM (2 Patients), 3:58 AM (2 Patients), 3:59 AM, 4:00 AM (2 Patients), 4:01 AM, 4:02 AM (2 Patients), and 4:03 AM. 05/14/2023 - Two levels of controls were run at 11:24 PM and 11:25 PM, and 21 of 21 Patients were tested prior to the controls. Patients were tested at 11:09 PM (2 Patients), 11:10 PM, 11:11 PM (2 Patients), 11:12 PM, 11:13 PM (2 Patients), 11:14 PM, 11:15 PM, 11:16 PM, 11:17 PM (2 Patients), 11:18 PM, 11:19 PM (2 Patients), 11:20 PM, 11:21 PM (2 Patients), 11:22 PM, and 11:23 PM. 05/28/2023 - Two levels of controls were run at 3:21 AM, and 23 of 23 Patients were tested prior to the controls. Patients were tested at 2:04 AM, 2:05 AM (2 Patients), 2:06 AM, 2:07 AM, 2:08 AM, 2:09 AM, 2:10 AM, 2:11 AM, 2:12 AM (2 Patients), 2:14 AM, 2:15 AM, 2:16 AM, 2:17 AM, 2:19 AM, 2:20 AM, 2:21 AM (2 Patients), 2:27 AM, 2:29 AM, 2:30 AM (2 Patients). 2. For C3 (Compliment 3) and C4 (Compliment 4) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/06/2022 - Two levels of controls were run at 3:00 PM and 3:04 PM, and 2 of 2 Patients were tested at 2:30 PM and 2:47 PM. 07/18/2022 - Two levels of controls were run at 8:39 PM and 8:49 PM, and 1 of 1 Patient was tested at 8:06 PM. 05/18/20223 - Two levels of controls were run at 6:18 PM and 6:26 PM and 1 of 1 Patients were tested in between the two levels of controls at 6:22 PM. 05/28/2023 - Two levels of controls were run at 3:34 PM and 3:35 PM and 1 of 1 Patient was tested at 2:30 AM. 3. For HPT (Haptoglobin) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/06/2022 - Two levels of controls were run at 3:00 PM and 3:03 PM, and 3 of 3 Patients were tested at 3:48 PM, 3:49 PM and

3:57 PM. 05/08/2023 - Two levels of controls were run at 11:36 PM and 11:38 PM and 2 of 2 Patients were tested at 1:09 AM and 1:32 AM. 05/13/2023 - No controls were run and 2 of 2 Patients were tested at 3:50 AM and 3:53 AM. 05/28/2023 - Two levels of controls were run at 3:34 PM and 3:35 PM and 1 of 1 Patient was tested at 2: 08 AM. 4. For CER (Carbepenem-Resistant Enterobacterales) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/14/2022 - Two levels of controls were run at 2:20 PM and 2:28 PM, and 2 of 2 Patients were tested in between the two levels of controls at 2:22 PM. 5. For Immunoglobulins (Ig) G, Ig A, Ig M, Ig U, Lambda (LAM), and Kappa (KAP) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/17/2022 - No controls were run for Ig A, IgG, IgM, and LAM, and 2 Patients were run. One Patient was tested for Ig A, IgG, and IgM at 8: 01 PM. One Patient was tested for Ig A, IgG, IgM, and LAM at 8:06 PM. 07/18/2022 - Two levels of controls were run at 8:39 PM and 8:49 PM for Ig A, IgG, IgM, KAP, LAM and Ig U, and 4 of 4 Patients were tested prior to the controls being run. One Patient was tested for Ig A, IgG, and IgM at 8:06 PM. One Patient was tested for IgM and LAM at 8:06 PM. One Patient was tested KAP and LAM at 8:08 PM. One Patient was tested for KAP, LAM and Ig U at 8:11 PM. 05/07/2023 - No controls were run for KAP, LAM, and Ig U, and 1 Patient was tested for KAP, LAM, and Ig U at 8:02 PM. 05/08/2023 - Two levels of controls were run at 11:36 PM and 11:38 PM for KAP, LAM, and Ig U, and 3 of 3 Patients were tested prior to the controls. One Patient was tested for, KAP, LAM, and Ig U at 12:20 AM. Two Patients were tested for KAP and LAM at 1:07 AM and 1:08 AM. 05/13/2023 - No controls were run for Ig A, Ig G, and Ig M, and 2 of 2 Patients were tested. One Patient was tested for Ig A and Ig M at 4:07 AM. One Patient was tested for Ig A, Ig G, and Ig M at 4:14 AM. 05 /15/2023 - Two levels of controls were run at 11:40 PM and 11:58 PM for Ig A, Ig G, and Ig M, and 1 of 1 Patient was tested for Ig A, Ig G, and Ig M at 11:26 PM. 05/16 /2023 - Two levels of controls were run at 10:05 PM and 10:12 PM for Ig A, Ig G, Ig M, KAP, LAM, and Ig U, and 2 of 2 Patients were tested prior to both levels of controls being run. One Patient was tested for Ig A, Ig G, and Ig M at 10:04 PM. One Patient was tested for KAP, LAM, and Ig U at 10:06 PM. 05/28/2023 - Two levels of controls were run at 3:34 AM and 3:35 AM for KAP, and LAM, and 4 of 4 Patients were tested to prior controls being run. One Patient was tested for KAP and LAM, at 2:13 AM. One Patient was tested for Ig A, Ig G, and Ig M, at 2:21 AM Two Patients were tested for KAP, LAM, and Ig U at 2:23 AM and 2:24 AM. 6. For AAT (Alpha-1-Antitryppsin) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07 /14/2022 - No controls were run and 1 Patient was tested at 3:58 PM. 05/18/20223 - Two levels of controls were run at 6:18 PM and 6:26 PM and 1 of 1 Patients was tested in between the two levels of controls at 6:19 PM. 7. For AT3 (Antithrombin III) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/17/2022 - No controls were run and 1 Patient was tested at 8:00 PM. 8. For LPAX (Lipoprotein A) on the Beckman Coulter Immage 800 Immumochemistry analyzer. 07/11/2022 - Two levels of controls were run at 1:35 PM and 1:53 PM, and 1 of 1 Patient was run in between the two levels of controls at 1:39 PM. 05/08/2023 - Two levels of controls were run at 11:36 PM and 11:38 PM and 1 of 1 Patient was tested at 1:04 AM. 05/28 /2023 - Two levels of controls were run at 3:34 PM and 3:35 PM and 1 of 1 Patient was tested at 2:09 AM. 9. For HSV1 (Herpes Simplex Virus 1) on the DiaSorin Immunology analyzer. 05/23/2023- Two levels of controls were ran at 15:21 and 15: 21 and 6 of 6 Patients were tested at 14:48, 14:49, 14:46, 14:46, 14:47, and 14:48. 05 /31/2023- Two levels of controls were ran at 12:13 and 12:12 and 8 of 8 Patients were tested at 11:11, 11:10, 11:10, 11:10, 11:09, 11:09, 11:09, and 11:08. 07/12/2023- Two levels of controls were ran at 15:10 and 15:48 and 5 out of 5 Patients were tested at 14: 12, 14:11, 14:11, 14:11, and 14:10. 10. For HSV2 (Herpes Simplex Virus 2) on the DiaSorin Immunology analyzer. 05/23/2023- Two levels of controls were ran at 15:21

	and 15:22 and 7 out of 7 Patients were tested at 14:55, 14:56, 14:50, 14:51, 14:52, 14:53, and 14:53. 05/31/2023- Two levels of controls were ran at 12:13 and 12:14 and 9 out of 9 Patients were tested at 11:11, 11:12, 11:12, 11:12, 11:13, 11:13, 11:13, 11:14, and 11:14. 07/12/2023- Two levels of controls were ran at 15:11 and 15:11 and 6 out of 6 Patients were tested at 14:14, 14:13, 14:13, 14:13, 14:12, and 14:12. On 08/25/2023 at 11:40 AM, the Technical Supervisor acknowledged that patients were run before the controls.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of reagent containers, temperature logs, and interview, the laboratory failed to document corrective actions for freezer temperatures that were not within the acceptable temperature range from 01/01/2022 to 09/27/2023. Findings: During a tour of the laboratory on 08/21/2023 at 2:40 AM, reagents found in the laboratory's freezer that were stored at the wrong temperature. The following reagent were stored in the freezer located in the Microbiology room: Storage temperature -15 to -20 degrees Celsius (C) Beckman Coulter Vigil Protein Control Level 1 and 3 Beckman Coulter Access Total T4 Calibrators (Thyroxine) Storage temperature -20 degrees C and below Beckman Coulter Access Free T4 Calibrators Beckman Coulter Access Total BhCG (5th IS) Calibrators (Beta-human Chorionic Gonadotropin) Beckman Coulter Access Prolactin Calibrators Beckman Coulter Access BNP Calibrators (B-type Natruiretic Peptide) Beckman Coulter Access GI Monitor Calibrators (Gastro-Intestinal) Beckman Coulter Access BNP QC (quality control) Storage Temperature 2 to 10 degrees C, -20 degrees C after reconstitution Beckman Coulter Access Ultrasensitive Insulin Calibrators Storage temperature -20 to -70 degrees C Bio-Rad Liquichek Immunology Control Level 1 and 3 Bio-Rad Liquid Assayed Multiqual Level 1 and 3 Bio-Rad Liquichek Cardiac Markers Plus Control LT Level 1 and 3 Bio-Rad Liquichek Specialty Immunoassay Control Level 1 and 3 Bio-Rad Liquichek Immunoassay Plus Control Level 1 and 3 During a tour of the laboratory on 08/21/2023 at 2:40 AM, it was observed that the mercury thermometer in the freezer did not provide a temperature values below -5 degree C. Review of the Temperature Record for the freezer showed the temperature of the freezer was recorded to between -54 to -56 degrees C from 01/01/2022 to 08/26/2023, and -17.8 to -23.1 degrees C from 08/28/2023 to 09/27/2023. Review of the Temperature Record for the freezer showed there was no corrective action documented. On 08/21/2023 at 2:40 PM, the Technical Supervisor acknowledged the thermometer in the freezer did not provide a temperature values below -5 degree C. On 08/21/2023 at 4:27 PM, Technical Supervisor acknowledged there was no corrective action documented. On 08/25/2023 at 12:06, a new digital thermometer in the freezer was observed to have a temperature reading of -19.2 degrees C. On 08/25/2023 at 12:10 PM, the Testing

	Personnel E stated the old thermometer broke about two months ago and was replaced with the mercury thermometer. On 08/25/2023 at 12:10 PM, the Testing Personnel E stated she thinks she was calculating the temperature based on the position of the mercury.