Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2185575	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pathogen Dx, Inc	1230 E Pennsylvania Ste 102, Tucson, AZ	

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**
D3005	FACILITIES CFR(s): 493.1101(a)(3) 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. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory general supervisor (GS-TP1) on August 08, 2022, the laboratory failed for its molecular amplification procedures, (that is not contained in a closed system), to have a uni-directional workflow for specimen preparation, reagent preparation, and extraction procedures. Findings include: 1.The laboratory performs SARS CoV-2 (COVID-19) testing from specimens submitted from multiple collection sites, and performed using a laboratory developed test (LDT) which recieved FDA emergency use authorization (EUA) approval for their SARS CoV2 Rv RT-PCR assay. The laboratory initiated patient testing in November of 2020 for SARS CoV2 molecular testing. 2. The laboratory performs SARS CoV-2 RT-PCR specimen reception, preparation, extraction within the same room as the research and development portion of the facility also performs additional PCR testing. 3. The LDT for SARS CoV2 patient testing was rearranged from the original uni-directional flow to a restricted section of the research and development testing room, in an approximate eight (8) foot by ten (10) foot square, where patient sample accessioning, preparation, and extraction are performed. 4. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 09:00 am, the lack of uni-directional flow for the LDT SARS CoV2 testing performed. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory general supervisor (GS-TP1) on August 08, 2022, the laboratory failed to provide patient testing requisitions, test reports, and patient testing records (temperature logs, training and competency records) for initial testing performed in November and December of 2020. Findings include: 1. Request for initial testing records and patient reports performed in 2020, revealed that the laboratory had a complete staffing turnover the end of December 2020. Upon reinitiating patient testing in January 2022, the GS-TP1 stated that they could not locate initial patient requisitions, staff training and competency records, temperature logs and maintenance logs. 2. Request for thermal cycler printouts and PCR assay results revealed that the initial documents could not be located prior to exit of the survey on 08/09/2022 during interview with the GS-TP1 and the TS-TP2. 3. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 09;00 am, the lack of documentation of initial patient records, analyzer printouts, temperature and maintenance records. 4. The laboratory recorded performing 2353 PathogenDX Rv RT-PCR patient test in November and December of 2022.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's emergency use authorization (EUA) information for use (IFU) for their SARS CoV2 Rv RT-PCR testing, specimen requisition records and interview with the laboratory's general supervisor (GS-TP1) on August 08, 2022, the laboratory failed to follow written policies and procedures to ensure optimum integrity of a patient's specimen from the time of collection to the receipt of the specimen. Findings include: 1. The laboratory performs SARS CoV-2 (COVID-19) testing from specimens submitted from multiple collection sites, and performed using an FDA Emergency Use Authorized (EUA) molecular reverse transcriptase polymerase Chain Reaction (Rv RT-PCR) assay for the detection of SARS CoV-2 (COVID-19) virus on thier laboratory developed testing (LDT) platform. 2. The laboratory's PathogenDx Rv RT-PCR IFU specifies that the specimens must be maintained at 2-8 degree Celsius and tested within 72 hours, or frozen at -70 degrees Celsius. 3. The laboratory failed to record and document patient specimens temperatures upon receipt, to ensure acceptability of specimen integrity prior to testing. 4. The laboratory's GS-TP1 confirmed by interview on August 08, 2022 at 12: 44 p.m., the laboratory did not follow policies or procedures for identification and documenting the integrity of patient's specimens from the time of collection through

	the receipt of the samples. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples in November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
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 review of the laboratory's CMS-209 personnel form, the laboratory's lack of delegation of responsibility Policy or procedure and interview with the laboratory general supervisor listed on the CMS-209 (GS-TP1) on August 08, 2022, the laboratory failed to establish written policies and procedures to assess employee and supervisor competency. Findings include: 1. The laboratory's CMS-209 personnel form lists two (2) testing personnel (TP). The general supervisor (GS-TP1) and the technical supervisor (TS-TP2). 2. The laboratory lacked documentation of training or competency assessments for the two (2) testing personnel listed on the CMS-209 form. 3. The laboratory lacked a policy or procedure for documenting training and competency assessments for persons performing preanalytical, analytic and post-analytic patient testing. 4. The laboratory lacked a policy or procedure for evaluation and documentation of the general supervisor and technical superviosor competency. 5. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 11:00 am, the lack of policy or procedures for performing and documenting training and competency for testing personnel, and supervisor competency. 6. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
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 review of the laboratory records and lack of documentation for verification of accuracy, and interview with the laboratory General Supervisor (GS-TP1) on August 08, 2022, the laboratory failed to perform the verification of accuracy for SARS CoV-2 testing. Findings include: 1. The laboratory performs SARS CoV-2 Reverse Transcriptase Real time-PCR (Rv RT-PCR) testing with their Laboratory developed test (LDT) which recieved the Food and Drug Administration (FDA) approval under an Emergency Use Authorization (EUA). 2. The laboratory failed to perform and document twice annual verification of accuracy for the SARS CoV 2 Rv RT-PCR testing in 2021 or 2022. 3. The laboratory failed to establish a policy or procedure for performing twice annual verification of accuracy for SARS CoV 2 testing. 4. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 10: 35 am, the lack of performing twice annual verification of accuracy. 5. The laboratory

	reported performing 2353 SARS CoV-2 Rv RT-PCR patient tests during November-December 2020, and 995 SARS CoV-2 Rv RT-PCR patient tests from January 2022-July 2022.
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 record review and the lack of a general laboratory's Policies and Procedures (P&P) and interview with the general supervisor (GS-TP1) on August 08, 2022, the laboratory failed to establish 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. Findings include: 1. The laboratory lacked a general P&P which included an ongoing mechanism to perform and document quality issues regarding specimen acceptability, tracking or correction of problems regarding patient specimens submitted for testing. See D5203 2. During review of patient testing records, it was revealed that two (2) of six (6) patient specimens reviewed in 2022 were not tested at the laboratory due to being an unacceptable specimen. 2a. The laboratory lacked documentation of specimen rejection and corrective actions taken. 3. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 11:25 am, the lack of a general P&P for performing quality assessments for SARS CoV-2 patient testing. 4. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review of the laboratory's information for use (IFU) for its laboratory developed test (LDT) and interview with the laboratory general supervisor (GS-TP1) on August 08,2022, the laboratory failed to follow written policies and procedures for specimen acceptability and rejection. Findings include: 1. The laboratory performs molecular reverse transcriptase polymerase Chain Reaction (RT-PCR) for detection of SARS nCoV-2 (COVID-19) virus. 2. The laboratory information for use (IFU) states "Store specimens at 2-8 degree C for up to 72 hours after collections. If a delay in testing or shipping is expected, store specimens at -70 degrees C or below." 3. The laboratory lacked documentation of temperatures of patient specimens at time of receipt. 4. The laboratory GS-TP1 confirmed by interview on August 08, 2022. at 11:

	00 am, the lack of documentation of temperatures for patient specimens upon receipt. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
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: Based on the lack of documentation of temperature, humidity, and maintenance records, observation and interview with the general supervisor (GS-TP1) on August 08, 2022, the laboratory failed to follow their own client manufacturer information for use (IFU) for monitoring and documenting the criteria for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Findings include: 1. The laboratory's developed test assay (LDT) client IFU provides the following temperatures requirements in which the LDT assay kits and reagents are to be stored: Storage Instructions: . PathogenDx DetectX-Rv One Step Reverse Transcription Kits should be stored at -20 +/-5 C. . PathogenDx DetectX-Rv Primers should be stored at -20 +/- 5 C. . PathogenDx DetectX-Rv External Positive Control should be stored at -20 +/- 5 C. . PathogenDx DetectX-Rv Cod UNG should be stored at -20 +/- 5 C. Avoid freeze-thaws past six cycles. Mix gently before use. . PathogenDx DetectX-Rv 96-Well Microarray Plate is provided in a moisture barrier bag with desiccant. The plates should be stored in this manner to protect them from light and moisture. If only a partial plate was used, the plates should be stored in the provided case inside the moisture barrier bag if the remainder of the plate is to be used for testing additional patient samples. Store the microarray plate at room temperature. . PathogenDx HYB Buffer 1 should be stored at room temperature (15-30 C). . PathogenDx HYB Buffer 2 should be stored at -20 +/- 5 C. . Ceres Wash Buffer should be stored at room temperature (15-30 C). . Ceres Lysis Buffer should be stored at room temperature (15-30 C). . Ceres Beads should be stored at 4 C. 2. Tour of the laboratory and record review revealed that the laboratory did not have documentation of temperatures for their freezer, refrigerator, storage room temperatures, and recording of humidity documentation for their assay kits and reagents. 3. Tour of the laboratory and observation of the laboratory's sample preparation room, storage rooms and processing room revealed that the laboratory did not have thermometers or barometers for recording and maintaining the temperature requirements for its LDT PCR assay. 4. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 0200 pm, the lack of documentation for the required temperatures for the performance and storage of their LDT PCR test. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
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: Based on lack of a patient report, and interview with the laboratory general supervisor (GS-TP1) on August 09, 2022, the laboratory failed to develop a test report which indicates the name and address of the laboratory location where the test was performed, the test report date, the test performed, specimen source, the test result and interpretation, and information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. Findings include: 1. The laboratory performs molecular reverse transcriptase polymerase Chain Reaction (RT-PCR) for detection of SARS nCoV-2 (COVID-19) virus for patients collected from hospitals and other collection sites. 2. Record review of patient testing results revealed that the laboratory did not have a test report which indicated that the tests were performed at the Pathogen DX laboratory and the other required information as listed above. 3. Review of two (2) pateint test records performed for the second referral location did not include the location where the test had been performed. 4. The laboratory GS-TPS1 confirmed by interview on August 09, 2022 at 11:45 am, the lack of a patient test report for Pathogen DX SARS CoV-2 patient testing. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, observations and interview with the general supervisor (GS-TP1) and the laboratory director on August 09, 2022, the laboratory director failed to meet the qualification requirements to provide over all management and direction for ensuring quality patient testing for SARS CoV-2 (COVID-19). See D6099, D6102, and D6107.
D6099	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(9) The laboratory director must ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

	This STANDARD is not met as evidenced by: Based on review of the laboratory personnel records, the CMS-209 personnel form and interview with the general supervisor (SG-TP1)on August 08, 2022, the laboratory director failed to ensure that a clinical consultant is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. Findings include: 1. The laboratory director failed to ensure that a qualified Clinical Consultant was available for laboratory Clients relating to the laboratory's developed test for SARS CoV2 COVID-19 testing. See D6134. 2. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of documented records, and interview with the general Supervisor (GS-TP1) on August 08, 32022. the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of personnel records revealed the lack of documentation of training and competency for two (2) of two (2) testing personnel prior to testing patient molecular reverse transcriptase Polymerase Chain Reaction (RT-PCR) for detection of SARS CoV-2 (COVID-19) virus. 2.Review of the CMS-209 revealed that the laboratory failed to have a qualified Clinical Consultant identified for providing patient consultation to clients regarding the SARS CoV-2 (COVID-19 testing. See D6134. 3. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 11:25 the lack of documentation of training and competency for the testing personnel, Technical Supervisor and the Clinical consultant. 4. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on lack of documentation during record review and interview with the general supervisor (GS-TP1) on August 8, 2022, the laboratory director failed to identify and specify in writing, the roles and responsibilities of the technical supervisor (TS-TP2), the general supervisor (GS-TP1) and the clinical consultant. Findings include: 1. The laboratory lacked written documentation designating a technical supervisor (TS-TS2), general supervisor (GS-TP1) to the personnel as listed on the CMS-209 form. 2. The laboratory director failed to identify a Clinical Consultant. See D6134. 3. The laboratory director failed to provide training and competency assessments for the testing personnel in order to identify which procedures each testing individual is authorized to perform. See D5209. 4. The laboratory GS-TP1 confirmed by interview on August 08, 2022 at 10:15 am, the lack of designation of duties and responsibilities for testing personnel. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 2022.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory CMS-209 personnel form, and interview with the laboratory general supervisor (GS-TP1) and the laboratory director (LD) on August 09, 2022, the laboratory failed to have a clinical consultant identified that met the qualifications as listed in 42 C.F.R. 493.1455. See D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the submitted CMS-209 personnel form, review of personnel qualifications and interview with the laboratory general Supervisor on August 08, 2022, the laboratory failed to identify a qualified clinical consultant to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Findings include: 1. The laboratory initiated a laboratory developed (LDT) patient testing method by molecular reverse transcriptase Polymerase Chain Reaction (RT-PCR) for detection of SARS CoV-2 (COVID-19) virus in November of 2020. At the time of initiation the laboratory had a qualified clinical consultant identified on the CMS-209 personnel form. 2. The laboratory

	underwent a complete personnel change in December of 2020, after which no patient testing was being performed untill January of 2022. Upon initiating patient testing in January of 2022, a clinical consultant was identified as the GS-TP1. 3. GS-TP1 is a medical technologist by degree and does not meet the qualifications as a Clinical Consultant. 4. The laboratory director and GS-TP1 confirmed by interview on August 09, 2022 the lack of designation of a qualified clinical consultant. 5. The laboratory reports performing 2353 SARS CoV-2 patient samples from November - December, 2020 and 995 SARS CoV-2 patient samples from January 2022 through July 22, 2022.