Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2308713	07/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ankem Ravindra Md Pa	1211 Sw Bascom Norris Drive, Lake City, 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	An announced CLIA Initial survey was conducted at Ankem Ravindra MD PA on 07 /30/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6063 493.1421 Condition: Laboratory Testing Personnel
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 observation, record review, and interview, the Laboratory failed to record room temperature and use Abbott iSTAT cartridges that were at the correct temperature (See D5413); failed to perform thermo probe verification every six months (See D5429); failed to perform quality control prior to reporting Patients on the Piccolo chemistry analyzer (See D5441); and failed to run quality control on the Abbott iSTAT for 32 out of 34 days that Patients were ran (See D5445).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation, record review, and interview, the Laboratory failed to follow the manufacturer's instruction to use Abbott iSTAT cartridges at the required temperatures and failed to monitor room temperature since testing began 11/12/2024. Findings Included: 1. Tour on 07/30/2025 at 12:00 PM of the Cath area where testing on the Abbott iSTAT was performed revealed no cartridges outside of the refrigerator and no thermometer to monitor room temperature. 2. Review of the "Procedure for Handling Cartridges" procedure for the Abbott iSTAT confirmed that "A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 degrees C or 64-86 degrees F). For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used." 3. Interview on 07/30/2025 at 12:00 PM Testing Person #B confirmed the cartridge was taken directly from the refrigerator to be used for testing prior to warming to room temperature and that they were not monitoring the room temperature.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 record review and interview, the Laboratory failed to follow the manufacturer's instructions to check the thermal probe on the Abbott iSTAT every six months since testing began 11/12/2024. Findings Included: 1. Review of the Abbott i-STAT System Manual revealed the thermal probe check be verified every six months. 2. Review of maintenance records revealed no documentation of the thermal probe check being checked. 3. Interview on 07/30/2025 at 12:00 PM Testing Person #B confirmed that there was no documentation of a thermal probe check.
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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to Quality Control (QC)

	prior to reporting patient results on the chemistry Piccolo analyzer, for 3 out of 9 months (11/14/24-01/30/25) with a total of 244 patients. Findings include: 1. Review of the "Standard Operating Procedure" revealed 2 QC levels to be run daily for chemistry analyzer, or on days with patient testing. 2. Review of the monthly QC reports revealed that patients were reported without 2 levels of QC being run on the following days: 11/14/24 (10 patients), 11/18/24 (7 patients), 11/19/24 (3 patients), 11 /21/24 (14 patients), 11/25/24 (5 patients), 11/26/24 (7 patients), 12/03/24 (7 patients), 12/04/24 (3 patients), 12/05/24 (11 patients), 12/09/24 (5 patients), 12/10/24 (4 patients), 12/11/24 (7 patients), 12/12/24 (12 patients), 12/16/24 (3 patients), 12/18/24 (11 patients), 12/19/24 (12 patients), 01/06/25 (3 patients), 01/07/25 (5 patients), 01/08 /25 (3 patients), 01/13/25 (13 patients), 01/14/25 (20 patients), 01/28/25 (15 patients), 01/29/25 (3 patients), 01/30/25 (15 patients). 3. During an interview at interview at 12: 10 pm on 07/29/25 with TP#A confirmed the Laboratory was only performing QC on the Piccolo once a month.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to perform quality control (QC) every day of testing for 32 out of 34 days Patient testing was performed. Findings Included: 1. Review of the Abbott iSTAT procedure states "Until recently, regulations and laboratory accreditation standards specified the use of traditional quality control regimens, including the daily use of liquid control materials." "quality control regimens should be established using information from the manufacturer and scientific literature." 2. Interview on 07/30/2025 at 12:00 PM Testing Person #B stated that they were supposed to perform QC monthly, but they did not have an IQCP (Individualized Quality Control Plan). 3. Review of QC records revealed level 1 and level 2 QC were performed on 01/06/25, 03/07/25, 04/29/25, and 05/14/25. 4. Patients were ran on 11/04/24, 11/19/24, 11/20/24, 11/26/24, 12/09/24, 01/13/25, 01/14/25, 01 /21/25, 01/24/25, 01/27/25, 01/29/25, 01/31/25, 02/07/25, 02/13/25, 02/24/25, 03/04 /25, 03/07/25, 03/24/25, 03/31/25, 04/01/25, 04/03/25, 04/07/25, 04/17/25, 04/21/25, 04/24/25, 04/29/25, 04/30/25, 05/06/25, 05/07/25, 05/15/25, 05/22/25, 05/28/25, 06/03 /25, and 07/30/25. 5. Interview on 07/30/2025 at 12:30 PM Testing Person #B confirmed the QC not ran monthly and Patients performed. She pulled the Abbott iSTAT from service until an IQCP could be performed.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation,

	properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review and interview, it was found that the Laboratory Director (LD) did not verify that 6 out of 6 testing persons (TP) in the Cathlab did not have proof of initial training. Findings include: 1.)Review of the CMS 209, Laboratory Personnel Report, singed by the LD on 07/23/2025, showed 2 TP in main Laboratory (TP#A, TP#B), and 6 in Cathlab (TP#C, TP#D, TP#E, TP#F, TP#G, TP#H). 2.) Absence of employee files for TP#C, TP#D, TP#F, TP# G, TP#H, revealed no documentation of date of hire, initial training documentation, and education. 3.) An interview at 1:30pm with TP#A confirmed that 6 out of 6 Cathlab TP did not have employee files "on-site."
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) did not verify 6 out of 6 Testing Persons (TP) in the Cathlab for documentation of education (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) did not verify 6 out of 6 Testing Persons (TP) in the Cathlab for documentation of education. Findings include: 1. Review of the CMS 209, Laboratory Personnel Report, singed by the LD on 07/23/2025, showed 2 TP in main Laboratory (TP#A, TP#B), and 6 in Cathlab (TP#C, TP#D, TP#E, TP#F, TP#G, TP#H). 2. Absence of employee files for TP#C, TP#D, TP#F, TP# G, TP#H, revealed the Laboratory did not have proof of education

	(diplomas). 3. Interview with TP#A at 1:30pm confirmed there were no employee files on site.