

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645095	(X3) Date Survey Completed 06/25/2021
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
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based review of the laboratory's policies, manufacturer's instructions, laboratory records, and interview with laboratory staff, the laboratory failed to meet the requirements for preanalytic systems as evidenced by: 1. The laboratory failed to follow their own policies for their specimen acceptability criteria and to ensure specimen integrity in the preanalytic system (see D5311-A). 2. The laboratory failed to follow their written policy for transport requirements established for mycobacteriology specimens for 19 of 40 specimens received in the laboratory (see D5311-B). 3. The laboratory failed to make available a electronic or paper manual for their clients and have up to date information on specimen storage, specimen acceptability/ rejection and specimen preservation (see D5317)</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and</p>

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory's policies, manufacturer's instructions, laboratory records, and interviews with the laboratory staff, the laboratory failed to follow their own policies for their specimen acceptability criteria and to ensure specimen integrity in the preanalytic system as evidenced by: SARS-CoV-2 specimens In review of the laboratory's policy Detection of influenza and SARS-CoV-2 by a real-time RT PCR Multiplex Assay states, "store specimens at 2-8 degrees and ship overnight on ice packs ..." In review of the manufacturer's instructions for Influenza SARS-CoV-2 Multiplex assay states, "store specimens at 2-8 degrees and ship overnight on ice packs ... " In review of the laboratory's policy SOP 2.1.2 Unsatisfactory specimens state, "Specimen should be rejected under the following conditions: improper collection storage, or transport of sample." In review of the laboratory's excel spreadsheet labeled, "Bureau of Public Health Laboratories Test Catalogue" the laboratory did not have SARS-CoV-2 tests listed. It did not include the conditions of transport in the document. This document was presented to the surveyor as their client service manual effective 9/6/2019. In review of the Florida Department of Health After Hours Specimen Delivery log, the following SARS-CoV-2 specimens were marked as no under the column "is refrigeration required" 6-05-2021 @1512 COVID-19 specimens 6-20-2021 @1518 COVID-19 specimens 6-21-2021 @1728 COVID-19 specimens 6-21-2021 @ 2129 COVID-19 specimens 6-22-2021 @1250 COVID-19 specimens 6-22-2021 @2129 COVID-19 specimens 6-23-2021 @1205 COVID-19 specimens The following specimens did not have any indication of what temperature they are required to be stored. On the worksheet to track specimens from the courier they were left blank under the column "is refrigeration required." 6-07-2021 @0601 COVID-19 specimens 6-07-2021 @0802 COVID-19 specimens 6-16-2021 COVID-19 from duval county In interview with the laboratory director and Serology Technical Supervisor on 6/24/2021 @1400 they stated "We cannot tell which COVID specimens were recorded as room temperature." They were unsure which SARS-CoV-2 assay these specimens were used on, where they came from, and how many specimens there were in each delivery. Microbiology (enterics) In review of the manufacturer's instructions for the Medical Chemical Corporation instructions under collection, storage, and transport states, "If immediate transportation to a laboratory is not possible refrigerate at 2-8 degrees C for up to 96 hours." In review of the laboratory's procedure under enteric culture- stool pg. 4 states,"specimens must be submitted in Modified Cary-Blair derived or type of transport media only within 48 hours of collection." In review of 4 of 14 patients, the following patients were pass the 48 and 96 hour time frame. a. Patient #JBC21000169 collected 5/26/2021, date received 6/2/2021, no documentation on the lab's enteric culture record as when they were plated. b. Patient #JBC2100226 collected 06/2/2021, date received 06/21/2021, no documentation on the lab's enteric culture record as when they were plated. c. Patient #JBC2100227 collected 6/16/2021, date received 06/21/2021, no documentation on the lab's enteric record as when they were plated. d. Patient #JBE2100223 collected 5/11/2021, date received 05/18/2021, no documentation on the lab's enteric record as when they were plated Sample requirement HSV-1 and HSV-2 In review of the laboratory's policy "rPCR of Herpesvirus (CMV, HHV-6, HSV-1, HSV-2) on the Applied Biosystems 7500 Fast DX Standard Operation Procedure, " pg 4 states under sample requirements: "Specimens must be maintained at the proper temperature as follows: 2 to 8 degrees C for up to 72 hours or -70 C or colder continuously." In review of the laboratory's policy "SOP section 2.1.2 Unsatisfactory specimens" states "A specimen should be rejected under the following

conditions: Improper collection, storage, or transport of sample." In review of the following patients they did not meet the 72 hour time frame: a. Sample# JVT21009541 date collected: 6/09/2021 date received: 6/16/2021 b. Sample# JVT21009540 date collected 6/10/2021 date received: 6/6/2021 c. Sample#JVT21008971 date collected 5/20/2021 date received: 5/27/2021 d. Sample# JVT21008972 date collected 5/20/2021 date received: 5/27/2021 e. Sample#JVT21005398 date collected 3/16/2021 date received: 03/25/2021 f. sample#JVT21009451 date collected 06/03/2021 date received: 06/03/2021 g. sample#JVT21009544 date collected 06/11/2021 date received: 06/16/2021 h. sample#JVT21006514 date collected 04/08/2021 date received: 04/13/2021 i. sample#JVT21009453 date collected 06/4/2021 date received: 06/10/2021 In interview with the virology General Supervisor @1245 on 6/22/2021 stated, "I don't think the correction times is correct." On a follow-up interview with the Laboratory Director on 6/22/2021 @1405 she stated that she thought it may be a LIS limitation or /and an IT issue that the specimens on the final reports may not be reflecting the receipt time in the lab. In addition, she thought they may have to change their process to when they accession the specimens when they get them rather than days later when they are ready to test. 41221 B. Based on sample record review, the laboratory's written procedure, interview with accessioning staff and laboratory supervisor and direct observation, the laboratory failed to follow their written policy for transport requirements established for mycobacteriology specimens for 19 of 40 specimens received in the laboratory within 24 hours for 6/23/21. Findings: 1) In review of the BD MAX Real-time PCR Standard Operating Procedure Version 2, November 1, 2018 under VII. Sample Requirements states, "Specimens should be collected in a sterile container and stored at 2-8 C and should arrive in the Mycobacteriology Laboratory within 24 hours of collection." 2) A sampling of 40 requisitions and preliminary reports for specimens received on 6/23/21 were reviewed. 19 of 40 reports showed specimen receive time in the laboratory was greater than 24 hours after collection. All specimens were processed for testing. Examples: LIMS Report# Specimen Type Date Collected Date Received 10698296 CSF 06/18/2021 06/23/2021 10698220 Bronchial Lavage 06/17/2021 06/23/2021 10698222 Bronchial Lavage 06/17/2021 06/23/2021 10698223 Bronchial Wash 06/18/2021 06/23/2021 10698240 Bronchial Wash 06/21/2021 06/23/2021 (Remaining samples listed in evidence) 3) Based on observation on 06/23/2021 at 1045 hours in the TB laboratory processing area, 8 shipping containers containing specimens were unpacked for processing. The laboratory did not have means to ensure specimens were 2-8 degrees Celsius. The laboratory does not have documentation to ensure conditions of transport were within their acceptability criteria. 4) In interview with accessioning staff in the triage area on 06/23/2021 at 1040 hours the surveyor asked "How do you know how the specimens for each area should be received?" Triage staff stated that someone from each laboratory department will tell them. 5) In interview with the Mycobacteriology laboratory supervisor in her office on 06/24/2021 at 1415 hours it was confirmed that all 40 specimens received on 06/23/2021 were processed and tested. The supervisor confirmed that no specimen is rejected unless it is missing a crucial identifier such as a name. 6) The laboratory has an approximate annual mycobacteriology test volume of 84,500.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's client service manual spreadsheet, and interview, the laboratory failed to make available a electronic or paper manual for their clients and have up to date information on specimen storage, specimen acceptability/rejection and specimen preservation as evidenced by: 1. In interview with the Laboratory Director on 6/23/2021 @ 1530 stated she didn't think they had a client service manual, but later was able to find the excel spread sheet on the computer. In questioning further after she found the manual, the Laboratory Director stated that she didn't know if her clients had the manual available to them. She stated that in the past she has sent out memos or had her staff talk with the laboratories on the phone if they had questions concerning testing. 2. In review of the laboratory's excel spread sheet labeled, "Bureau of Public Health Laboratories Test Catalogue." The following tests in the chart worksheets did not have specimen storage and preservation and conditions for transport listed: Vaccina Virus Detection Detection PCR Arbovirus Plague, reduction test Arbovirus IgG Varicella Zoster Virus IgM Hepatitis A, PCR Enteric Culture Throat (Beta Strep) Aerobic isolate ID Aerobic isolate (for Diphtheria) Anaerobic cultures TB cultures Real time PCR NAAT for TB AFB cultures for ID TB drug Susceptibilities Syphilis confirmation TPA Syphilis Total antibody Syphilis RPR Chlamydia screen and Gonorrhea HIV-1 Oral sure CD4/CD8 count/ratio HIV-1 viral load HIV-1 Genotyping Gonorrhea Culture Herpes Simplex virus type IgG Parasite, blood Toxoplasma IgG Cytomegalovirus IgG Zika Virus Varicella zoster virus IgG Ehrlichia IgG Rocky Mountain Spotted Fever IgG Rubella IgM Measles IgG Q fever IFA Chikungunya virus Dengue virus DNA probe/Gen probe (mycobacterium) Ebola GeneXpert MTD/RTF Hep B Surface Antigen Confirmation Test Legionella IFA Mumps IgG and IGM Mycology culture Ova and parasites, intestinal Salmonella typing Gene Expert PCR The following tests did not have listed conditions for specimen acceptability and rejection: Vaccina Virus Detection Detection PCR Arbovirus Plague, reduction test Varicella Zoster virus culture Arbo virus IgG VZV IgM Hepatitis A PCR B. pertussis Culture PCR Syphilis confirmation TPA Measles IgG Q fever IFA DNA probe/Gen probe (mycobacterium) Hep B Surface Antigen Confirmation Test Mumps IgG and IGM Mycology culture Ova and parasites, intestinal Gene Expert PCR 3. In the exit conference on 6/25/2021 @ 1041 with the Laboratory Director and her staff, she stated that she was aware that it was not updated.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's COVID-19 verification studies document review, interview with the viral technical supervisor and laboratory director, the laboratory failed to demonstrate that they had validated test performance specifications for their

SARS- CoV-2 multiplex rRT-PCR EUA (emergency use authorization) test for 5 of 7 ABI 7500 instruments that was used before patient testing as evidenced by: 1. The laboratory could not provide documentation to show that they had performed validations on the ABI 7500 instruments used for the CDC multiplex SAR-CoV-2 PCR on instruments labeled 1,3,4,5,6 by the laboratory. 2. They did not have the following documentation that showed Accuracy Precision 3. In an interview with the virology Technical Supervisor on 6/22/2021 @1301 she stated that they only did validations on 2 of the 7 instruments. 4. In an interview with the Laboratory Director on 6/22/2021 @1515 she stated, "We should have done all of the instruments." (referring to validation of ABI 7500)

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 review of Abbott Architect Maintenance History log, corrective action log and interview with Technical Supervisor the laboratory failed to ensure corrective actions were documented. Findings: 1. The laboratory failed to document corrective action for Abbott Architect i200SR in Serology from date placed in service March 2020 to June 2021. The manufacturer manual on page 9-1, includes a space for comments on Maintenance History Log when procedures are not completed (Failed). 2. The laboratory uses the Abbott Architect i2000SR manufacturer computer system to track maintenance activities. The review of the Maintenance History Log did not have any comments documented on the report when the maintenance Failed (Table 9-1). Review of the paper Corrective Action log found the laboratory had not documented any corrective actions for the new instrument since it was replaced in March 2020. The log book did not have any entries for the Abbott Architect i2000SR. 3. The laboratory has a paperless maintenance system for the Abbott Architect computer system (Section 9-18) and prints reports on a daily basis. The laboratory provided documentation of instrument report that had failure codes listed, without documentation of corrective actions on the report or a paper corrective action log. 3. The Technical Supervisor confirmed on June 24, 2021 at 10:00am that the laboratory did not document corrective action for the Abbott Architect i2000SR Maintenance History Log.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported

from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on record review and interview with Laboratory Director and Laboratory Administrator the laboratory failed to ensure performance of electronic test results verification was sent to the laboratory final destination. Findings: 1. The laboratory failed to provide documentation of their completed electronic test verification of a test report performed in 2020 and 2021. The laboratory Quality Assessment monitors did include electronic test verification. 2. The review of the laboratory Quality Assessment procedure manual failed to include laboratory verification of test result guidance. 3. An interview with the Laboratory Administrator on June 24, 2021 at 9:00AM confirmed that the laboratory did not perform electronic test verification for test reports.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of 11 of 11 patient test reports in June, the laboratory's policy, manufacturer's instructions, interview with the Virology Technical supervisor and the laboratory director, the laboratory failed to follow CDC Influenza SARS-CoV-2 Multiplex manufacturer's instructions and their own policy for reporting SARS-CoV-2 patient test results as evidenced by: 1. According to CDC Emergency use Authorization (EUA) manufacturer's instructions effective 2 July 2020, a table is provided which outlines how test results should be reported on the final report. Based on this table, it states under report, "negative". With two negative influenza results and SARS-CoV-2 is positive the laboratory is to report, "Positive for COVID-19" 2. In review of the laboratory's policy titled, "Detection of Influenza and SARS-CoV-2 by a Real-time PT PCR Multiplex Assay," table is provided which outlines how test results should be reported on the final report. Based on this table, states under Multiplex assay interpretation report "negative". With two negatives influenza results and SARS-CoV-2 is positive the laboratory is to report, "Positive for COVID-19" 3. In review of the 10 of 10 patient negative test reports, the laboratory did not report the actual result of the test as negative as stated in their policy and manufacturer's instructions. In review of 1 of 1 positive results, the laboratory did not have the actual result on the patient test report as described by the policy or manufacturer's insert. 4. In interview with the laboratory director on 6/22/2021 @ 1403 stated, "You're right we are not following the manufacturer's instruction or our policy."

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Newborn Screening Laboratory competency assessment records and staff interview, the Technical Supervisor failed to evaluate the semi-annual competency assessments for new testing personnel. Findings: 1. A review of the Newborn Screening Laboratory competency assessment records for calendar year 2019, 2020 and 2021 revealed the semi-annual assessments for nine of nine new testing personnel were performed by laboratory staff other than the Technical Supervisor. 2. During interview on June 23, 2021, at 11:30am, the Newborn Screening Technical Supervisor confirmed she did not perform the semi-annual competency assessments.