Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0723018	05/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Parkman Road Medical Associates Inc	2390 Parkman Road Northwest, Warren, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the laboratory personnel failed to follow the laboratory's own policy and procedure for the BD Affirm; Candida Albicans, Gardnerella Vaginalis and Trichomonas quality control (QC) testing since the policy revision approval by the Laboratory Director on 09/01/2017. All patient BD Affirm testing performed beyond seven days after the last QC test had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "IQCP Plan for BD Affirm VPIII", provided on the date of the inspection, revealed the laboratory's "QC Plan" which stated the following: "Every 15 days of running the samples external positive and negative controls are run in the same way as the pt samples per manufactures instructions." with the following hand written note: "*changed as of 9/1/17" and the following hand written footnote: "9/1/17 QC is run every 7 days of doing pt samples with Gibson trivalent (pos & neg). Controls are run the same way as pt samples per manufactures instructions 'Laboratory Director's signature'". pt; patient pos; positive neg; negative 2. Review of the laboratory's "QC (EQC) LOG" found the hand written statement "As of 9/1/17 QC will be run every 7 days of doing pt samples with trivalent pos & neg swabs." EQC; equivalent quality control 3. Further review of the laboratory's "Affirm VPIII Lab Testing Log" and "QC (EQC) LOG" from 09/01/2017 to the date of the inspection revealed the laboratory did not perform the external pos and neg trivalent QC swabs every 7 days of patient testing as listed below: Date external pos/neg trivalent QC performed 09/01/2017 03/07/2018 10/02/2018 09/14/2017 03/21/2018 10/11/2018 09

	/29/2017 04/04/2018 10/25/2018 10/13/2017 04/18/2018 11/08/2018 10/26/2017 05/03 /2018 11/20/2018 11/09/2017 05/17/2018 12/11/2018 11/22/2017 05/31/2018 12/27 /2018 12/07/2017 06/20/2018 01/10/2019 12/21/2017 07/12/2018 01/21/2019 01/04 /2018 07/25/2018 02/13/2019 01/16/2018 08/08/2018 02/26/2019 01/26/2018 08/22 /2018 03/11/2019 02/09/2018 09/06/2018 03/26/2019 02/23/2018 09/20/2018 4. TP#2 confirmed that the laboratory revised the BD Affirm QC frequency to every seven days of patient testing on 09/01/2017. The interview occurred on 05/09/2019 at 12:30 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 an interview with Testing Personnel (TP) #2, the laboratory failed to include on the final test report the name and address of the laboratory where the testing was performed when the tests were sent to an outside laboratory for one out of two test reports for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) and the specimen source for five out of five test reports for the BD Affirm testing. Findings Include: 1. Review of the laboratory's "CLIA Annual Test Volume Log", provided on the date of the inspection, revealed four moderately complex tests listed; wet mount preparation, Candida Albicans (BD Affirm), Gardnerella Vaginalis (BD Affirm) and Trichomonas (BD Affirm). 2. Review of five of the laboratory's corresponding test records and final test reports did not find the name and address of the laboratory location on the final test report of where the CT/NG testing was performed for one out of two patients who had this testing performed. 3. Review of the same five corresponding test records and final test reports did not find the specimen source for any of the BD Affirm final test reports reviewed for Candida Albicans, Gardnerella Vaginalis and Trichomonas. 4. TP#2 confirmed that the name and address of the laboratory location of where the testing was performed was not indicated on one out of the two patient reports reviewed when the test was sent out, the specimen source for the BD Affirm testing was not indicated on five out of the five patient reports reviewed and that the laboratory will be contacting their Information Technology Vendor for resolution. The interview occurred on 05/09/2019 at 12:20 PM.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the Laboratory Director failed to ensure the laboratory's quality assessment program was maintained effectively to assure the quality of the BD Affirm testing procedures performed. All patient testing performed in this laboratory from 09/01/2017 to the date of the inspection had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 06/28/2017 and 06/28/2018 "Annual QA Checklist" did not find any issues identified or any corrective actions implemented. 2. Review of the laboratory's BD Affirm quality control (QC) policy revision and quality control log sheets from 09/01/2017 to the date of the inspection, revealed the laboratory did not follow their own approved policy and procedure, did not conduct BD Affirm QC every seven days of patient testing and the lack of QC was not identified by the laboratory during any quality assessment activities. 3. Review of the laboratory's final test reports revealed they failed to include on the final test report the name and address of the laboratory where the testing was performed when the testing was sent to an outside laboratory and the specimen source for five out of five test reports for the BD Affirm testing and the lack of required components on the test report was not identified by the laboratory during any quality assessment activities. 4. Review of the laboratory's 2017 and 2018 competency assessment documentation revealed the Technical Consultant (TC) failed to evaluate and document three out of the four annual competency assessments in 2017 and 2018 for TP#1 and TP#2 and the lack of assessment documentation was not identified by the laboratory during any quality assessment activities. 5. Review of the laboratory's personnel education documentation revealed the laboratory failed to have foreign equivalency documentation of TP#2's education achieved abroad on or within seven days of the date of the inspection in order to make a determination if TP qualification requirements had been met and this lack of documentation was not identified by the laboratory during any quality assessment activities. 6. TP#2 confirmed that the laboratory's quality assessment activities did not identify the above mentioned deficiencies. The interview occurred on 05/09/2019 at 12:35 PM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the Technical Consultant (TC) failed to evaluate and document three out of the four annual competency assessments in 2017 and 2018 for TP#1 and TP#2 for the moderately complex BD Affirm testing procedures performed. All patients tested in this laboratory in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 "Laboratory Personnel Report (CLIA)" revealed three individuals, including the Laboratory Director, listed and credentialed by the Laboratory Director on 04/10/2019 to perform moderately complex laboratory testing. 2. Review of the laboratory's 2017 and 2018 competency assessment documentation, provided on the date of the

	inspection, revealed three out of four "Lab Personnel Evaluation Checklist"s for TP#1 and TP#2 with no indication of the TC's signature as the assessor of their competency as listed below: TP#1; 10/23/2017 TP#2; 10/23/2017 and 10/22/2018 3. The Inspector requested the laboratory's 2017 and 2018 competency assessment documentation indicating the TC's signature as the assessor of TP#1 and TP#2's competency from TP#2. TP#2 confirmed the TC did not sign/date the "Lab Personnel Evaluation Checklist" for TP#1 in 2017 and TP#2 in 2017 and 2018 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/09/2019 at 10:55 AM.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the laboratory failed to provide foreign equivalency documentation of TP#2's education achieved abroad on or within seven days of the date of the inspection in order to make a determination if TP qualification requirements had been met. All moderately complex BD Affirm testing conducted by TP#2 in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 "Laboratory Personnel Report (CLIA)" revealed three individuals listed and credentialed by the Laboratory Director on 04/10/2019 to perform moderately complex laboratory testing. 2. Review of the laboratory's education documentation, provided on the date of the inspection, revealed TP#2 had achieved foreign education, however did not find any foreign equivalency documentation. 3. The Inspector requested the foreign equivalency documentation for TP#2 from TP#2. TP#2 confirmed that the requested documentation was not available and was unable to provide any records of foreign equivalency on or within seven days of the date of the inspection. The interview occurred on 05/09/2019 at 10:10 AM.