Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2064013	08/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Medipath Llc	4665 Ponce De Leon Blvd, Coral Gables, FL	

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	A recertification survey conducted on 08/03-05/2021 found that the MEDIPATH LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Condition: -D 2000- Enrollment and Testing of Samples
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 lack of records and interview with laboratory director (LD), the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for bacterial Vaginosis (BV), human papilloma virus (HPV), Chlamydia trachomatis/Neisseria Gonorrhea (CT)NG), Vaginitis Candida (CV), trichomonas vaginalis, herpes simplex 1 and 2. Findings include: -Review of test menu included in the 116- form revealed that the laboratory is currently performing detection test for: human papilloma virus, Chlamydia trachomatis/Neisseria Gonorrhea (CT/NG), Vaginitis Candida, trichomonas vaginalis, herpes simplex 1 and 2 using molecular technology methods. -The laboratory started patient testing since October 2020 for the methods of reference. In this period the laboratory had the following test volume for each test: a) BV= 624 b) CT/NG=1177 c) HPV=1 d) CV=554 e) Trichomonas=250 -

	Review of College of Americans Pathologists (CAP) records revealed that the Laboratory failed to enroll in proficiency testing for the tests listed above. During an interview on 08/03/2021 at 11:30 AM, the LD confirmed that the facility failed to enroll in PT for 2021 for the tests of reference.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have written step by step procedures for Human papillomavirus (HPV), Chlamydia (CT), Gonorrhea (GC), Bacterial vaginosis (BV) and SARS-CoV-2 (COVID-19) performed on the Hologic Panther. The laboratory failed to have a step by step procedure for Influenza (FLU) A /B/ Respiratory syncytial virus (RSV) performed on the Panther fusion. Review of Hologic Panther Procedure Manual revealed no written documentation of a step by step procedure on how to perform HPV, CT, GC BV and COVID-19 on a Hologic Panther onsite. Review of Panther Fusion Procedure Manual revealed no written documentation of a step by step procedure on how to perform FLU A/B/ RSV on Panther Fusion onsite. Review of Molecular Instrument logs showed Hologic Panther 1 and Hologic Panther 2 started use for molecular testing in 06/24/2020 and the Panther Fusion started use for molecular testing in 03/11/2021. During an interview on 08/05/2021 at 2:33 PM, the laboratory director and laboratory manager confirmed no written procedure for the following tests listed using the Hologic Panther and Panther Fusion.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assessment (QA) failed to ensure the laboratory enrolled in proficiency testing for molecular microbiology since October 2020 to 08/03/2021. Findings include: -Review of QA policy reviewed on 07/27/2021 revealed that the policy failed to include a plan to ensure Proficiency Testing (PT) enrollment for regulated analytes before adding them to the testing menu. -The QA failed to identify and correct the failure to enroll in PT for the following tests: human papilloma virus, Chlamydia trachomatis/Neisseria Gonorrhea (CT/NG), Vaginitis Candida, trichomonas vaginalis, herpes simplex 1 and 2 using molecular technology methods since October 2020 to 08/03/2021. During an interview on 08/03/2021 at 2:30 PM, with the laboratory director, he confirmed that the QA failed to ensure the PT enrollment for the analytes of reference.
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 interview, the laboratory director failed to ensure the laboratory enrolled in proficiency testing for the following tests: human papilloma virus, Chlamydia trachomatis/Neisseria Gonorrhea (CT/NG), Vaginitis Candida, Trichomonas vaginalis, herpes simplex 1 and 2 using molecular technology methods since October 2020 to 08/03/2021. See D 2000