Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0166442	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hill Ob-Gyn Associates	1000 East Genesee Street, Suite 600, Syracuse, NY	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's competency assessment policies, the testing personnel's competency records, and an interview with a license practical nurse (LPN) testing person, the laboratory failed to follow the laboratory's written competency assessment policies and failed to perform an annual competency evaluation for the two testing personnel in the 2018 calendar year. FINDINGS: The LPN/testing person confirmed on February 27, 2019 at approximately 11:30 AM, the laboratory failed to follow the laboratory's written competency assessment policies, that requires an annual evaluation for all laboratory testing personnel. a. the laboratory director failed to perform annual competency evaluations for the two testing personnel in the 2018 calendar year.
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 surveyor's review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) reports for 2017 and 2018 and an interview with the LPN /testing person, the laboratory failed to review and evaluate all three PT summary

	reports for the 2017 and 2018 test events. FINDINGS: 1. The LPN/testing person confirmed on February 27, 2019 at approximately 11:00 AM, the laboratory failed to review and evaluate all three PT summary reports for the 2017 and 2018 test events. a. The laboratory PT policy requires the laboratory director to review and evaluate all PT summary reports. b. There was no evidence of review of the for all three test events in 2017 and 2018 that were scored at 100%. 2. The laboratory failed to maintain the plan of correction from the survey conducted on March 8, 2017. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 8, 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the LPN/testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2018 calendar year.
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 the surveyor's review of the laboratory's Individual Quality Control Plan (IQCP), Quality Control (QC) records for the Affirm VPIII Microbial Identification Test system and an interview with the LPN/testing person, the laboratory failed to follow the establish Quality Control Plan (QCP) section of the IQCP for the Affirm VPIII. FINDINGS: 1. The LPN/testing person confirmed on February 27, 2019 at approximately 10:30 AM, the laboratory failed to follow the establish QCP section of the IQCP for the Affirm VPIII, which states QC is performed weekly and with each new lot/shipment of PAC test cassettes using the Trivalent QC swab. 2. The surveyor found that the testing personnel were not consistent with performing a weekly QC for the Affirm VPIII, no QC records were available for the following weeks : a. January 8 through 19, 2018 - 23 patient samples were tested and reported during this time b. April 2 through 6, 2018 - 8 patient samples were tested and reported during this time c. May 14 through 18, 2018 - 3 patient samples were tested and reported during this time d. July 16 through 20, 2018 - 7 patient samples were tested and reported during

	this time e. August 10 through 17, 2018 -13 patient samples were tested and reported during this time f. September 10 through 14, 2018 - 19 patient samples were tested and reported during this time g. October 15 through 19, 2018 - 5 patient samples were tested and reported during this time h. November 12 through 16, 2018 - 4 patient samples were tested and reported during this time i. December 10 through 14, 2018 - 12 patient samples were tested and reported during this time j. January 14 through 18, 2019 - 14 patient samples were tested and reported during this time k. January 28 through February 1, 2019 - 7 patient samples were tested and reported during this time
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 surveyor's review of the laboratory's established policies & procedures, laboratory records and interview with the LPN/testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory; 1. maintained the plan of correction from the survey conducted on March 8, 2017. 2. reviewed the scored proficiency testing reports received from AAFP, refer to D6018; 3. maintained the laboratory's QCP for the Affirm VPIII Microbial Identification Test system, refer to D6020; 4. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.
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 on the surveyor's review of AAFP PT summary reports and an interview with the LPN/testing person, the laboratory director failed to review (sign and date) the scored proficiency testing reports received from AAFP to evaluate the laboratory's performance for the 2017 and 2018 test events. Refer to D5211 THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON MARCH 8, 2017.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor's review of QC records and an interview with LPN/testing person, the laboratory director failed to ensure that the QC program for bacteriology, mycology and parasitology testing was maintained to assure quality of laboratory services. Refer to D5445
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 surveyor's review of the laboratory QA policy and interview with the LPN /testing person, the laboratory director failed to follow their QA procedure for having an ongoing mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology, mycology and parasitology in the calendar year 2018 and up to survey date. Refer to D5209, D5211, D5291 and D5445