Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2087522	08/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Lab Houston Lp	9130 South Texas 6, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of a competency assessment for one general supervisor in 2021. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 1 general supervisor. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment for the general supervisor in 2021. 3. An interview with the compliance specialist on 8/2/22 at 10:45 a.m.. in room number one, after review of the records, confirmed the above findings.
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 the review of the laboratory's policy, the College of American Pathologists (CAP) proficiency testing records from 2021 to 2022, and confirmed in an interview found the laboratory failed to document the review of two of five proficiency testing events: CAP ID3-C 2021 Influenza A, Influenza B, RSV, and CAP COV2-A 2022 SARS-CoV-2. Molecular. The findings were: 1. Review of the laboratory's policy titled Proficiency Testing Guidelines (Reference #1650-17) under Evaluation Reports revealed "4. The evaluation report and Summary Review of CAP SURVEY results will then be reviewed and signed by the Medical Director of Laboratory or designee and testing personnel in a timely manner." 2. Review of the CAP proficiency testing records from 2021 to 2022 revealed two of five proficiency testing events were not reviewed and signed by the medical director of laboratory or designee and testing personnel. CAP ID3-C 2021 Influenza A, Influenza B, RSV CAP COV2-A 2022 SARS-CoV-2. Molecular. 3. An interview with the technical consultant on 8/2/22 at 2: 30 pm in room number one confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) instructions, the laboratory's CAP proficiency testing records from 2022, and staff interview, it was revealed that the laboratory failed to have documentation of evaluating proficiency testing results returned as 'Code 26: Educational challenge' for two PT events reviewed in 2022. Findings include: 1. A review of the CAP testing instructions revealed "Code 26: Educational challenge: Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. Response to the CAP is not required." 2. A review of the CAP proficiency testing records from 2022 revealed the following two events that had analytes flagged with Code 26: Educational challenge and there was no documentation of the self-evaluation per CAP requirements: - UDC-A 2022 Forensic Urine Drug Test Confirmatory Fentanyl UDC-10 See note [26] NorFentanyl UDC-10 See note [26] - UDC-B 2022 Forensic Urine Drug Test Confirmatory Fentanyl UDC-17 See note [26] NorFentanyl UDC-17 See note [26] 3. An interview with the compliance specialist on 8/2/22 at 11:40 a.m. in room number one, after review of the records, confirmed the above findings. ***NOTE: This is a repeat deficiency found during the survey performed on 9/2/21.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on the review of the CAP proficiency testing records in 2021, the CAP proficiency testing (PT) instructions, the laboratory's PT records, and confirmed in an interview found the laboratory failed to verify 1 of 2 events of accuracy assessments of COVID test in 2021. The findings were: 1. Review of the CAP proficiency testing records in 2021 for the COVID test revealed not graded "See note [33]" for one of two events in 2021. CAP COV2-B 2021 SARS-CoV-2, Molecular 2. Review of CAP proficiency testing instruction (Rev 1/2021) under Actions Laboratories Should Take when a PT Result is Not Graded revealed "Code 33: Exception Reason Code Description: Specimen determined to be unsatisfactory after contacting the CAP. Action Required: Document that the laboratory has contacted the CAP and no replacement specimens were available. Perform and document alternative assessment (ie. split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested." 3. Review of the laboratory's PT records titled Proficiency Survey Investigation Form for Survey COV2-B (Survey date: 12/21 /21) revealed under Corrective Action (if applicable): "Alternative testing". 4. Further review of the laboratory's PT records revealed no documentation of performing alternative testing for survey COV2-B. 5. Review of the CMS 116 application signed by the laboratory director on 8/1/2022 revealed the annual COVID (Virology) volume was 8,000. 6. An interview with the technical consultant on 8/3/22 at 3:00 pm in room number one confirmed the above findings. Key: CAP=College of American Pathologists CMS=Center of Medicare and Medicaid Services
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of the laboratory's validation procedures and confirmed in an interview found the laboratory's laboratory director (LD) failed to approve, sign, and date for one of one of two laboratory's validation procedure for RPP test. The findings were: 1. Review of the laboratory's validation procedures titled Respiratory Validation Kit for QuantStudio 12K Flex (SN: 285882151) 96-well Platform under 7. Approval revealed the laboratory director failed to approve, sign and date the validation procedure. 2. An interview with the technical consultant on 8/3/22 at 9:38 pm in room number one confirmed the above finding. Key: RPP=Respiratory Pathogen Panel
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 the review of the laboratory's validation records for RPP test, manufacturer's package insert, patient reports, and confirmed in an interview found the laboratory failed to have documentation for preanalytical study (sample stability study) for refrigerated temperature to include all 34 of 34 bacterial and viral targets on patient reports for RPP test in a one of one laboratory developed polymerase chain reaction (PCR) test. The findings were: 1. Review of patient RPP test reports revealed the RPP test includes 34 bacterial and viral targets. A. baumannii Adnovirus Bordetella pertussis Bocavirus Chlamydophila pneumoniae E. cloacae EBV (monobucleisus) Enterovirus Haemophilus influenzae RSV Coronavirus (229E) Coronavirus (HKU1) Coronavirus (NL63) Coronavirus (OC43) HMPV A HMPV B Influenza A Influenza B K. aerogenes Parainfluenza virus (type 1) Parainfluenza virus (type 2) Parainfluenza virus (type 3) Parainfluenza virus (type 4) Rhinovirus Staphylococcus aureus Streptococcus pneumoniae Moraxella catarrhalis Mycoplasma pneumoniae Streptococcus pyogenes Legionella pneumophilia P. aeruginosa K. pnumoniae P. mirabilis S.epidermidis 2. Review of the laboratory's records revealed the laboratory performed laboratory developed RPP testing using the QuantStudio 12K Flex (SN: 285882151) 96-well Platform PCR instrument. 3. A phone interview with the testing personnel 2 (TP#2) on 9/7/2022 at 11:10 am stated there were only 2 clinics within the same complexity of the facility performed RPP test. TP#2 stated the patient samples were stored in the clinic's refrigerator around 5C. TP#2 picked up the patient samples from the refrigerator and walked them back to the facility within minutes. However, they did not check the temperature again when the patient samples arrived the facility. 4. An interview with the technical consultant on 8/2/2022 at 2:00 pm in room number one revealed the laboratory uses Beaver sample collection kit for RPP test. 5. Review the Beaver sample collection kit package insert under Description revealed "The stored samples can be used in subsequent clinical experiments such as DNA/RNA extraction, PCR testing or sequencing." 6. Further review the Beaver sample collection kit package insert under Storage revealed "After use, the sample can be stored at room temperature for 1 week, or for a longer time storage, please place it at -20C and below." 7. Review of the RPP validation records revealed no documentation of preanalytical study for samples at refrigerated temperatures on all 34 of 34 bacterial and viral targets. 8. Random review of patient results from 4/12 /2022 to 7/9/2022 revealed 16 patients had RPP testing. 4/12/2022 MRN/CHART#: 00019857 4/13/2022 MRN/CHART#: 00019862 4/14/2022 MRN/CHART#: 0002194 4/14/2022 MRN/CHART#: 0002193 5/5/2022 MRN/CHART#: 00020005 5/9/2022 MRN/CHART#: 00020017 5/25/2022 MRN/CHART#: 0009827 6/13/2022 MRN /CHART#: 0003670 6/22/2022 MRN/CHART#: 00020224 6/22/2022 MRN /CHART#: 00020225 6/24/2022 MRN/CHART#: 00020234 6/30/2022 MRN /CHART#: 00020259 7/5/2022 MRN/CHART#: 00020267 7/6/2022 MRN/CHART#: 00020271 7/7/2022 MRN/CHART#: 00020279 7/9/2022 MRN/CHART#: 00020277 9. An interview with the technical consultant on 8/3/22 at 10:00 pm in room number one confirmed the above findings. Key: RPP=Respiratory pathogen panel
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of the laboratory's patient test plates from April 2022 to July 2022, and staff interview, it was revealed that the laboratory failed to ensure quality control values were acceptable prior to reporting patient test results for three of three days reviewed from April 2022 to July 2022 for respiratory pathogen PCR testing. Findings include: 1. A review of the laboratory's policy titled 'Plating and Data Review QuickSheet' revealed the following: "Internal Control: RNase P Control (RP) Patient sample control. Endogenous human protein. - Positive- Appropriate collection, extraction, and plating methods used. - Negative- Indicates issue during collection, extraction, or plating. Re-extract sample." 2. A review of the laboratory's patient test plates revealed the laboratory included one RP control for each patient sample that was added to the 96 well plate, each plate having room for three patient samples. 3. A random review of the laboratory's patient test plates from April 2022 to July 2022 revealed the following 3 days where the RP controls were negative (undetermined) and the patient's results were reported: - Date: 4/27/22 Patient's samples on plate: 26687 and 26688 - Date: 6 /23/22 Patient's samples on plate: 27317 and 27318 - Date: 7/16/22 Patient sample on plate: 27511 4. An interview with the technical consultant on 8/3/22 at 12:55 p.m. in room number one, after review of the records, confirmed the above findings.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical supervisor failed to perform a competency assessment on one of four testing personnel performing high complexity testing in 2021. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified four testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical supervisor performing a competency assessment on testing person #4 in 2021. 3. An interview with the compliance specialist on 8/2/22 at 10:45 a.m. in the room number one, after review of the records, confirmed the above findings.