Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0994189	10/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Coreplus Servicios Clinicos Y Patologicos,Llc	Ave Sanchez Vilella Esq Pr-190, Suite #2-6, Carolina, PR	

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
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: Based on Proficiency Testing Program records review (year 2022), and laboratory staff interview, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Mycology- Dermatophyte Multiplex PCR assay in the MagNa Pure 96 analyzer. The findings includes: a. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program and College of American Pathologists (CAP) proficiency program. b. On October 18, 2022 at 12:00 pm the Puerto Rico proficiency testing program and CAP proficiency program were reviewed (year 2022). c. Proficiency Testing Program for Mycology- Dermatophyte Multiplex PCR assay in the MagNa Pure 96 analyzer was requested. d. On October 18, 2022 at 1: 05pm the laboratory staff confirmed that the laboratory failed to participate in Proficiency Testing Program for Mycology- Dermatophyte Multiplex PCR assay in the MagNa Pure 96 analyzer. The laboratory processed and reported one (1) patient specimens year 2022.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by:

	Based on College of American Pathologist (CAP) Proficiency Testing Program records review and cytologist supervisor interview on October 18, 2022 at 11:55 AM, it was determined that the laboratory failed to retain the papanicolaou (PAP) proficiency testing records for at least 2 years. The findings include: 1. The laboratory use the CAP proficiency testing program for the PAP proficiency testing since 2021. 2. On October 18, 2022 at 11:00 AM, the laboratory did not have available the CAP's Laboratory transcript with the score of the PAP proficiency testing evaluated during the year 2021. 3. On October 18, 2022 at 11:55 AM, the cytologist supervisor confirmed that the CAP transcript report for the year 2021 was not available in the laboratory.
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 personnel records review and laboratory cytotechnologist supervisor interview, it was determined that the laboratory failed to follow the established schedule for pathologist clinical consultant competence evaluation. The findings include: a. On October 18, 2022 at 2:00pm the personel record was reviewed. The laboratory schedule for pathologist clinical consultant competence evaluation showed that it must be performed every year. b. The laboratory did not perform the following competence evaluations since year 2021: Pathologist clinical consultant- #14829, Pathologist clinical consultant-# 15223. c. On October 18, 2022 at 2:45PM the cytotechnologist supervisor confirmed that the laboratory fail to performed the competence evaluation fo the Pathologist clinicaal consultant.
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 lack of written procedures; lack of temperature record of the transport cooler, random review of the patient's samples referral and laboratory staff interview; it was determined that the laboratory failed to establish and follow a written polices for the specimen transportation and specimen referral. The findings include: a. The laboratory refers patient samples to CorePlus Servicios Clinicos y Patologicos Ponce. b. On October 18, 2022 at 3:28 PM a record of temperature of the transport cooler and written procedures of specimen transportation and specimen referral was requested. However, the CorePlus Servicios Clinicos y Patologicos Carolina did not have any written protocol for the referral and transportation of patient's samples, neither had records of the temperatures of the transport cooler. c. Random review of the patient's

	samples referred to CorePlus Servicios Clinicos y Patologicos Ponce, showed that the laboratory delivered a total of 8,260 samples (February 2021= 1,003; March 2021= 1,119; September 2021= 1,803; February 2022= 1,925; March 2022= 2,410). d. The technical laboratory staff confirmed on October 18, 2022 at 3:35 PM, that the laboratory did not have the written procedures and a record of temperature for the transport cooler.
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 laboratory test reports records (year 2022) review and laboratory supervisor interview, it was determined that the laboratory failed to include in the test report that the Mycology- Dermatophyte Multiplex PCR assay test performed in the MagNa Pure 96 analyzer, is a laboratory developed test (LDT) The findings include: a. The laboratory develop the test for mycology- Dermatophyte Multiplex PCR assay in the MagNa Pure 96 analyzer. The test was validated and approved by the Laboratory director on April 20, 2022. b. On October 18, 2022 at 11:58 AM the laboratory test reports for Mycology- Dermatophyte Multiplex PCR assay in the MagNa Pure 96 were reviewed. c. The laboratory test report showed that the LDT statement was not included. d. The laboratory supervisor confirmed on October 18, 2022 at 12:05 PM, that the test report did not include the LDT statement. The laboratory process and report one (1) patient sample (year 2022)
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: 1- Based on College of American Pathologist (CAP) Proficiency Testing Program records review and cytologist supervisor interview on October 18, 2022 at 11:55 AM, it was determined that the laboratory director failed to ensure that the laboratory retain

	the proficiency testing records for at least 2 years. Refer to D 3037 (The laboratory failed to retain the papanicolaou (PAP) proficiency testing records for at least 2 years). 2- Based on personnel records review, written procedures, and laboratory general supervisor interview, it was determined that the laboratory director failed to ensure. Refer to D 5209 (The laboratory fail to perform a evaluation of competence for pathologist clinical consultant). Refer to D 5311 (The laboratory fail to establish a written procedure for the referral specimen and lack temperature record of transport cooler). 3- Based on test report review for Mycology- Dermatophyte Multiplex PCR assay in the magna Pure 96 analyzer, the laboratory failed to include that the test was a Laboratory develop test (LDT) statement. Refer to D 5805
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 P. R. Proficiency Testing Program records review, College of American Pathologist and interview with the laboratory supervisor on October 18, 2022 at 1:05 PM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the following test: Dermatophyte Multiplex PCR assay in the Magna Pure 96 analyzer. Refer to D 2004