

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645095	(X3) Date Survey Completed 03/27/2025
Name of Provider or Supplier Florida Dept Of Health Bureau Of Public Health Lab	Street Address, City, State 1217 N Pearl St, Jacksonville, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policies and procedures, record review, and interview with technical supervisor #10 (TS #10), the laboratory failed to follow written laboratory procedures for one of one QC (Quality Control) lot change. Findings include: 1. Direct observation on 03/27/25 at 12:55 pm during a laboratory tour, revealed the laboratory performed the molecular detection of drug resistance in Mycobacterium tuberculosis complex using the Deeplex assay (Next Generation Sequencing). 2. Review of the laboratory's written policies and procedures titled, "Molecular Detection of Drug Resistance in Mycobacterium tuberculosis complex with the Deeplex Assay" section, "VIII. Quality Control/Quality Assurance" stated the following: a. "e. Prior to use of a new lot of Deeplex Myc-TB reagents, the reagents will be compared to the previous lot by testing one previously assayed sample." 3. Record review on 03/27/25 of lot changes documented on the "Deeplex Worksheet" from 01/06/25 through 01/31/25 revealed no evidence the laboratory compared the new lot (Lot# 241209DP46 - put into place on 01/31/25) to the previous lot (Lot# 231212DP41 - put into place on 01/06/25). 4. Interview on 03/27/25 at 03:15 pm with TS #10 confirmed the findings above.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed</p>

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, review of the laboratory's policy, email from General Supervisor #9 (GS) and interviews with GS #9 (GS) and Technical Supervisor (TS) #4, the laboratory failed to follow manufacturer's instructions and the laboratory's policy with Abbott Architect HIV, AG/AB and Abbott Architect Anti-HCV Assays for the second recentrifugation of specimens for 2025 as evidenced by: 1. Based on review of the manufacturer's instructions for Abbott Architect HIV, AG/AB states, "To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at >10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if they: Contain Fibrin, red blood cells, or other particulate matter or were frozen and thawed. " Based on review of the manufacturer's instruction for Abbott Architect Anti-HCV states, "To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at >10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if they: Contain Fibrin, red blood cells, or other particulate matter or were frozen and thawed " 2. In review of the laboratory's two policies titled: Abbott Architect HIV, AG /AB and Abbott Architect Anti-HCV Assays, both state the following: "To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at >10,000 RCF (Relative Centrifugal Force) for 10 minutes before testing if they: Contain Fibrin, red blood cells, or other particulate matter or were frozen and thawed." 3. In review of the GS #9 email sent on March 26,2025 at 1112 titled Immediately Cease Second Centrifugation directed at all serology staff states "Please do not second spin samples for the Hepatitis bench until further notice. If you have a sample that warrants recentrifugation per manufacturer's recommendations, please pour off before recentrifuging. The PI is attached for reference". 4. In interview with GS #9 on March 26,2025 at 1046 she stated that they recentrifuge all specimens with the primary tube and do no transferred in a centrifuge tube if it meets the criteria i.e. any clots. 5. In interview with TS #4 on March 26, 2025 at 1413 he confirmed that the HIV AB/AG was also not following manufacturer's instructions when recentrifugation was warranted. 6. The laboratory performed 14,631 Anti-HCV annually and 59,818 HIV AB/AG annually.

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:

I. Based on the observation of the media laboratory, lack of temperature records, and interview with the media preparation room personnel, the laboratory failed to

document the condition of storage for biological chemicals stored in the media laboratory for 21 out of 21 months (July 17, 2023, to March 27, 2025). Findings Included: 1. Observation of the media laboratory revealed, the following sampling (13 bottles) of biological chemicals labeled with storage conditions: a. 1 of 1 bottle of OXOID Bacteriological Peptone, Lot#3530167, expiration date: 2027/09, stored at: 10C - 30C. b. 1 of 1 bottle of OXOID CM0115 Simmons Citrate Agar, Lot#3450933, expiration date: 2027/03, stored at: 10C - 30C. c. 1 of 1 bottle of OXOID CM0119B Charcoal Agar, Lot#3513916, expiration date: 2027/07, stored at: 10C - 30C. d. 1 of 1 bottle of OXOID SS Agar, Lot#3642868, expiration date: 2027/07, stored at: 10C - 30C. e. 1 of 1 bottle of OXOID CM0007 MacConkey Agar, Lot#3566108, expiration date: 2027/10, stored at: 10C - 30C. f. 1 of 1 bottle of BD Peptone, Lot#4207141, expiration date: 2028-03-28, stored at: 2C - 25C. g. 1 of 1 bottle of BD Casitone, Lot#2024882, stored at: 2C - 25C. h. 1 of 1 bottle of BD Difco Cooked Meat Agar, Lot#3277640, expiration date: 2026-08-10, stored at: 2C - 25C. i. 1 of 1 bottle of BD Difco Cystine Agar, Lot#1153608, expiration date: 2026-05, stored at: 2C - 25C. j. 1 of 1 bottle of BD Difco Malonate Broth, Lot#4003561, expiration date: 2025-11-30, stored at: 2C - 25C. k. 1 of 1 bottle of BD BBL Motility Test Medium, Lot#2298713, expiration date: 2026-10-31, stored at: 2C - 25C. l. 1 of 1 bottle of BD BBL Litmus Milk, Lot#2214358, expiration date: 2026-05-31, stored at: 2C - 25C. m. 1 of 1 bottle of Remel GC Agar Base, Lot#814254, expiration date: 2028-06-20, Store tightly closed in a dry place below 30C. 2. The laboratory could not provide documentation for monitored temperature in the media laboratory. 3. An interview with the media preparation room personnel on March 26, 2025, at 2:30 pm, confirmed temperatures were not monitored in the media room from July 2023 to March 2025. Key: Celsius - C. II. Based on manufacturer's instructions, observation, record review, and interview with technical supervisor #2 (TS #2), the laboratory failed to store the TruSight Cystic Fibrosis Library Prep kit according to manufacturer's instructions for three of three months. The laboratory failed to document the temperature for three of three months for the electric slide warmer used in the detection of mycobacteria. Findings include: A. NEWBORN SCREENING (NBS) - TRUSIGHT CYSTIC FIBROSIS LIBRARY PREP KIT: 1. Review of manufacturer's instructions on 03/25/25 titled "TruSight Cystic Fibrosis Package Insert" (page 10) section "TruSight Cystic Fibrosis Library Prep, Box 1" states, "Box 1 reagents are shipped frozen and are stable when stored at -25C to -15C." 2. Observation on 3/26/25 at 10:55 am of the WVR Freezer (location HY33402 and serial# SYM-WB51857053-1508) revealed three boxes of TruSight Cystic Fibrosis Library Prep kit (Lot# A179518) with a manufacturer's storage requirement of -25C to -15C. 3. Record review of WVR freezer temperature records (location HY33402 and serial# SYM-WB51857053-1508) from 01/02/25 through 03/26/25 revealed the following: a. January 2025 - 11 of 23 documented temperatures colder than -25C (specific days 8,9,15,16,18,21,24,24,29,30,31) b. February 2025 - 3 of 23 documented temperatures colder than -25C (specific days 5,20,27) c. March 2025 - 9 of 21 documented temperatures colder than -25C (specific days 13,14,18,19,20,21,22,25,26) 4. Interview with TS #2 on 03/26/25 at 11:05 confirmed the findings above. B. TUBERCULOSIS (TB) - ACID-FAST STAIN PROCEDURE FOR MYCOBACTERIA: 1. On 03/27/2025, review of the laboratory' procedure, titled, "Acid-Fast Stain Procedures for Mycobacteria Standard Operating Protocol" section "VII. Sample Requirements:" stated the following: a. "1. Concentrated or unconcentrated specimens (use auramine O staining method and Ziehl-Neelson for confirmation). Read and report smears with each batch of AFB specimens processed." b. Page 4, ..."f. Transfer the air-dried slide to an electric slide warmer (85 degree centigrade) for an additional 15 minutes, at which time the slide can be removed for staining." 2. Review of the laboratory's environmental monitoring logs from January 2025 through March 2025 revealed the laboratory did not monitor and document the

electric slide warmer for three of three months. 3. Interview on 03/27/25 at 02:00 pm with technical supervisor #10 confirmed the above findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observations of chemicals and interviews with Technical Supervisors (TS) #5 and the media preparation personnel, the laboratory failed to label clinical chemicals with expiration dates in two of the four laboratories observed. Findings Included: 1. On March 26, 2025, at 10:45 a.m., observation of the media laboratory revealed one bottle of Acros Organics Pyridoxal hydrochloride (HCL), Lot#A036352, received October 19, 2016, no expiration date. 2. On March 27, 2025, at 3:41 pm, observation of the microbiology laboratory revealed 2 of 2 bottles of iodine did not have expiration dates: a. Fisher Potassium Iodine, Lot#942646, Received August 18, 2011. b. Fisher Chemical Iodine, Lot#934812, Received October 18, 1993. 3. An interview with the media preparation personnel on March 26, 2025, at 11:00 a.m confirmed the Pyridoxal hydrochloride used to make Orthana Arginine media was not labeled with an expiration date. 4. An interview with TS#5 on March 27, 2025, at 4:00 pm, confirmed the potassium iodide and stock iodine bottles used for microscopic parasite examinations were not labeled with an expiration dates.

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 a review of the intestinal Ova & Parasites (O&P) standard operating procedure (SOP), lack of centrifuge maintenance documentation, and interview with technical supervisor (TS) #5, the laboratory failed to document centrifuge function checks for one of one Centra GP8R centrifuge used to spin down intestinal O&P specimens. Findings Included: 1. The Intestinal O&P SOP, 2. Intestinal O&P Prep Protocol, i, states, "Centrifuge tubes for three minutes at 2000 RPM and allow to come to a full stop". 2. On March 27, 2025, at 11:35 am, the laboratory could not provide documentation of centrifuge function checks for 1 of 1 IEC Centra GP8R centrifuge used to spin down intestinal O&P specimens. 3. From January 1, 2024, to March 26, 2025, 1,457 intestinal specimens' specimen were examined. 4. An interview with TS#5 on March 27, 2025, at 11:45 am, confirmed the IEC Centra GP8R centrifuge function checks were not performed.

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:

I. Based on a review of the Biofire Torch Respiratory Panel (RP2.1) quality control (QC) records and interview with technical supervisor (TS) #8, the laboratory failed to perform two external controls each day of patient testing for the Biofire RP2.1 for 21 out of 21 months (July 2023 to March 2025). Findings Included: 1. On March 27, 2025, at 2:20 p.m., the laboratory could not provide documentation of external QC performed each day specimens were analyzed with the RP2.1 panel from July 15, 2023, to March 27, 2025. 2. The laboratory could not provide an individualized quality control plan for the frequency of QC performed for the RP2.1 panel used from July 15, 2023, to March 27, 2025. 3. From July 15, 2023, to March 27, 2025, 171 specimens were analyzed with the Biofire RP2.1 panels. 4. An interview with TS#8 on On March 27, 2025, at 2:30 pm, confirmed QC was not performed each day of patient testing. II. Based on observation, record review, and interview with technical supervisor #10 (TS #10), the laboratory failed to perform QC (Quality Control) as stated in the laboratory's IQCP (Individualized Quality Control Plan) for six of ten months (06/17/24 through 03/03/25). Findings include: 1. Direct observation on 03/27/25 at 12:45 pm during a laboratory tour, revealed the laboratory performs the detection of Mycobacterium tuberculosis complex and its resistance to rifampin using the GeneXpert analyzer. 2. Interview on 03/27/25 at 2:00 pm with TS #10 confirmed an IQCP was approved by the laboratory director on 06/16/2022. 3. Record review of the laboratory's QCP (Quality Control Plan) stated, "Three levels of external controls (one negative control, one wild type M. tuberculosis complex DNA, and one MDR M. tuberculosis complex DNA) will be tested as follows: with each new lot or shipment of MTB/RIF cartridges, at least once monthly, after system maintenance or PM, after software upgrades, and after instrument relocation." 4. Record review of QC between 06/07/24 through 03/03/25 revealed the laboratory failed to perform external QC for six of ten months as follows: a. External QC not performed between 06/07/25 and 08/20/24 b. External QC not performed between 08/20/25 and 12/18/25 c. External QC not performed between 12/18/25 and 03/03/25 5. Interview on 03/27/25 at 2:20 pm with TS #10 confirmed the findings above.

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 a review of the Giemsa Plus Stain for Blood and Tissue Parasites standard operating procedure (SOP), lack of quality control documents, and interview with technical supervisor (TS) #5, the laboratory failed to document blood parasite quality control (QC) for 123 of 123 specimens examined from July 2023 to March 2025.

Findings Included: 1. The Giemsa Plus Stain for Blood and Tissue Parasites SOP states, VIII. Quality Control, "All lots numbers of Giemsa Plus stain set have been tested using the QC Slide Malarial Blood slide and are acceptable." 2. On March 26, 2025, at 3:50 pm, the laboratory was able to provide documentation of QC performed for the blood parasite microscopic examination for 123 specimens examined from July 2023 to March 2025. 3. An interview with TS#5 on March 26, 2025, at 4:00 pm confirmed QC was not documented for blood parasite microscopic examination.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with technical supervisor #10 (TS #10), the laboratory failed to perform comparison studies on eight different BioRad Variant 250 HPLC (High-Performance Liquid Chromatography) analyzers used to perform hemoglobinopathies variants at least twice a year for one of one year (2024). The laboratory failed to perform comparison studies on two different BD Max analyzers used to perform Mycobacterium tuberculosis complex testing at least twice a year for one of one year (2024). Findings include: A. NEWBORN SCREENING (NBS) - BIORAD VARIANT 250 HPLC ANALYZERS: 1. Direct observation on 03/27/25 at 12:40 pm during a laboratory tour, revealed the laboratory performs Mycobacterium tuberculosis complex testing using two BD Max analyzers interchangeably: a. BD Max - serial #CT0578 b. BD Max - serial #CT1519 2. Record review on 03/27/25 from January 2024 through December 2024 revealed one comparison study (performed on 06/19/24). 3. Interview on 03/27/25 at 1:00 pm with TS #10 confirmed the laboratory performed one comparison study between January 2024 through December 2024. B. TUBERCULOSIS (TB) - BD MAX ANALYZERS: 1. Direct observation on 03/26/25 at 10:15 am during a laboratory tour, revealed the laboratory performs hemoglobinopathies (Types A, F, C, D, E, S) on eight different BioRad Variant 250 HPLC analyzers. 2. On 03/26/25 a request for comparison studies between the analyzers from January 2024 through December 2024 revealed no evidence a comparison study was performed at least twice a year for one of one year (2024). 3. Interview on 03/26/25 at 11:40 am with TS #2 confirmed the above findings.