Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1077453	01/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Luminis Health Primary Care Kent Island	1630 Main Street Suite 101, Chester, 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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the proficiency testing summaries and interview with the current technical consultant, the laboratory did not ensure that proficiency testing (PT) reports were submitted to the PT agency within the required time frame. Findings: 1. The PT records from 2016 and 2017 (6 events) were reviewed. 2. For the second event of 2016 the laboratory received a score of 0% for failure to submit the hematology results. The laboratory's investigation did not identify the reason for the failure to submit the results and implement corrective actions to prevent the error from happening in the future. 3. During the survey on 01/19/2018 at 1:00 PM the current technical consultant confirmed the laboratory did not investigate the failures and implement corrective actions for the failures in PT
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the current technical consultant, the laboratory did not have post analytical policies and procedures for entering patient test results into the electronic medical record (EMR) and storage of the instrument printout once the results were entered into the EMR. Findings: 1. Review of the procedure manual showed that there were no written post analytical procedures for manually entering patient test results into the EMR and storage of the original instrument printout with the patients test results. 2. During the exit interview on 01/19/18 at 1:00 PM the current technical consultant confirmed that the policy and procedure manual did not contain post analytical policies and procedures.
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 review of the proficiency testing summaries and interview with the current technical consultant, the laboratory director did not ensure that all proficiency testing (PT) reports were reviewed in a timely manner and evaluated to identify problems that require corrective action. Findings: 1. The PT records from 2016 and 2017 (6 events) were reviewed. 2. For the second event of 2016 the laboratory received a score of 0% for failure to submit the hematology results. The laboratory's investigation did not identify the reason for the failure to submit the results. The PT samples were tested after the due date but an independent evaluation was not performed to verify that the laboratory got the correct answers. The laboratory did not implement corrective actions to prevent the error from happening in the future. 3. For the third event of 2017 the laboratory received a score of 80% for hematocrit and hemoglobin. The laboratory records did not show that an investigation of the failure was performed. 4.

	During the survey on 01/19/2018 at 1:00 PM the current technical consultant confirmed the laboratory did not investigate the failures and implement corrective actions for the PT failures.
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 competency evaluation documentation and interview with the current technical consultant (TC), the qualified TC failed to perform and document the competency evaluation reviews on all testing personnel. Findings: 1. The laboratory currently has 15 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)". 2. The annual competencies evaluations for 2016 and 2017 were reviewed. The evaluations for 2016 were performed and signed by multiple testing personnel who were not qualified as a TC (Bachelor of Science with two years experience). 3. During the survey on 01/19/18 at 1:00 PM the current TC confirmed that the evaluations for 2016 were not performed by a qualified TC (Bachelor of Science with two years experience).
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and interview with the current technical consultant (TC), the laboratory records show that a qualified TC was not performing the monthly quality control (QC) reviews. Findings: 1. Review of the QC records show that the laboratory supervisor who does not have a Bachelors of Science degree had been reviewing the monthly QC reports from December 2015 through March 2017, May 2017, June 2017 and December 2017. 2. QC reviews are the responsibility of a qualified TC and cannot be delegated to anyone other than a qualified TC with a Bachelors of Science (4 year degree) and 2 years experience in the speciality of hematology. 3. During the survey on 01/19/2018 at 1:00 PM the current TC listed on the Personnel Laboratory Report (CLIA) (CMS-209) confirmed that the QC data was being reviewed by someone that was not qualified as TC during the unannounced internal audit and not every month.