Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0683133	07/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Palm Beach County Health Department-Laboratory	1150 45th St Rm L-200, West Palm Beach, 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 recertification survey was conducted at Palm Beach County Health Department Laboratory on June 6, 2025 to July 16, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6168 - 493.1487 Condition: Testing Personnel
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on interview, review of American Proficiency Institute Proficiency Testing (PT) records and the procedure manual, the laboratory failed to run proficiency testing samples for hematology in the same manner as it runs patients for two (2024 2nd, 2025 1st) of five (2024 1st, 2nd, 3rd; 2025 1st, 2nd) events. Findings: 1. Review of the Proficiency Testing (PT) Procedure noted "PT Survey samples are to be handled same as a patient sample." 2. Review of the PT documents contained two sets of instrument printouts with test results for each PT sample (five per event) for the 2024 2nd and 2025 1st events. 3. During an interview on 06/05/2025 at 3:15 PM, Technical Supervisor B acknowledged the PT samples were run twice and patients are not normally run twice.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on observation, record review and interview, the Laboratory failed to pull chemistry quality control Architect instrument printouts for October 2023 and June 2024. Findings: 1. Tour of the Laboratory on 06/05/2025 at 12:00 PM, revealed an Architect in use for Chemistry testing. The Architect did not have any stored Chemistry quality control results for the months of October in 2023 and June in 2024. 2. Review of record retention policy revealed there was no procedure for record retention. 3. On 06/05/2025 at 12:08 PM, the Technical Supervisor stated the quality control results could not be pulled from the Architect for October 2023 and June 2024.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency evaluations and interview, the laboratory failed to to perform competency assessment for three of three Technical Supervisors (A, B, C) and two of two General Supervisors (A, B) for 2023 and 2024; and the Laboratory Director failed to sign off on the competency assessment for Testing Personnel D for two of two competency assessments in 2023 and 2024. Findings: Review of the Laboratory Personnel Report signed by the Laboratory Director on 06/02/2025 showed there were three Technical Supervisors and 13 Testing Personnel (A - L) listed on the form. A 1. Review of the employee competency assessment binders revealed there were no evaluations performed on the three Technical Supervisors and two General Supervisors for the duties they performed as supervisors. 2. During an interview on 06/06/2025 at 5:17 PM, Technical Supervisor A stated there were no competency evaluations for the Supervisors. B 1. Review of the competency assessment for Testing Personnel D, who was also Technical Supervisor B, revealed the competency assessments for Testing Personnel D were signed by a Testing Personnel. The Hematology/Coagulation Competency Checklist was signed by Testing Personnel J on 07/23/24 and 07/24/23. The Immunology Department Competency Checklist and Molecular Department Competency Checklists were signed by Testing Personnel K on 07/23/2024, and 07/24/2023. 2. During an interview on 06/06/2025 at 5:17 PM, Technical Supervisor B acknowledged her competency assessments as Testing Personnel were signed by another Testing Personnel.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test

	procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 record review, observation and interview, the laboratory failed to create a CAMP (Christie-Atkins-Munch-Petersen) test procedure for the laboratory to follow. Findings: Review of "Standard Operations Manual" revealed there was no procedure for CAMP test. On 06/06/2025 at 1:21 PM, the Technologist showed how he performed CAMP Test, and confirmed it was not listed in the procedure manual. During an interview with the Technical Supervisor on 06/05/2025 at 4:59 PM, the Technical Supervisor confirmed there was no current CAMP Test procedure.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to run and document positive and negative quality controls for QuantiFERON-TB Gold Plus (QFT-Plus) performed on Dynex from January 2023 to June 5, 2025. Findings: 1. The QuantiFERON-TB Gold Plus (QFT-Plus) Package insert read," Each laboratory should determine appropriate types of control materials and frequency of testing in accordance with local, state, federal or other applicable accrediting organizations." 2. Review of QFT-Plus logs revealed there was no documentation to indicate what a patient run was and what negative and positive control runs were from January 2023 to June 5, 2025. 3. Review of QFT-Plus procedure revealed there was no documentation of how to perform QFT-Plus and no procedure for how to perform positive and negative control runs for QFT-Plus. 4. Review of Dynex QFT-Plus instrument printout revealed no documentation of QFT -plus positive and negative control runs from January 2023 to June 5, 2025. 5. On 06/05/2025 at 4:48 PM, the Laboratory Supervisor stated controls were not recorded. 6. On 06/05/2025 at 5:00 PM, the Technologists stated there was no policy for running controls on Dynex with QFT-Plus. 7. On 06/05/2025 at 4:48 PM, the Laboratory Supervisor stated from January to December in 2023 there were 8884 patients run on Dynex for QFT-Plus and January to April in 2024 there were 1565 patients run on Dynex for QFT-Plus.

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, interview and record review, the Laboratory failed to document corrective actions for 34 temperatures recorded that were out of acceptable range for chemistry controls in the chemistry freezer from 10/2/24 to 6/5/25. Findings: 1. During a tour of the laboratory on 06/04/2025 at 3:15 PM, the following reagents were observed in the freezer: Bio-Rad Liquichek Lipids Controls Level 1 and Bio-Rad Liquichek Lipids Controls Level 3. 2. Review of the package insert of the controls showed the controls had a storage temperature of -20 - 70 degrees Celsius (C). 3. Review of the Quality Control - Temperature logs for freezer #14 showed the temperatures were out of range on the following dates: 10/02/2024 recorded -18 degrees C 10/07/2024 recorded -19 degrees C 10/08/2024 recorded -19 degrees C 10/11/2024 recorded -18 degrees C 10/15/2024 recorded -19 degrees C 11/19/2024 recorded -19 degrees C 11/26/2024 recorded -18 degrees C 12/30/2024 recorded -19 degrees C 01/03/2025 recorded -19 degrees C 01/07/2025 recorded -19 degrees C 01/10/2025 recorded -18 degrees C 02/03/2025 recorded -19 degrees C 02/04/2025 recorded -19 degrees C 03/10/2025 recorded -19 degrees C 03/11/2025 recorded -19 degrees C 03/12/2025 recorded -19 degrees C 03/13/2025 recorded -19 degrees C 03/14/2025 recorded -19 degrees C 03/17/2025 recorded -19 degrees C 03/18/2025 recorded -19 degrees C 03/19/2025 recorded -18 degrees C 03/20/2025 recorded -19 degrees C 03/21/2025 recorded -19 degrees C 03/24/2025 recorded -18 degrees C 03/27/2025 recorded -19 degrees C 04/10/2025 recorded -19 degrees C 04/17/2025 recorded -18 degrees C 04/30/2025 recorded -19 degrees C 05/05/2025 recorded -19 degrees C 05/22/2025 recorded -19 degrees C 05/28/2025 recorded -18 degrees C 05/29/2025 recorded -19 degrees C 05/30/2025 recorded -19 degrees C 06/05/2025 recorded -19 degrees C 4. Review of the procedure, Quality Assurance Temperature Guidelines noted, "All corrective action must be documented at the bottom of appropriate QC log." 5. Review of the Quality Control - Temperature logs for freezer #14 showed there was no documentation of corrective action taken. 6. During an interview on 06/06/2025 at 2:15 PM, Technical Supervisor C acknowledged there were temperatures out of range and no corrective action was recorded.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: Based on review of personnel records and interview, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of one (K) of 13 (A - L) Laboratory Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. (See D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records and interview, the laboratory failed to verify the educational qualifications (foreign equivalence evaluations) of one (K) of 13 (A - L) Laboratory Testing Personnel. The foreign equivalency evaluation is required to verify what the foreign education would be in the United States. Findings: 1. Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 06/02/2025, revealed there were 13 employees listed as high complexity testing personnel. 2. Review of personnel documentation showed Testing Personnel K's diploma was from Jamaica. Review of personnel documentation showed there was no

	documentation of foreign equivalence evaluations for Laboratory Testing Personnel K. 3. During an interview on 06/06/2025 at 4:20 PM, Testing Personnel K stated he would have to get a copy of his foreign equivalency evaluation.