Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D0709206	03/30/2023
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: A. Based on record review, surveyor observation, manufacturer's instructions, and interview with Technical Supervisor (TS#3), the laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Hologic Panther analyzer for 12 of 12 months. Findings include: 1. Record review conducted on 03/27 /2023 revealed that the laboratory failed to document the humidity where the Hologic Panther was used to perform HIV-1 RNA, Chlamydia trachomatis/Neisseria gonorrhoeae, Trichomonas vaginalis, and Confirmatory Hepatitis C patient testing during 2022. 2. Surveyor observation on 03/27/2023 at 12:35 pm of the laboratory testing area revealed a humidity reading of 15.4%. 3. Review of the Operator's Manual stated "Relative humidity from 20%- 85%". 4. Staff interview with TS#3 on 03/27/2023 at 01:25 pm confirmed the laboratory failed to ensure humidity was maintained as required by the manufacturer as indicated above. 5. The laboratory performed 90 HIV-1 RNA, 26, 429 Chlamydia trachomatis/Neisseria gonorrhoeae, 11, 741 Trichomonas vaginalis, and 271 Confirmatory Hepatitis C patient tests in 2022 B. Based on record review, manufacturer's instructions, and interview with Technical Supervisor (TS#7), the laboratory failed to ensure the humidity was maintained as required by the manufacturer for the ABI 7500 Fast DX analyzer for 12 of 12 months. Findings include: 1. Record review conducted on 03/29/2023 revealed

	that the laboratory failed to document the humidity where 3 different ABI 7500 Fast DX instruments were used to perform Measles, Mumps, and Shiga-toxin RT-PCR patient testing during 2022. 2. Review of the Operator's Manual stated "Humidity: 20 - 80%, relative humidity, noncondensing". 3. Staff interview with TS#7 on 03/29 /2023 at 11:10 am confirmed the laboratory failed to ensure humidity was maintained as required by the manufacturer as indicated above. 4. The laboratory performed 12 Mumps, 3 Measles, and 53 Shiga-toxin patient tests in 2022
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on a lack of documentation and staff interview with the Technical Supervisor (TS#7), the laboratory failed to evaluate the test performance of the 4 ABI instruments used to perform Measles and Mumps RT-PCR patient testing in 2022. Findings include: 1. Record review conducted on 03/29/2023 of the molecular laboratory's comparison of test result documentation revealed that the laboratory failed to evaluate Measles and Mumps RT-PCR test performance on the 3 different ABI 7500 Fast DX instruments named Seth, Cain, and Abel used to perform patient testing during 2022. 2. Record review conducted on 03/29/2023 of RT-PCR Measles and Mumps 2022 patient test records revealed that the 3 different ABI 7500 Fast DX instruments named Seth, Cain, and Abel were used for patient testing during 2022. 3. Record review conducted on 03/29/2023 of the approved CLN-SOP Quality Assurance Plan Revision 5 (ID 3138) stated in section 7.10, A, "Twice a year the laboratory must compare and evaluate the test results that are performed by the laboratory when using the same test for different methodologies or instruments". 4. Staff interview with TS#7 on 03/29/2023 at 2:30 pm confirmed the findings above. 5. The molecular laboratory performed 12 Mumps and 3 Measles by RT-PCR patient tests in 2022. B. Based on a lack of documentation and staff interview with the Technical Supervisor (TS#7), the laboratory failed to evaluate the test performance of the 3 ABI instruments used to perform Shiga-toxin RT-PCR patient testing in 2022. Findings include: 1. Record review conducted on 03/29/2023 of the molecular laboratory's comparison of test result documentation revealed that the laboratory failed to evaluate Shiga-toxin RT-PCR test performance on the 3 different ABI 7500 Fast DX instruments named Seth, Cain, and Abel used to perform patient testing during 2022. 2. Record review conducted on 03/29/2023 of RT-PCR Measles and Mumps 2022 patient test records revealed that the 3 different ABI 7500 Fast DX instruments named Seth, Cain, and Abel were used for patient testing during 2022. 3. Record review conducted on 03/29/2023 of the approved CLN-SOP Quality Assurance Plan Revision 5 (ID 3138) stated in section 7.10, A, "Twice a year the laboratory must compare and evaluate the test results that are performed by the laboratory when using the same test for different methodologies or instruments". 4. Staff interview with TS#7 on 03/29/2023 at 01:03 pm confirmed the findings above. 5. The molecular laboratory performed 53 Shiga-toxin by RT-PCR patient tests in 2022.