Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383830	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Unitypoint Clinic Ob/Gyn Clive	12339 Stratford Drive, Clive, IA	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by the Practice Manager at approximately 1:30 pm on 01/30/2018, the laboratory failed to perform a self evaluation of ungraded PT results for two out of four PT testing events (2017 events 1 and 2) in 2016-2017. The findings include: 1. For 2017 testing event 1, the laboratory received ungraded PT test results for specimens VS-04 and VS-05 for the analyte, Gardnerella vaginalis. 2. For 2017 testing event 2, the laboratory received ungraded PT test results for specimen VS-08 for the anlayte, Gardnerella vaginalis and specimens VS-07 and VS-09 for the analyte, Trichomonas. 4. At the time of the survey, the laboratory did not perform a self-evaluation of the ungraded PT results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the GeneXpert System Maintenance Log and confirmed by the

	Practice Manager at approximately 2:00 pm on 1/30/2018, the laboratory failed to perform and document daily maintenance on the GeneXpert analyzer for 30 out of 30 days; weekly maintenance for four out of four weeks; and monthly maintenance for one out of one month in September 2017. The findings include: 1. The laboratory used the GeneXpert analyzer to perform Group B Streptococcus, Neisseria gonorrhoeae, and Chlamydia testing. 2. Daily maintenance for the GeneXpert included: *Clean work area *Close all module doors *Discard used cartridges 3. Weekly maintenance for the GeneXpert included: *Power down the GeneXpert instrument *Power down the GeneXpert computer 4. Monthly maintenance for the GeneXpert included: *Archive tests *Purges tests *Replace fan filters 5. At the time of the survey, the laboratory did not have records documenting the required maintenance in September 2017.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) and confirmed by the Practice Manager at approximately 2:00 pm on 01/30/2018, the laboratory failed to include the quality control plan and quality assessment plan as part of the IQCP for the GeneXpert test system. The findings include: 1. The laboratory performed external quality controls on the GeneXpert test system monthly and with each new lot and/or shipment of test cartridges. 2. The IQCP developed by the laboratory only included a risk assessment plan and supporting data. 3. At the time of the survey, the IQCP did not include a quality control plan and a quality assessment plan.
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 review of the Quality Assessment (QA) policy, lack of QA records and confirmed by the Practice Manager at approximately 3:00 pm on 1/30/2018, the laboratory director failed to ensure that the laboratory maintained the quality assessment program for 12 out of 12 months from January 2017 - December 2017.

	The findings include: 1. The QA policy stated, "Once a month complete a monthly QA checklist, including a chart review portion." 2. At the time of the survey, the laboratory did not have documentation indicating that monthly QA reviews had been performed from January 2017 - December 2017.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel records, the GeneXpert validation records, and confirmed by the Practice Manager at approximately 1:45 pm on 01/30/2018, the technical consultant failed to document training for the GeneXpert System prior to reporting patient test results for eight out of eight testing personnel (laboratory personnel identifiers #1- #8, refer to the Laboratory Personnel Report). The findings include: 1. The laboratory verified the performance specifications for the GeneXpert test system to perform Group B Streptococcus, Neisseria gonorrhoeae, and Chlamydia testing in May 2017. 2. At the time of the survey, the laboratory did not have GeneXpert training records for testing personnel identifiers #1- #8.