Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D0709206	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rhode Island State Health Laboratories	50 Orms St, Providence, RI	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: A. Based on observation and staff interview, the Arbovirus/ Serology/ STD Laboratory, failed to be constructed and maintained to minimize contamination. Findings include: 1. Observation on 03/31/2021 at 2:20 PM of the Arbovirus/ Serology/ STD Laboratory in Room 417 and benches 1 through 4 in Room 418 revealed the following work surfaces were not maintained to minimize contamination: a. The Neisseria gonorrhoeae (GC), Chlamydia trachomatis (CT), COVID 19, sample processing and the MagNA Pure 96 loading benchtops were worn and had areas of exposed particleboard due to loss of laminate on the front edges. The sink area benches were rusted and the bottom floor of the sink cabinet was rusted with holes. b. The Human immunodeficiency virus (HIV), Arbrovirus and Syphilis sink areas had missing laminate exposing wood particleboard, and the metal workstations and drawers had multiple areas of rust. c. The centrifuge used for processing Syphilis serology samples was located on a benchtop that had laminate peeling away from the front edge. d. A metal movable cart was used to process HIV and Syphilis samples for testing on the Abbott ARCHITECT instrument due to lack of permanent bench space. 2. Interview with the Arbovirus/ Serology/ STD HIV/HCV Technical Supervisor (TS1) on 03/31/2021 at 2:30 PM revealed that the laboratory's policy to prevent contamination was to decontaminate all work surfaces at the end of each day. Upon further questioning, the TS1 confirmed that decontamination procedures were not suitable for porous (wood) or non-smooth (rust and taped) surfaces. B. Based on observation and staff interview, the Molecular Amplification Laboratory in Room 422 failed to be constructed and maintained to minimize contamination. Findings include:

	1. Observation at 2:45 PM on 03/31/2021 of the Molecular Amplification Laboratory in Room 422 revealed that the following work surfaces were not maintained to minimize contamination: a. The benchtops used to process COVID 19, Influenza, RSV, and Norovirus samples for testing had exposed particleboard due to loss of laminate on the front edges. b. The metal workstations and drawers had multiple areas of rust. c.The FilmArray Torch instrument was placed on a piece of cardboard. 2. Interview with the Molecular Technical Supervisor (TS2) on 03/31/2021 at 2:45 PM revealed that the laboratory's policy to prevent contamination was to decontaminate all work surfaces at the end of each day. Upon further questioning, the TS2 confirmed that decontamination procedures were not suitable for porous (wood, cardboard) or non-smooth (rust and taped) surfaces.
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 staff interview, the laboratory failed to establish performance specifications after modifying the intended use of the Cepheid GeneXpert MTB/RIF Assay for use with non-sputum respiratory specimens. Findings include: 1. Record review conducted on 03/29/2021 of the Xpert MTB/RIF Assay manufacturer instructions, Rev. D, March 2016, revealed the following: a. Under Section 3. Intended Use, "for the detection of Mycobacterium tuberculosis complex DNA in raw sputum or concentrated sputum sediment prepared from induced or expectorated sputum. In specimens where Mycobacterium tuberculosis complex (MTB-complex) is detected.." b. Under Section 12. Limitations: "The performance of the Xpert MTB/RIF Assay was evaluated using induced or expectorated sputa. Testing of other clinical samples (e.g., blood, CSF, gastric aspirate, stool, tissue, urine) has not been evaluated and may alter test performance." 2. Record review conducted on 03/29/2021 of the Cepheid GeneXpert MTB/RIF Non-sputum laboratory validation performed October 18, 2019 through January 14, 2020 approved by the Laboratory Director on 01/21/2020 revealed the laboratory verified the accuracy, precision, and reference range (normal values) performance specifications for decontaminated non-sputum respiratory specimens using the Cepheid GeneXpert MTB/RIF test system. The reportable range was not applicable. 3. Record review conducted on 03/29/2021 of Cepheid GeneXpert MTB/RIF Assay testing records revealed the laboratory tested 16 non-sputum respiratory patient samples January 2020 through March 2021. 4. Interview with the Mycobacteriology Technical Supervisor and the Laboratory Director on 03/29/2021 at 3:50 PM confirmed that the laboratory did not establish analytical sensitivity and analytical specificity performance specifications.

D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document and evaluate test performance using internal blind testing samples or external proficiency testing samples in the 2020 competency assessment for one of four testing personnel (TP1) performing Norovirus RT-PCR testing. Findings include: 1. Record review conducted on 03/30/2021 of 2020 employee competency assessment documentation found four TP performing Norovirus testing using the GeneXpert DX. The review revealed the competency assessment completed on 03/12/2020 for TP1 did not include an assessment of test performance through previously tested blinded samples or external proficiency testing samples. 2. Record review conducted on 03/30/2021 of the Quality Assurance Plan, CLN-QA published on 03/01/2019, Section 5.5, Competency Assessments revealed that the competency assessment element of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples was missing from this section. 3. Interview with Molecular Technical Supervisor and the Quality Assurance Manager on 03/30/2021 at 3:30 PM confirmed that the documentation of competency assessment completed on 03/12/2020 was incomplete for TP1 who performs Norovirus testing using the GeneXpert DX. 4. The Rhode Island Department of Public Health Laboratory tested 18 samples for Norovirus using theGeneXpert DX between 03/04/2020 - 11/13/2020.