Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2255017	10/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pharma Genlabs, Llc	8170 South Ave Suite 3, Youngstown, OH	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interviews with the Director of Human Resources (DoHR), the Vice President (VP)/National Sales Director (NSD), Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialty of bacteriology. All patient PCR (Polymerase Chain Reaction) urine pathogenic organism identification and antibiotic resistance testing performed in this laboratory from 08/04/2022 to 10/26/2022 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to enroll in a proficiency testing (PT) program for PCR organism identification and antibiotic resistance testing in urine specimens. (Refer to D2001)
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or

	test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on record review and interviews with the Director of Human Resources (DoHR), the Vice President (VP)/National Sales Director (NSD), Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the laboratory failed to enroll in a proficiency testing (PT) program for PCR organism identification and antibiotic resistance testing in urine specimens. All patient PCR (Polymerase Chain Reaction) urine pathogenic organism identification and antibiotic resistance testing performed in this laboratory from 08/04/2022 to 10/26/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, approved via signature and date by the Laboratory Director and provided for the inspection, did not find any mention of PT or the enrollment documentation for the regulated testing. 2. The Inspector requested the laboratory's PT policy and procedure and enrollment document for 2022 from TP#2 and the CLR. TP#2 confirmed the laboratory did not have a PT policy and procedure and was not enrolled with an HHS approved PT provider for the regulated testing of PCR urine pathogenic organism identification and antibiotic resistance testing. On 10/26/2022 at 9:15 AM, TP#2 and the CLR provided the laboratory's 2022 "Alternative PT" procedure and documentation of their 2022 alternative PT activities. 3. The DoHR and VP/NSD mentioned that the laboratory was misinformed and confirmed the laboratory utilized alternative PT specimens provided by their consulting company who assisted in the laboratory start-up and daily laboratory functions. The interviews occurred on 10 /26/2022 at 2:10 PM.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on record review and interviews with the Director of Human Resources (DoHR), the Vice President (VP)/National Sales Director (NSD), Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the laboratory failed to refer the PCR SARS CoV-2, PCR urine pathogenic organisms and antibiotic resistance data analysis, resulting and reporting to a CLIA certified laboratory. Findings Include: 1. Review of two out of two of the laboratory's final test reports found the test reports were printed on letterhead that only indicated the name and address of the laboratory location where the wet testing was performed, however was lacking the name and address of the laboratory location where the data analysis, resulting and reporting occurred. 2. The Inspector requested the laboratory's final test reports that included the names and addresses of both laboratory locations where the wet work and the data analysis, resulting and reporting occurred from TP#2. TP#2 stated and the DoHR and VP/NSD confirmed that the laboratory's start-up consulting company remotely logged in and accessed their laboratory information system (LIS) to conduct the data analysis, resulting and reporting of patient testing under this laboratory's CLIA number. The interview occurred on 10/26/2022 at 12:20 PM. 3. The Inspector requested the CLIA certificate for the start-up consulting laboratory location where they remotely logged in and accessed this laboratory's patient data for

	analysis, resulting and reporting from the CLR. The start-up CLR who was in attendance for this CLIA inspection confirmed that the start-up consulting laboratory location did not possess a CLIA certificate and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/26/2022 at 12:20 PM.
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 record review and interviews with Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the laboratory failed to include the name and address of the laboratory location where the data analysis of PCR patient testing was conducted, resulted and reported on the final test report. This deficient practice had the potential to affect all patients tested at this laboratory location under the sub-specialties of bacteriology from 08/04/2022 to 10/26/2022 and virology from 07/19 /2022 to 10/26/2022. Findings Include: 1. Review of two out of two of the laboratory's final patient test reports did not find the name and address of the laboratory location in which the data analysis of PCR patient testing was conducted, resulted and reported on the final test report. 2. TP#2 and the CLR confirmed the laboratory did not indicate the name and address of the laboratory location in which the data analysis of PCR patient testing was conducted, resulted and reported on the final test report. The interview occurred on 10/26/2022 at 11:10 AM.
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 and interviews with the Director of Human Resources (DoHR), the Vice President (VP)/National Sales Director (NSD), Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the Laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart for the laboratory procedures performed in the subspecialties of Bacteriology and Virology. All patient specimens tested for PCR SARS CoV-2, PCR urine pathogenic organisms and antibiotic resistance from 07/19/2022 to 10/26/2022 had the potential to be affected by this deficient practice. Findings Include: 1. The Laboratory Director failed to ensure that the laboratory was enrolled in an HHS approved PCR urine pathogen identification and antibiotic resistance proficiency

	testing (PT) program. (Refer to D6088) 2. The Laboratory Director failed to ensure that, prior to testing patients' specimens, seven out of 10 Testing Personnel (TP) had demonstrated and documented that they could perform all testing operations reliably to provide and report accurate results for the high complexity PCR SARS CoV-2, PCR urine pathogenic organisms and antibiotic resistance data analysis, resulting and reporting. (Refer to D6102)
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interviews with the Director of Human Resources (DoHR), the Vice President (VP)/National Sales Director (NSD), Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the Laboratory Director failed to ensure that the laboratory was enrolled in an HHS approved PCR urine pathogen identification and antibiotic resistance proficiency testing (PT) program. This deficient practice had the potential to affect all patient PCR urine pathogen identification and antibiotic resistance testing performed from 08/04/2022 to 10/26 /2022. Findings Include: 1. Review of the laboratory's CLIA Annual Test Volume Log, provided for the inspection, found "UTI pathogens & antibiotic resistance" listed with a volume of 5000 tests performed annually. 2. Review of the laboratory's policies and procedures, approved via signature and date by the Laboratory Director and provided for the inspection, did not find any mention of PT or the enrollment document for the regulated testing. 3. The Inspector requested the laboratory's PT policy and procedure and enrollment document for 2022 from TP#2. TP#2 confirmed the laboratory was not enrolled with an HHS approved PT provider for the regulated testing of PCR urine pathogenic organism identification and antibiotic resistance testing. TP#2 and the CLR provided the laboratory's 2022 "Alternative PT" procedure and documentation of the laboratory's 2022 alternative PT activities. The interviews occurred on 10/26/2022 at 9:15 AM. 4. The DoHR and VP/NSD mentioned that the laboratory was misinformed, did not enroll with an HHS approved PT provider and confirmed the laboratory utilized alternative PT specimens provided by their consulting company who assisted in the laboratory start-up and daily laboratory functions. The interviews occurred on 10/26/2022 at 2:10 PM.
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 record review and interviews with Testing Personnel (TP) #2 and the consulting laboratory representative (CLR), the Laboratory Director failed to ensure that, prior to testing patients' specimens, seven out of 10 Testing Personnel (TP) were

	trained and had documentation as evidence that they could perform all testing operations reliably to provide and report accurate results for the high complexity PCR SARS CoV-2, PCR urine pathogenic organisms and antibiotic resistance data analysis, resulting and reporting. All patient PCR testing procedures performed by TP#4, TP#5, TP#6, TP#7, TP#8, TP#9 and TP#10 from 07/19/2022 to 10/26/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's competency assessment documentation, provided for the inspection, did not find TP#4, TP#5, TP#6, TP#7, TP#8, TP#9 and TP#10, who were identified as the individuals who remotely logged into the laboratory's laboratory information system (LIS) and accessed the laboratory's patient data for analysis, resulting and reporting, were trained, had demonstrated competency assessments documented prior to testing implementation (07/19/2022 for SARS CoV-2 and 08/04/2022 for PCR urine pathogenic organisms and antibiotic resistance) by a qualified Technical Supervisor or General Supervisor and were listed on the laboratory's CMS-209. 2. The inspector requested the laboratory's TP training and competency assessment policy and procedure and the 2022 training and assessment documentation for TP#4, TP#5, TP#6, TP#7, TP#8, TP#9 and TP#10 prior to beginning patient PCR testing at this laboratory from TP#2 and the CLR. Although it was stated that the consulting company did not have their own CLIA certificate, the CLR mentioned that the TP were trained and their competencies were assessed by an individual at the consulting company. TP#2 confirmed that neither the qualified and listed TS nor the GS assessed the competency of TP#4, TP#5, TP#6, TP#7, TP#8, TP#9 and TP#10 prior to beginning patient PCR testing at this laboratory and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10 /26/2022 at 10:20 AM.