Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0997516	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
John A Murphy Md Pc	2450 Ne Maryrose Pl, Ste 220, Bend, OR	

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 for the BD Affirm Vaginitis testing system and interview with the Clinical Coordinator on 04/20/2021 at approximately 1330, the laboratory failed to maintain continous Proficency Testing (PT) enrollment for thr regulated analyte Candida species. Findings include: 1. The laboratory failed to have written documentation of PT enrollment for five (5) of five (5) PT events for 2020 and 2021. 2020 Events 1, 2, 3 Not enrolled with College of American Pathologists PT program for Candida species 2021 Events 1 & 2 Not enrolled with College of American Pathologists PT program for Candida species 2. This is a repeat deficiency from survey performed on 08/05/2019. The laboratory enrolled in College of American Pathologists (CAP')PT program for event #3 in 2019 but failed to renew the PT from CAP for 2020 and 2021. 3. The Clinical Coordinator confirmed by interview 04/20 /2021 at approximately 1330 that the laboratory had not maintained enrollment for PT for 2020 and 2021. 4. The laboratory performs approximately 120 BD AFFIRM Candida species patient tests per year.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii)

	For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of the laboratory's BD AFFIRM Vaginitis testing revealed that the laboratory had no documentation of enrollment in a Proficiency Testing (PT) program or performing twice annnual verification of accuracy for the analytes Gardenrella vaginalis and Trichomonas species. Interview with the Clinical Coordinator confirmed the laboratory failed to maintain the accuracy of its testing in accordance with 493.1236(c)(1) Findings include: 1. Record review of the BD AFFIRM Vaginitis assay revealed that the laboratory had no documentation of enrollment in a PT program or performing twice annual verification of accuracy for the analytes Gardenerella vaginalis and Trichomonas species for two (2) of two (2) events required for 2020 and one (1) of two (2) for 2021. 2. This is a repeat citation from survey 08/05 /2019 in which the laboratory's submitted plan of correction stated they would enroll in a PT program for maintaining twice annual accuracy of testing for the analytes Gardenerella vaginalis and Trichomonas species. 3. The Clinical Coordinator confirmed this by interview on 04/20/2021 at approximately 1330 that the laboratory failed to maintain enrollment for accuracy for the analytes G. vaginalis and Trichomonas species. 4. The laboratory reports performing 120 tests each for G. vaginalis and Trichomonas species annually.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon review of the single College of American Pathologists (CAP) Proficiency Testing (PT) event (#3) from October of 2019 available for review during survey 04 /20/2021 and interview with the Clinical Coordinator, the Laboratory Director (LD) failed to attest to the performance of the PT for this event. Findings include: 1. Upon review of the attestation form for the CAP PT event #3 dated October 2019, the LD failed to sign off on the attestation form. 2. The Clinical Coordinator confirmed that the LD had not signed off on the attestation form during interview on 04/20/2021 at approximately 1330.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a tour of the laboratory area at this facility 04/20/2021 at 1430, the

	laboratory failed to ensure that expired reagents were not being used for the BD AFFIRM vaginitis test system. Findings include: 1. Observation of the area where the instrument for the BD AFFIRM instrument and reagent supplies are kept, it was noted that there were expired reagents. Substrate Solution dated 12/13/2020, lot number 9296539. 2. The laboratory had no written documentation of the reagent lot numbers in use or their date of expiration. 3. The Clinical Coordinator confirmed that there was no documentation of current lot in use and no documentation of lot to lot change during interview 04/20/2021 at 1430.
D5419	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. This STANDARD is not met as evidenced by: Based on inspection of reagents and cartridges on hand at this facility and interview with the Clinical Consultant, the laboratory failed to ensure components of reagents and kits were not interchanged. Findings include: 1. Upon inspection of the area where the BD AFFIRM instrument and reagents/cartridges are kept during survey 04 /20/2021, it was noted that multiple lot numbers of the PAC cartridge were being used. Lot numbers 0230048 expiration 08/06/2021 and lot number 0290934 expiration 11/14/2021 were found together using kit and reagents from an unknown kit lot number. 2. The Clinical Coordinator stated that they had combined kits because they were not outdated during interview 04/20/2021 at approximately 1500. 3. The original box containing the original materials for that kit with it's lot number could not be located during survey 04/20/2021. 4. The Clinical Coordinator confirmed she did not know where the original box for the kit was located 04/20/2021 at approximately 1500. 5. See Dtag D5417
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel training and competency records and interview with the Clinical Coordinator, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory. See D6018, D6029. This is a repeat citation from survey on 08/05/2019.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based upon review of the single Proficiency Testing (PT) event #3 from College of American Pathologists (CAP) from October of 2019 available for review during survey 04/20/2021 and interview with the Clinical Coordinator, the Laboratory Director (LD) failed to attest to the performance of the PT for this event. Findings include: 1. Upon review of the attestation form for the CAP PT event #3 dated October 2019, the LD failed to sign off on the attestation form.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 review of testing personnel (TP) competency records and interview with the Clinical Coordinator, the Laboratory Director (LD) failed to ensure the Clinical Coordinator, also a TP, had the requisite training and experience prior to performing patient testing. Findings include: 1. There was one written document of training for the Clinical Coordinator, hired 04/14/2020, which is dated 05/01/2020. There is no written documentation of the requisite 6 month and 12 month competency assessment for the BD AFFIRM Vaginitis test for this TP. 2. The Clinical Consultant confirmed that she had not received 6 month and 12 month competency evaluation in her first year of employment during interview on 04/20/2021 at approximately 1400. 3. This is a repeat citation from survey 08/05/2019.