Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0215494	01/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Luminis Health Ob/Gyn - Annapolis	2000 Medical Parkway Suite 304, Annapolis, MD	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record and patient sample log review and interview with the technical consultant (TC), the laboratory did not handle bacteriology, mycology, and parasitology PT specimens in the same manner as patient samples. Findings: 1. All patient samples which enter the laboratory are recorded on a patient log. 2. A review of patient logs from January, 2017 to December, 2018 showed that PT samples performed on the BD Affirm MicroProbe Processor were not documented on the patient log along with patient specimens in 4 of 6 PT events; and 3. PT specimens performed on the Cepheid GeneXpert for Group B Strep were not documented on the patient log along with patient specimens in 2 of 4 PT events. Patient logs were not available for review for 2 of 4 events; and 4. PT specimens performed on the Cepheid GeneXpert for Chlamydia trachomatis and Neisseria gonorrhoeae were not documented on the patient log along with patient specimens in 2 of 5 PT events. Patient logs were not available for review for 3 of 5 events. 5. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that PT samples were not handled in the same manner as patient specimens.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 1/30/2017 for failing to ensure that PT records are maintained for a minimum of two years. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT records were maintained for a minimum of two years from the date of the PT testing event. Findings: 1. A review of bacteriology PT records from 2017 to 2018 showed that the attestation form which documents that PT samples were tested in the same manner as patient specimens was not available for the 1st event, 2017 for PT performed on the BD Affirm MicroProbe; and 2. The attestation form was not available for the 3rd event of 2017 for PT performed on the Cepheid GeneXpert for Chlamydia trachomatis and Neisseria gonorrhoeae as well as the PT results summary. The PT report form used by the laboratory to record PT results for bacteriology was blank. 3. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that documents from the PT events listed above were not maintained with the PT records reviewed.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with technical consultant (TC), the laboratory failed to ensure that corrective action was taken and documented for failed PT. Findings: 1. The laboratory failed Chlamydia/GC with DNA PT (60%) for 1st event, 2018. 2. No corrective action was documented for the failed PT. 3. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that there was no corrective action taken or documented for the failed PT.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 1/30/2017 for not performing quality assurance procedures. The plan of correction stated that this would be corrected. Based on procedure manual and quality assurance (QA) record review and interview with the technical consultant (TC), the laboratory did not follow established QA procedures to monitor, assess, and, when indicated, correct problems identified in the general laboratory system. Findings: 1. The procedure, "Quality Assurance Plan" states that "a quarterly QA review with the laboratory director and technical consultant will take place." 2. Procedure manual review showed that the laboratory had two "Quality Assurance Checklists," one labeled "monthly" and one labeled "quarterly." 3. A review of QA records from 2017 to 2018 showed that there were no QA reviews performed from April to August, 2018. 4. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that the laboratory did not follow written QA policies and procedures.
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 standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individual Quality Control Plan (IQCP) for performing testing on the BD Affirm Microbial Identification System and the Cepheid GeneXpert. Findings: 1. During an interview at 9:15 AM, laboratory staff stated that positive and negative external QC is performed with each new lot and/or shipment of kits for the BD Affirm Microbial Identification System and the Cepheid GeneXpert, or at least every 30 days. The laboratory staff stated that they did not have an IQCP in place to reduce the amount of QC required when performing testing on these analyzers. 2. A review of QC records from 2017 to 2018 showed that external QC was not run daily with patient testing for either analyzer; and 3. External QC was not performed on the BD Affirm from 3/17/18 to 11 /4/18. Laboratory staff stated that they were performing patient testing during that time but they "thought that the positive and negative control on each card was the QC." 2. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that an IQCP had not been performed for testing on the BD Affirm Microbial Identification System and the Cepheid GeneXpert and that QC had not been run at least once each day patient specimens are tested .

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory director was cited during the re-certification survey on 1/30/2017 for not ensuring that corrective actions were performed and documented when the laboratory received unacceptable proficiency testing results. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director did not ensure that corrective action was taken and documented for failed microbiology PT for 1st event, 2018. Refer to D2026.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on competency assessment record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the policies for monitoring the laboratory staff included the evaluation of the technical consultant. Findings: 1. The laboratory's competency and evaluation records for 2017 and 2018 were reviewed. The documentation did not include an evaluation of the technical consultant. 2. During an interview on 1/8/19 at 1:15 PM, the TC confirmed that the LD had not performed annual competency assessments evaluating the TC.