Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2074451	04/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vista Clinical Diagnostics	3303 North Main Street Suite C, Danville, VA	

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
D0000	An announced CLIA Recertification survey was conducted at Vista Clinical Diagnostics on April 24-26, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record reviews for hematology and interviews, the laboratory failed to maintain the preventative maintenance (PM) records for the two (2) hematology instruments for 2017 and the package insert for the Tosoh Bioscience quality control materials in 2015 that was in use up to September 30, 2017. Findings include: 1. Review of the hematology records for 2 hematology instruments (serial numbers 54451bg and 54432bg) revealed that the laboratory did not maintain the 2017 PM records. The PM records included documentation of the performance of the required calibration procedures in 2017. 2. Review of the Tosoh G8 quality control records for the hemoglobin A1c (HgA1c) analyte revealed that the laboratory failed to maintain the package insert for lot number 7040 (expiration date September 2017) that was placed into use from September 28, 2015 through September 30, 2017. 3. An interview with the lab director and general supervisor at approximately 3:30 PM on April 26, 2018 confirmed that the laboratory failed to maintain the above records.
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 review of the Laboratory Personnel Report (CLIA) (CMS- 209 Form) and interviews, the laboratory failed to establish written procedures for competency assessment for individuals performing the job duties of technical supervisor and general supervisor at the dates of survey on April 24-26, 2018. Findings include: 1. The CMS-209 Form indicates TP A is technical supervisor, and TP B is general supervisor. (See attached list.) 2. Review of available laboratory procedures revealed no written procedures available for review for performing competency assessments for the technical supervisor, and general supervisor. 3. Interviews with the general supervisor and laboratory director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory did not have written procedures for competency assessment for individuals performing the job duties of technical supervisor and general supervisor. This is a repeat deficiency.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the procedure manuals, quality control (QC) records, patient records and interviews, the laboratory failed to: 1) follow the laboratory's procedure for performing QC and background counts for the Reticulocyte counts (Cross Reference D5401), 2) perform QC procedures each day of patient testing for the Abbott Cell Dyn hematology analyzer Ruby 1 (serial number 54451BG) (Cross Reference D5447 part A), 3) perform QC procedures each day of patient testing on the Roche Cobas e600 chemistry analyzer for the free thyroxine (FT4) analyte (Cross Reference D5447 part B), 4) ensure that the Tosoh Bioscience QC results, lot number 7040 (exp 9/2017), was within the manufacturer established range (Cross Reference D5481), 5) Prothrombin Time and Internal Normalized Ration (PT/INR) coagulation QC materials every 8 hours of operation (Cross Reference D5545), and 6) perform and document corrective actions for the humidity % that was below the manufacturer's defined criteria (Cross Reference D5781).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on the review of the procedure manual, quality control (QC) records, patient records and interviews, the laboratory failed to follow the laboratory's procedure for performing QC and background counts for the Reticulocyte (Retic) counts on October 1, 14, 18, 2016; November 1, and 30, 2016; December 19 and 27, 2016; January 9, 23 and 25, 2017, and February 2, 2017. Findings include: 1. Review of the procedure manual for the Retic counts (signed by the lab director on January 1, 2016) revealed the following statement: " Reticulocyte Background procedure- 12. Verify that the Retic background count is within acceptable limit of less than or equal to 100. 13. If the Retic background count is unacceptable, repeat it. Running Quality Control: 1. Run the quality control samples each day that reticulocyte specimens are run." 2. Review of the QC records for the Retic counts revealed the following dates in which the background counts and QC materials were not performed prior to testing patient samples: October 1, 14, 18, 2016, November 1, and 30, 2016, December 19 and 27, 2016, January 9, 23 and 25, 2017, February 2, 2017. 3. Reivew of the COPIA Electronic Medical Record (EMR) patient test records for the dates above revealed a total of 16 patients was reported. 4. An interview with the general supervisor and laboratory director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory staff failed to follow the written procedure for performing QC and background counts for the Retic analyte.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the procedure manual, and interviews, the laboratory failed to have a written procedure that defined acceptable temperature and humidity percentage criteria at the dates of survey on April 24-26, 2018. Findings include: 1. Review of the general operating procedure manual revealed no documentation of a written procedure that defined the acceptable temperature and humidity percentage criteria. 2. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory did not have a written procedure that defined acceptable temperature and humidity percentage criteria at the dates of survey on April 24-26, 2018.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: A. Based on the review of the hematology procedure, quality control (QC) records, patient records and interviews, the laboratory failed to perform QC procedures each day of patient testing for the Abbott Cell Dyn hematology analyzer Ruby 1 (serial number 54451BG) on September 17, 2016, October 7, 2016 and November 1, 2016 prior to testing one hundred and eighty-eight (188) patients. Findings include: 1. Review of the hematology procedure titled CBC and Platelet Count (reviewed by the lab director on January 10, 2018) revealed the following statement: "Control Procedure- Run three levels of QC at the beginning of each eight hours of operation. Do not perform patient testing until QC tests are performed and within acceptable limits." 2. Review of the Ruby 1 QC documentation and the COPIA Electronic Medical Record (EMR) revealed that the laboratory failed to perform QC prior to testing patients on: September 17, 2016 (21 patients resulted), October 7, 2016 (77 patients resulted) and November 1, 2016 (90 patients resulted). A total of 188 patients resulted. 3. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory staff failed to perform QC procedures for the above-specified dates prior to testing patients. B. Based on the review of chemistry procedure, quality control (QC) records, patient records, and interviews, the laboratory failed to perform QC procedures each day of patient testing on the Roche Cobas e600 chemistry analyzer for the free thyroxine (FT4) analyte on February 28, 2017. Findings include: 1. Review of the chemistry procedure (reviewed by the lab director on January 10, 2018) revealed the following statement: "Run QC samples each day patient samples are run. Do not perform patient testing until QC tests are performed and within acceptable limits." 2. The inspector randomly selected the month of February 2017 for QC review. The review revealed that on February 28, 2017, there was no documentation of the performance of QC assayed on that day for the FT4 analyte. The lab staff did not document review or reason for the missing QC data on that date. Review of the COPIA Electronic Medical Record (EMR) revealed that three (3) patients had been resulted for the FT4 analyte on February 28, 2017. 3. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory staff failed to perform QC procedures for the above-specified date prior to testing patients.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records and interviews, the laboratory failed to ensure that the Tosoh Bioscience QC results, lot number 7040 (exp 9/2017), was below the manufacturer established upper limit of 6.1% from March 6, 2016 through September 15, 2017. Findings include: 1. A review of the Tosoh Bioscience QC materials (lot number 7040, expiration 9/2017) via the Orchard/Harvest laboratory information system (LIS) demonstrated that the QC results shifted above 6.1% on March 6, 2016. The lab staff did not document the review of the shift or change in manufacturer ranges. 2. Further review of the QC documentation revealed the following dates in which QC was accepted above the manufacturer range of 6.1%:

	March 6, 2016; May 23, 2016; June 17 and 27, 2016; July 1, 2, and 4, 2016; August 6, 2016; September 9, 10, 12, 13, 14, 15, 16, and 19, 2016; October 14, 2016; November 14, 18, 19, 21, 22, 23, 24, 25, 26, 28, 29, and 30, 2016; December 1, 2, and 3, 2016; January 9, 13, 16, 20, 21, 23, 24, 25, 26, 27, 28, 30, and 31, 2017; August 23, 24, 28, 30 and 31, 2017; September 1, 2, 4, 5, 11, 12, 13, and 15, 2017. A total of fifty-eight days. 3. A call to the Tosoh technical service on April 25, 2018 at approximately 12: 00 PM confirmed that the manufacturer established range for acceptable QC range was 5.0-6.1%. 4. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory failed to ensure that the QC results was within the manufacturer established range from March 6, 2016 through September 15, 2017.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the review of the quality control (QC) records, coagulation procedure, and interviews, the laboratory failed to perform Prothrombin Time and Internal Normalized Ration (PT/INR) coagulation QC materials every 8 hours of operation on June 24, 2016, July 15, 2016, January 5 and 6, 2017, March 2, 7, 28 and 29, 2017, April 24 and 27, 2017. Findings include: 1. An interview with the general supervisor on April 25, 2018 at approximately 10:00 AM revealed that the laboratory is open for approximately 17 hours and that there are two (2) Compact/STA coagulation instruments, STA 1 (serial number 311A499) and STA 2 (serial number 311A500) that are utilized for patient testing. The laboratory rotates daily testing between the 2 instruments. 2. Review of the QC records for the STA 1 and STA 2 revealed the following dates in which QC materials were assayed once during the 17 hours of operation: - STA 1- July 15, 2016 - STA 2- June 24, 2016, January 5 and 6, 2017, March 2, 7, 28 and 29, 2017, April 24 and 27, 2017. 3. Review of the coagulation procedure (reviewed by the lab director on January 10, 2018) defined that QC materials are to be assayed each day of patient testing but did not define that the QC must be ran every 8 hours. An interview with the general supervisor April 25, 2018 at approximately 12:00 PM revealed that the testing personnel are verbally instructed to run the coagulation QC materials every 8 hours of daily testing. 4. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory staff failed to perform the coagulation QC materials every 8 hours of operation for the above-specified dates.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the operator's manual, humidity percentage (%) records, and interviews, the laboratory failed to perform and document corrective actions for the humidity % that was below the manufacturer's define criteria for thirty-one (31) of sixty (60) days reviewed in 2016, seventy-five (75) of one-hundred and twenty (120) days reviewed in 2017 and forty-one (41) of fifty-nine (59) days reviewed in 2018. Findings include: 1. Review of the operator's manual for the Roche Cobas 6000 chemistry analyzer revealed that the manufacturer's acceptable ambient humidity percentage is between 30-80%. 2. Review of the laboratory's humidity records revealed the following dates in which the ambient humidity was recorded below 30%: November 10, 12, 14-17, 21-24, 26, 28-29, 2016; December 3, 12-17, 19-24, 26-31, 2016. A total of 31 dates out of range. January 2-5, 7, 9-14, 16-17, 19-20, 26-28, 30-31, 2017; February 1-4, 6-7, 10-11, 13-14, 16-18, 21, 27-28, 2017; November 11, 13, 16-18, 20-21, 23-25, 27-30, 2017; December 1-2, 4-9, 11, 13-16, 18-23, 25-30, 2017. A total of 75 dates out of range. January 1-6, 8-13, 15-20, 22-27, 30-31, 2018; February 1-3, 5-10, 13-14, 17, 24, 27-28, 2018. A total of 41 dates out of range. The inspector requested to review corrective actions taken by the laboratory for the above-specified dates and out of range ambient humidity percentage. No documentation was available for review. 3. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory did not perform and document corrective actions for the ambient humidity percentage that failed to meet the manufacturer's acceptable criteria for the above-specified dates 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 the review of temperature records, instrument quality control (QC), quality assurance plan, monthly reviews, and interviews, the laboratory's established quality assurance plan failed to identify and address issues in the analytic systems of Hematology, Coagulation, and Chemistry. (Cross reference D5401, D5447, D5481, and D5545.) Findings include: 1. Review of the 2016 and 2017 temperature and humidity records, chemistry and hematology QC records, revealed no evidence of the following: - QC and background counts for the Reticulocyte (Retic) counts on October 1, 14, 18, 2016, November 1, and 30, 2016, December 19 and 27, 2016, January 9, 23 and 25, 2017 and February 2, 2017, - QC materials performed each day of patient testing for the Abbott Cell Dyn Ruby hematology analyzer Ruby 1 on September 17, 2016, October 7, 2016 and November 1, 2016, - coagulation QC materials assayed every 8 hours of operation on June 24, 2016, July 15, 2016, January 5 and 6, 2017, March 2, 7, 28 and 29, 2017, April 24 and 27, 2017, - QC materials performed each day of patient testing for the Roche Cobas e600 chemistry analyzer on

	February 28, 2017. - corrective actions for the humidity % that was below the manufacturer's define criteria. 2. Review of the policy for Quality Assessment Plan revealed the following: "XVI. Quality Control (QC) Assessment: a. QC is performed and documented for each procedure as recommended by the manufacturer and as described by the division procedure manual. b. QC is evaluated with each patient run to determine if the patient run is acceptable. c. QC data is charted each day of business or monthly, depending on the manufacturer's directions, and observed for accuracy and precision of the test procedures. i. When problems occur, corrective action is taken and documented on the monthly QA audit form." 3. Review of the monthly QA audit forms from January 1, 2016 through March 30, 2018 did not provide documentation of the identification and corrective actions taken for the issues listed above. The audit forms were signed by the general supervisor and the laboratory director. 4. An interview with the general supervisor and lab director on April 26, 2018 at approximately 3:30 PM confirmed that the laboratory's established quality assurance plan failed to identify and address issues in the analytic systems.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of procedures, quality control (QC) records and interviews, the lab director failed to ensure that the quality control protocols were maintained prior to reporting patients. Cross Reference D5401, D5447, D5545, D5481.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of temperature records, instrument quality control (QC), quality assurance plan, monthly reviews, and interviews, the laboratory director failed to ensure that the established quality assurance plan identified and addressed issues in the analytic systems of Hematology, Coagulation, and Chemistry. Cross Reference D5791.