

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2192997	<b>(X3) Date Survey Completed</b>  09/27/2022
<b>Name of Provider or Supplier</b>  Princeton Eye And Ear	<b>Street Address, City, State</b>  2999 Princeton Pike, 2nd Floor, Lawrenceville, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3005</b>	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the area where Molecular testing was performed and interview with the General Supervisor (GS), the laboratory failed to have molecular amplification procedures that are contained in closed system that has a uni-directional workflow from November 2020 to the date of the survey. The findings include: 1. The laboratory was not performing DNA extraction under an BSL-2 hood. 2. The Master Mix was being prepared and added to the sample plate under the same hood. 3. The Quantstudio 12K PCR analyzer was not in a separate room. 4. The GS confirmed on 9/27/22 at 11:00 am the laboratory failed to have molecular amplification procedures that are contained in closed system that has a uni-directional workflow.</p>
<b>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the NJ State License, Test Requisitions (TR) and interview with the state surveyor, the Laboratory Director failed to be in compliance with the State of New Jersey requirements to get approval from the state before</p>

	<p>performing testing on patient samples other than nasopharyngeal run on the Quantstudio 12K analyzer from November 2020 to the date of survey. The finding include: 1. TR revealed that the laboratory was running patient samples that were not nasopharyngeal. 2. The General Supervisor (GS) via telephone confirmed on 10/4/22 at 10:00 am the laboratory did not have a New Jersey State Licence for patient samples other than nasopharyngeal.</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the General Supervisor (GS) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Respiratory Panel testing on the Quantstudio 12K from November 2020 to the date of survey. The findings include: 1. There was no supporting documentation that CA was completed. 2. The GS confirmed on 9/27/22 at 10:20 am the laboratory did not follow the CA procedure.</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Microbiology 1st and 2nd event 2022. The findings include: 1. The laboratory did not evaluate "Not Graded" response from API for the following: a. Rhinovirus sample RSP-1 2022 1st event b. Rhinovirus sample RSP-10 2022 2nd event 2. The GS confirmed on 9/27/22 at 10:30 am that the laboratory failed to evaluate the above mentioned coded results.</p>
<p><b>D5305</b></p>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.</p>

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Test Requisitions (TR) and interview with the General Supervisor (GS), the laboratory failed to ensure that TR included all relevant and necessary information for accurate and reliable testing and reporting from November 2020 to the date of survey. The finding includes: 1. A review of 10 TR revealed 2 out of 10 did not have a specimen type. 2. The GS confirmed on 9/27/22 at 12:50 pm that all relevant and necessary information was not on the TR.

**D5401**

**PROCEDURE MANUAL**

CFR(s): 493.1251(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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS), the laboratory failed to follow all procedures written for "Laboratory Information System" (LIS) from November 2020 to the date of the survey. The findings include: 1. There was no documented evidence the below mentioned procedure was followed: a. "LIS performance will be monitored periodically as part of our quality management program". 2. The GS confirmed on 9/27/22 at 1:30 pm that the laboratory did not follow the PM.

**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 surveyor review of the Performance Specification (PS) record, Test Requisitions (TR) and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were adequate for the Quantstudio 12K Analyzer before use from November 2020 to the date of survey. The findings include: 1. A review of TR revealed the laboratory was analyzing specimens that were not nasopharyngeal. 2. The laboratory has PS for nasopharyngeal specimens only. 3. The

GS confirmed on 9/27/22 at 2:00 pm that PS was performed on the Quantstudio 12K analyzer for nasopharyngeal specimens only.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of qu Control Verification (QCV) records and interview with the General Supervisor (GS), the laboratory failed to verify QC material before use for Molecular Bacteriology, Mycology and Virology tests performed on the QuantStudio 12K from 11/12/21 to the date of survey. The GS confirmed 9/27/22 at 1:15 pm that QC material was not verified before putting in use.

**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:

a) Based on surveyor review of the Test Report (TR), Patient Requisition Form (PTF) and interview with the General Supervisor (GS), the laboratory failed to report qualitative Molecular PCR Respiratory Panel tests results accurately from November 2020 to the date of survey. The findings include: 1. The laboratory performed Laboratory Developed Test (LDT), non Food and Drug Administration (FDA) cleared tests and there was no statement stating "This test is LDT and has not been FDA cleared or approved." 2. A review of 10 TR revealed, 10 out of 10 did not have a specimen source. 3. A review of 10 TR and PTF revealed that 10 out of 10 TR did not match the PTF as follows: a. The TR had additional test results for tests not ordered by the physician on the PTF. 4. The GS on 9/27/22 at 1:00 pm that Respiratory Panel tests were not reported accurately.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that PS were adequate to perform Molecular Bacteriology, Mycology and Virology tests on the QuantStudio 12K from November 2020 to the date of survey. The findings include: 1. Specimen stability studies were not performed on site. 2. Carryover and cross contamination studies were not performed. 3. The Laboratory did not have a procedure detailing the validation process including acceptable criteria. 4. The GS confirmed on 9/27/22 at 1:25 pm that the LD did not ensure the PS were adequate.