Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645095	01/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Florida Dept Of Health Bureau Of Public Health Lab	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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 review of proficiency test records and interview with staff, the laboratory failed to perform proficiency testing in the same manner and using the same methods as patient testing. Findings: 1. Review of American Association of Bioanalysts (AAB) Bacteriology proficiency test records on January 17, 2019, at 3:30pm revealed the laboratory used various commercial microbial identification systems (MIS) to identify bacteria in proficiency test samples in addition to the routine laboratory tests performed on patient samples. The laboratory routinely identifies bacteria in patient samples using individual biochemicals, records the reactions and submits the reactions to an online database which calculates the phenotypic identification. The records reviewed included the following proficiency testing events and test methods performed by the laboratory. a. 2016 - Event 3: The laboratory used the "API Staph" MIS and individual biochemicals to identify bacteria in samples 1, 2 and 5; and used the "API Strep 20" MIS and individual biochemicals to identify bacteria in sample 2. b. 2017 - Event 1: The laboratory used the "API Staph" MIS and individual biochemicals to identify bacteria in samples 2 and 3. The laboratory used the "API Strep 20" MIS and individual biochemicals to identify bacteria in sample 5. c. 2017 - Event 2: The laboratory used the "API Staph" MIS and individual biochemicals to

	identify bacteria in sample 1; and used the "API 20 Strep" MIS and individual biochemicals to identify bacteria in samples 1 and 2. The laboratory used the "RapID ANA II" MIS and individual biochemicals to identify bacteria in sample 1. d. 2017 - Event 3: The laboratory used the "API 20 Strep" MIS and individual biochemicals to identify bacteria in sample 2; used "API Staph" MIS and individual biochemicals to identify bacteria in sample 3 and 5; and used the "RapID ANA II" MIS and individual biochemicals to identify bacteria in sample 3. e. 2018 - Event 1: The laboratory used the "API Staph" MIS, the "RapID ANA II" MIS and individual biochemicals to identify bacteria in sample 3. f. 2018 - Event 2: The laboratory used the "API Staph" MIS and individual biochemicals to identify bacteria in sample 3. g. 2018 - Event 3: The laboratory used the "API 20 Strep" MIS and individual biochemicals to identify bacteria in samples1 and 2; and used the "API Staph" MIS and individual biochemicals to identify bacteria in samples 3 and 5. 2. On January 17, 2019 at 8: 15am, the surveyor requested quality control records for the "API Staph", "API 20 Strep" and "Rapid ANA II" MISs. TP-M stated the laboratory does not perform quality control testing on the microbial identification systems because these test methods are not used for patient testing.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records for the years 2016, 2017 and 2018, and interview with staff, the Laboratory Director or designee and testing personnel failed to sign proficiency test attestation statements. Findings: 1. Review of American Proficiency (API) GC Culture test records on the morning of January 15, 2019, revealed the Laboratory Director or designee, and testing personnel failed to sign API's attestation statements attesting to the routine integration of the proficiency samples into the patient workload using the laboratory's routine methods for the following testing events: a. 2017 - Event 3 b. 2018 - Event 2 and 3 2. Review of AAB Bacteriology test records for on the morning of January 15, 2019, revealed the Laboratory Director or designee, and testing personnel failed to sign AAB's attestation statement attesting to the routine integration of the proficiency samples into the patient workload using the laboratory's routine methods for the following testing events: a. 2017- Event 1 and 3 b. 2018 - Event 2 and 3 3. Review of AAB Parasitology test records on the morning of January 15, 2019, revealed the Laboratory Director or designee, and testing personnel failed to sign AAB's attestation statement attesting to the routine integration of the proficiency samples into the patient workload using the laboratory's routine methods for the following testing events: a. 2018 - Event 2 and 3 4. During interview on January 16, 2019 at 4pm, the technical supervisor (TS-M) confirmed the attestation statements listed above were not signed by the Laboratory Director or designee and testing personnel.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on review of proficiency test records and interview with staff, the laboratory failed to test proficiency samples the same number of times that patient samples are tested. Findings: 1. Review of API GC Culture proficiency testing records on the morning of January 15, 2019, revealed samples were tested by two testing personnel for the following events. a. 2016 - Event 3: Test records included two different "Oxidase Positive Worksheet", a form used by the testing personnel to record test results. One "Oxidase Positive Worksheet" was dated October 20, 2016 and the other was dated October 21, 2016. The forms contained no name or initials of the testing personnel, but handwriting was different. Two API "Data Entry Worksheet" forms were included in the records, both containing test results. One form was signed by TP-M and dated October 28, 2016. The other form was signed by TP-M1 and dated October 31, 2016. b. 2017 - Event 1: Test records included forms for recording test results for Accuprobe Neisseria gonorrhoea Culture Identification Kit. Accuprobe testing performed on March 7, 2017 was labeled with the following sample numbers and the testing personnel's name: GC-01 TP-M1; GC-04 TP-M1; GC-01 TP-M; GC-02 TP-M; GC-04 TP-M and GC-04 TP-M. c. 2017 - Event 3: Test records included forms for recording test results for Accuprobe Neisseria gonorrhoea Culture Identification Kit. Accuprobe testing performed on October 3, 2017 was labeled with the following sample numbers and the testing personnel's name: GC-12 TP-M1; GC-15 TP-M1; GC-12 TP-M and GC-15 TP-M. d. 2018 - Event 2: Test records included forms for recording test results for Accuprobe Neisseria gonorrhoea Culture Identification Kit. Accuprobe testing performed on July 3, 2018 was labeled with the following sample numbers and the testing personnel's name: GC-02 TP-M1; GC-09 TP-M1 and GC-09 TP-M. API "Data Entry Worksheet" forms were included in the records, both containing test results. One form was signed by TP-M and dated July 5, 2018. The other form was signed by TP-M1 and dated July 5, 2018. e. 2018 - Event 3: Test records included forms for recording test results for Accuprobe Neisseria gonorrhoea Culture Identification Kit. Accuprobe testing performed on October 3, 2018 was labeled with the following sample numbers and the testing personnel's name: GC-12 TP-M1; GC-13 TP-M1;GC-12 TP-M ad GC-13 TP-M. API "Data Entry Worksheet" forms were included in the records, both containing test results. One form was signed by TP-M and dated October 5, 2018. The other form was signed by TP-M and dated October 12, 2018. The record also included two "Oxidase Positive Worksheet" forms. One was dated September 28, 2018, the other had no date. Neither form included the testing personnel name or initials, but handwriting was different. 2. During interview on the morning of January 17, 2019, TP-M confirmed the proficiency testing listed above was performed by both TP-M and TP-M1. TP-M confirmed patient samples were routinely tested only one time, by one testing personnel.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, review of the Quality Assurance Plan for the Microbiology Laboratory and interview with staff, the laboratory failed to

	review proficiency test scores. Findings: 1. Review of AAB proficiency test records revealed the laboratory failed to review test scores for the programs Bacteriology and Parasitology for all three events in years 2017 and 2018. 2. During interview the morning of January 16, 2019, TS-M confirmed the laboratory did not document review of proficiency test scores for the programs and events listed above. 3. The Quality Assurance Plan for the Microbiology Laboratory states the following on page number 4 under the heading "E. Proficiency Testing": "4. Results are evaluated by survey provider against peer group responses and reported back to the laboratory. Internally, results are evaluated by the section supervisor. Outliers (if present) are investigated, and after investigation, the report should be signed by the CLIA Laboratory Director".
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, review of the Quality Assurance Plan for the Microbiology Laboratory and interview with staff, the laboratory failed to follow it's policy to investigate unacceptable proficiency test results. Findings: 1. Review of API proficiency testing records on the morning of January 15, 2019, revealed the following scores. Bacteriology program: a. 2017 - Event 2 - 80% b. 2017 - Event 3 - 80% c. 2018 - Event 1 - 90% Parasitology program: a. 2017 - Event 3 - 90% 2. During interview on the morning of January 16, 2019, TS-M confirmed the laboratory did not investigate the proficiency test samples scored as unacceptable for the events listed above. 3. The Quality Assurance Plan for the Microbiology Laboratory states the following on page number 4 under the heading "E. Proficiency Testing": "4. Results are evaluated.....supervisor. Outliers (if present) are investigated, and after investigation, the report should be signed by the CLIA Laboratory Director. 5. If the laboratory testing of a PT challenge does not produce acceptable results, the cause of the error must be investigated and corrected."
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by:

	Based on record review and interview the laboratory failed to document the validation protocol actual measurements taken, reactions and observations for accuracy, precision, reportable ranges and reference interval. Findings include: 1. The Virology laboratory failed to verify and document the accuracy, precision, reference range and reportable range for the quantitative Rickettsia Real -Time PCR assay and CDC Rubella Virus Real Time RT-PCR prior to the start of testing in 2017 and 2018. The laboratory validation protocol did not have a summary and conclusion that showed the evaluation/calculations for each new test performed. 2.The Virology laboratory implemented the Rickettsia on October 17, 2017 and CDC Rubella Virus Real Time RT-PCR on October 9, 2018 but failed to include accuracy, precision or reportable range in the validation protocol approved by the laboratory director. The laboratory failed to calculate the percent within run, between run and total precision by dividing observed results over known results to determine a percentage. 3. During the interview on January 17, 2019 at 1:00pm the Technical Supervisor confirmed the laboratory validation protocol did not include written summary and calculations to show the validation performance of accuracy, precision, reference and reportable range for each new test procedure.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, the laboratory procedure manual, the owner manual for the GeneXpert Carba-R Assay, the Individualized Quality Control Plan (IQCP) for the GeneXpert Carba-R Assay and interview with laboratory staff, the laboratory failed to perform quality control testing for the GeneXpert Carba-R Assay as required and failed to establish a complete IQCP. Findings: 1. Bacteriology quality control records reviewed on the afternoon of January 16, 2019, did not include records for external quality control for the GeneXpert Carba-R assay. 2. During interview on the morning of January 17, 2019, TS-M stated the GeneXpert Carba-R assay contains two internal controls and the laboratory does not perform any additional quality control testing. 3. The laboratory's procedure for the GeneXpert Carba-R assay states on page 2 under "VII. Quality Control" the following: "Each test includes a Sample Processing Control and a Probe Check Control. Sample Processing Control (SPC)-Ensures the sample was processed correctly. The SPC contains spores of Bacillus globigii in the form of a dry bead that is included in each cartridge to verify adequate processing of the sample. The SPC verifies that lysis of bacteria has occurred if the organisms are present and verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria. Probe Check Control

	(PCC)-Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. Probe Check passes if it meets the assigned acceptance criteria." 4. The manufacturer's manual for the GeneXpert Carba-R assay states on page 8 under "11 Quality Control" the following: "Built-in Quality Controls Each test includes a Sample Processing Control and a Probe Check Control. Sample Processing Control (SPC)-Ensures the sample was processed correctly. The SPC contains spores of Bacillus globigii in the form of a dry bead that is included in each cartridge to verify adequate processing of the sample. The SPC verifies that lysis of bacteria has occurred if the organisms are present and verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria. Probe Check Control (PCC)-Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. Probe Check passes if it meets the assigned acceptance criteria. External Controls External controls described in Section 6.4 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable. Always use external controls, according to the manufacturer ' s instructions." 5. On the morning of January 18, 2019, the laboratory director provided an IQCP for the GeneXpert Carba-R assay. Review of the IQCP on January 23, 2019 revealed the IQCP was incomplete and unacceptable due to the following: a. The introductory section of the IQCP refers to "lysis of MTB" at the bottom of page 2. The GeneXpert Carba-R assay is FDA approved for testing of Enterobacteriaceae, Pseudomonas aeruginosa, and Acinetobacter baumannii only. b. The Risk Assessment (RA) refers to "appropriate storage conditions for sputum specimens" for mitigating risks associated with specimen storage on the top of page 2. The GeneXpert Carba-R assay is not FDA approved for testing of sputum specimens. c. In several areas, the Risk Assessment suggests the storage of reagents and performance of the test at room temperature is mitigated by use of a thermostat in the storage and testing area and mitigated by a 24 hour recorder on the refrigeratosr and freezers. The Risk Assessment does not address the monitoring of temperatures by laboratory staff. d. On page 5, the IQCP refers to "Internal Controls (SPC, PCC, QC1 and QC2) are performed for each test to ensure that the proper specimen processing.....no reagent quality issue." The laboratory procedure manual and manufacturer's manual to not reference the use of internal controls QC1 and QC2. d. The laboratory did not provide historical external quality control data to support the Quality Control Plan (QCP). e. The IQCP does not contain Quality Assessment monitoring of the IQCP.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on interview with staff, review of test records and review of manufacturer package insert, the laboratory failed to document quality control testing for the RIM E. coli 0157:H7 Latex Kit. Findings: 1. STEC (Shiga toxin-producing E.coli) Microbiology Worksheets were reviewed at approximately 2pm on January 16, 2019. The top portion of the worksheet contains a chart for documenting the sample identification code, the culture results, the PCR (polymerase chain reaction) results and the serotying results. The bottom portion of the worksheet contains space to record the lot numbers and expiration dates for the media, PCR reagents and serogrouping reagents used in the testing process. The serogrouping reagents included both the RIM E. coli 0157:H7 Latex Kit and Somatic O Antibodies for Big 6 (anti-sera). Lot numbers were recorded for each test, but no expiration dates were recorded. No quality control results for any testing were recorded on the worksheets. 2. Review of the RIM E.coli 0157:H7 Latex Kit manufacturer's package insert at approximately 2pm on January 16, 2019, revealed the following instructions: "Quality Control A Positive and Negative Control is included with each kit. Test controls with each new kit lot number and shipment or following applicable regulatory guidelines." 3. During interview on January 17, 2019, at 8:15am, the TP-M stated the laboratory does not document quality control results for the RIM E.coli 0157:H7 Latex Kit.