Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1016327	03/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of American Academy Family Physicians (AAFP) proficiency testing records from 2016 and 2017 and confirmed in interview, the laboratory failed to test all proficiency samples in the same manner as it tests patient specimens. Findings were: 1. A review of 6 American Academy Family Physicians (AAFP) proficiency testing (PT) events from 2016 and 2017 revealed 5 of 6 events were tested by the same testing person (TP# 7). The facility listed seven testing persons involved in testing patient specimens. By not involving all testing personnel who normally test patient specimens in the testing of proficiency testing samples, the facility failed to treat proficiency samples in the same manner as patient samples. 2. An interview with

	the facility manager on 03/12/18 at 1140 hours in the office confirmed the above findings. She was unaware the PT testing needed to be rotated.
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 on a review of the laboratory proficiency American Academy Family Physicians (AAFP) testing records and confirmed in interview, laboratory director failed to attest to the routine integration of the proficiency testing samples into the patient workload on 6 of 6 test events of 2016 and 2017. Findings were: 1. A review of six proficiency testing events from 2016 and 2017 revealed that 6 of 6 events did not have an attestation statement signed by the laboratory director. 2. An interview with the facility manager on 3/12/18 at 1140 hours in the office confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Academy Family Physicians (AAFP) proficiency testing (PT) records and staff interview, the laboratory failed to document the review of the PT results. The findings were: 1. A review of the laboratory's 2016 (Events A, B, C) and 2017 (Events A, B, C) of the AAFP proficiency testing records revealed that the laboratory failed to document the review of the results for 6 of 6 testing events. 2. An interview with the facility manager on 03/12/2018 at 1140 hours in the office confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the manufacturer's instructions, patient test records, environmental records, and confirmed in interview, the laboratory failed to have an effective mechanism to monitor & evaluate the overall quality of the analytic systems. Findings were: 1. The laboratory failed to have complete test documentation for BD

	AFFIRM tests to include date and time the specimen was tested. Refer to D5787 2. The laboratory failed to document corrective actions when the temperature was out of range for the storage of the BD Affirm VPIII test kits. Refer to D5785
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, laboratory environmental logs, and confirmed in interview, the laboratory failed to document corrective actions when the temperature was out of range for the storage of the BD Affirm VPIII test kits. Findings were: 1. Review of the BD Affirm VPIII Microbial Identification Test (670160JAA, 08/2010) revealed the "testing environment temperature is between 22 and 28 C... all reagents and PACs must be at 22-28 C prior to use." 2. Review of the laboratory policy IQCP Quality Control Plan approved 1/1 /2016 revealed "each documentation of temperature or humidity must be evaluated at the time of recording that it meets defined acceptability criteria. If the temperature or humidity is outside of acceptable range, an evaluation of reagent integrity and/or equipment function should be made to determine effect on patient care. Results should only be released if the evaluation of testing shows no negative effect on testing results." 3. Review of the laboratory environmental logs from January 2017 - February 2018 revealed 127 of 287 days with no documentation of the above corrective action when the room temperature was outside of the 22-28 C range. Date temp (C) 01/04/2017 21 01/05/2017 21 01/06/2017 21 01/09/2017 21 01/10/2017 21 01/11/2017 21 01/13/2017 21 01/17/2017 21 01/18/2017 21 01/19/2017 21 01/24 /2017 21 01/25/2017 21 01/26/2017 21 01/27/2017 21 01/30/2017 21 01/31/2017 21 02/01/2017 21 02/02/2017 21 02/03/2017 21 02/07/2017 21 02/08/2017 21 02/09 /2017 21 02/10/2017 21 02/13/2017 21 02/14/2017 21 02/15/2017 21 02/16/2017 21 02/17/2017 21 02/21/2017 21 02/22/2017 21 02/23/2017 21 02/24/2017 21 02/27 /2017 21 02/28/2017 21 03/06/2017 21 03/07/2017 21 03/08/2017 21 03/09/2017 21 03/10/2017 21 03/13/2017 21 03/14/2017 21 03/15/2017 21 03/16/2017 21 03/19 /2017 21 03/21/2017 21 03/23/2017 21 03/24/2017 21 03/25/2017 21 03/26/2017 21 03/27/2017 21 03/29/2017 21 03/30/2017 21 04/03/2017 21 04/04/2017 21 04/05 /2017 21 04/06/2017 21 04/07/2017 21 04/10/2017 21 04/11/2017 21 04/12/2017 21 04/13/2017 21 04/17/2017 21 04/18/2017 21 04/19/2017 21 04/20/2017 21 04/21 /2017 21 04/24/2017 21 04/28/2017 21 05/03/2017 21 05/04/2017 21 05/05/2017 21 05/08/2017 21 05/10/2017 21 05/11/2017 21 05/12/2017 21 05/17/2017 21 05/18 /2017 21 05/19/2017 21 05/23/2017 21 05/24/2017 21 05/25/2017 21 05/26/2017 21 05/30/2017 21 05/31/2017 21 06/02/2017 21 06/05/2017 20 06/06/2017 21 06/07 /2017 21 06/08/2017 21 06/09/2017 20 06/12/2017 21 06/13/2017 21 06/14/2017 21 06/15/2017 21 06/16/2017 20 06/19/2017 21 06/20/2017 21 06/21/2017 21 06/22 /2017 21 06/23/2017 21 06/26/2017 20 06/27/2017 20 06/28/2017 21 06/29/2017 21 07/05/2017 21 07/06/2017 21 07/07/2017 20 07/10/2017 21 07/11/2017 20 07/12 /2017 20 07/13/2017 20 07/14/2017 20 07/17/2017 21 07/18/2017 21 07/19/2017 20 07/20/2017 21 07/21/2017 20 07/24/2017 20 07/25/2017 20 07/26/2017 20 07/27 /2017 20 07/28/2017 20 07/31/2017 21 08/02/2017 20 08/03/2017 21 08/04/2017 21 08/07/2017 21 08/08/2017 20 08/09/2017 20 08/10/2017 20 08/11/2017 20 02/28 /2018 21 4. Review of the patient test logs from January 2017 - February 2018

	revealed the laboratory performed patient testing for the above dates. Refer to Patient alias list. 5. An interview with the lab director on 03/12/18 at 1150 hours in the office confirmed the above findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test logs, BD AFFIRM VPIII package insert instructions and verified by interview, the laboratory failed to have complete test documentation for BD AFFIRM tests reviewed, date and time the specimen were tested was not documented. Findings were: 1. A review of the BD Affirm VPIII package insert (670160JAA, 2010/08) revealed 3 different time frames for specimen processing based on type of collection system and storage temperature (1 hour, 4 hours and 72 hours): a. "When using either the Affirm VPIII Sample Collection Set or swabs contained in the Affirm VPIII Microbial Identification Test Kit: The total time between placing the swab into the sample collection tube and proceeding with the sample preparation should be no longer than 1 h if the sample is stored at room temperature." b. When using either the Affirm VPIII Sample Collection Set or swabs contained in the Affirm VPIII Microbial Identification Test Kit: The total time between placing the swab into the sample collection tube and proceeding with the sample preparation should be no longer than 4 h if the sample is stored at 2 to 8 degrees Centigrade c. "When using the Affirm VPIII Ambient Temperature Transport System (ATTS): The total time between sample collection and proceeding with sample preparation should be no longer than 72 h when the specimen is stored at ambient conditions. d. "NOTE: Prepared specimens may be stored at room temperature for up to 24 h." 2. A review of the BD Affirm VPIII package insert under "LIMITATIONS OF THE PROCEDURE" revealed "Test results may be affected by improper specimen collection, handling and/or storage conditions. A negative test result does not exclude the possibility of vaginitis/vaginosis." 3. Review of Affirm VPIII Testing Logs from 2016 and 2017 revealed no documentation of the date and time the specimen was tested (automated processing). Refer to Patient Alias list. 4. An interview of the laboratory director on 03/12/18 at 1055 hours in the laboratory confirmed the above findings. She acknowledged that the log only has the date and time the specimen was collected and prepared but not the date and time it was tested. With the system of specimen handling and processing in place at the time of the survey, the laboratory could not ensure that they were meeting the time limit for all BD Affirm specimen processing. The laboratory performs approximately 2295 BD Affirm tests per year. Note: This is a repeat deficiency from the 01/15/16 and 03/30 /12 surveys. Key: h = hour BD Affirm VPIII test system is a trade name for an analyzer that reports qualitative results using a direct RNA capture probe for the detection and differentiation of three organisms: Gardnerella Vaginalis, Candida species and Trichomas vaginalis.
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 review of the laboratory quality assessment records, review of laboratory procedures, and review of laboratory records, the laboratory's quality assessment policies failed to monitor assess and correct problems in analytic systems. Findings were: 1. The laboratory failed to have complete test documentation for BD AFFIRM tests to include date and time the specimen was tested. Refer to D5787 2. The laboratory failed to document corrective actions when the temperature was out of range for the storage of the BD Affirm VPIII test kits. Refer to D5785
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems developed and used for the BD Affirm VPII performed in the laboratory provided quality laboratory services for all aspects of test performance. (Refer to D5785, D5787)
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: A review of proficiency testing records and confirmed in interview revealed that the laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. (refer to D5211)

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory personnel files, and confirmed in interview, the technical consultant failed to perform annual competency for 1 of 7 testing person (TP) for the BD Affirm VPII patient testing for the year 2016 and 2017. (TP #1) Findings were: 1. A review of the laboratory policy IQCP Quality Control Plan approved 1/1/16 revealed that "competency is performed initially, at 6 months, at 12 months and annually thereafter." 2. A review of the laboratory personnel records revealed testing person #1 (hire date 05/29/2012) had a competency performed 02/02 /18. The laboratory was asked for documentation of annual competency for testing person #1 for 2016 and 2017. No documentation was provided. 3. An interview with the facility manager on 03/12/18 at 1145 hours in the office confirmed the above findings.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory personnel files, and confirmed in interview, the technical consultant failed to perform semi-annual competency for 2 of 7 testing person (TP) during the first year of testing patient specimens for the BD Affirm VPII. (TP # 3, 5) Findings were: 1. A review of the laboratory policy IQCP Quality Control Plan approved 1/1/16 revealed that "competency is performed initially, at 6 months, at 12 months and annually thereafter." 2. A review of the laboratory personnel records revealed testing person #3 (hire date 2/1/16) had a competency performed 09/19/17 and 02/05/18. The laboratory was asked for documentation the initial and 6 month competency for testing person #3. No documentation was provided. 3. A review of the laboratory personnel records revealed testing person #5 (hire date 10/14/16) had a competency performed 09/19/17. The laboratory was asked for documentation the initial and 6 month competency for testing person #5. No documentation was provided. 4. An interview with the facility manager on 03/12/18 at 1145 hours in the office confirmed the above findings.