Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0923623	09/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Donald R Schneider Md & Zachary R Schneider Md	2538 Davidsonville Road, Gambrills, 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
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/28/2016 for not signing attestation statements. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the LD signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of 6 hematology PT events from 2016 to 2018 showed that the LD did not sign the attestation statement for the 1st event of 2017. 2. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that the attestation statement was not signed by the LD.
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 9/28/2016 for not maintaining proficiency testing documents 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 laboratory director (LD), 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 6 hematology PT events from 2016 to 2018 showed that hematology instrument printouts from the 3rd event of 2017 were not available for review at the time of the survey. 2. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that the hematology printouts from the PT event listed above were not maintained with the PT records reviewed.
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 standard operating procedure manual (SOPM) and record review and interview with the laboratory director (LD), the laboratory did not ensure written quality assurance (QA) policies were followed to monitor, and correct problems identified in the analytic phase of patient testing. Findings: 1. The laboratory utilizes a Medonic CA 620 hematology analyzer to perform CBCs. A review of the SOPM showed the procedure, "Quality Control Decisions and Actions for Quantitative Tests on the Hematology Analyzer" which states, "Monthly QC will be pltted to note trends as well as comparison with other Medonic users. Currently, we send out monthly evaluations to CDS for evaluation." 2. During an interview at 11:30 AM, laboratory staff stated that they no longer send "monthly evaluations" out and that the last one was sent on 5/31/16. 3. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that the laboratory was not following written QA policies to detect shifts and trends in quality control and correct problems as they occur.
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:

	Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/28/2016 for not ensuring that all proficiency reports were evaluated by the laboratory director. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the LD did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of hematology PT records from 6 events from 2016 to 2018 showed that PT results were not reviewed and signed by the LD for the 3rd event, 2017 and the 1st event, 2018. 2. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that hematology PT results were not reviewed and signed for 2 out of 6 PT events from 2016 to 2018.
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: Based on standard operating procedure manual (SOPM) and proficiency testing (PT) record review and interview with the laboratory director (LD), the LD failed to ensure that a corrective action plan was followed when PT results were found to be unacceptable. Findings: 1. The laboratory procedure, "Quality Assurance Monitors" states that "All proficiency testing results will be reviewed and analyzed by the Laboratory Director or his/her designated responsible party, and testing staff. Any results outside the acceptable range will be investigated. Remedial and/or corrective actions will be documented." 2. The laboratory received a 64% for their hematology PT results for the 1st event of 2018. 3. The PT results for this event were not reviewed by the LD and no corrective action was performed and documented for the failed PT. 4. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that the corrective action plan had not been followed for failed hematology PT for the 1st event of 2018.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of training and competency records and interview with the laboratory director (LD), the LD, acting as technical consultant did not ensure that testing personnel were competent in performing problem solving skills that involved patient testing. Findings: 1. Annual competency assessment records for 2016 and 2018 were reviewed. The competency assessment checklist did not include an evaluation of the laboratory staff's problem solving skills. 2. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that annual competency assessments performed on laboratory staff did not include an evaluation of the staff's problem solving skills.

D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 9/28/2016 for not performing annual competency assessments on testing personnel. The plan of correction stated that this would be corrected. Based on competency assessment record review and interview with the laboratory director (LD), the LD, acting as technical consultant did not ensure that testing personnel responsible for hematology testing are evaluated annually. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." A review of competency assessments performed from 2016 through 2018 showed that annual competency assessments were not performed on 3 of 3 testing personnel in 2017. 2. During an interview on 9/25/18 at 11:45 AM, the LD confirmed that annual competency assessments were not performed on testing personnel in 2017.