Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0895823	01/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Valley Regional Laboratory Inc	619 W Grand Ave, Rainbow City, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records for 2016 (Event #2) - 2018, a lack of documentation, and an interview with the laboratory manager/owner, the surveyor determined the laboratory failed to enroll in proficiency testing for 2018. The findings include: 1. An offsite review, prior to the onsite survey, revealed no data had been reported for the laboratory for proficiency testing, 2018. 2. In an interview on 1/23/19 at 11:17 AM, the surveyor asked if the laboratory had participated in proficiency testing for 2018, since no data had reported to the CMS (Centers for Medicare and Medicaid) database. The laboratory manager (owner) stated the laboratory had problems, explained as financial; and the former responsible laboratory staff had failed to ensure enrollment in proficiency testing for 2018. Patient testing in Hematology and Chemistry continued during this period, when the laboratory was not enrolled in proficiency testing. The surveyor confirmed the laboratory's enrollment for 2019.
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 a review of proficiency testing records for 2016 (Event #2) - 2018, a lack of documentation for Hematology, Event #2, 2017, and an interview with the laboratory manager/owner and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to participate in proficiency testing for Hematology, Event #2 of 2017. This affected one of five testing events reviewed by the surveyor. The findings include: 1. On 1/23/2019, a review of the AAB (American Association of Bioanalyts) proficiency testing records for 2017 revealed no documentation (no original provider package, instrument printouts, worksheets, results, reviews/evals, or attestation statement) for Hematology, Event #2, 2017. 2. At 9:32 AM on 1/24/2019, the surveyor requested documentation of Event #2, 2017 for Hematology, as none was included in the proficiency testing manual provided for the surveyor's review on 1/23 /2019. At this time, the laboratory manager stated the staff could not locate nor provide any documentation to support the laboratory's participation in Event #2, 2017 for Hematology. (Chemistry documentation was provided). The laboratory manager confirmed, and the surveyor had reviewed, the laboratory did participate in the first and third testing events of 2017. The laboratory manager stated he did not understand why there was no documentation, but felt certain the laboratory participated in Event #2 also. TP #1 confirmed the laboratory could not provide documentation of the testing for Hematology for Event #2. The laboratory manager reviewed on-line evaluations for the laboratory, and stated the proficiency testing provider had no documentation of submission of results for Event #2.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, a review of the maintenance records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform timer and RPM (Revolutions per Minute) verifications of the centrifuges, at least least semiannually, as defined in the policy and procedure. The findings include: 1. A review of the laboratory's policy and

	procedures manual revealed the following for laboratory equipment: timers (centrifuge) are checked semiannually. Records are kept for two years. RPM checks are performed on all centrifuges semiannually. Records are maintained for two years. 2. A review of the maintenance logs for 2016 (August - December), 2017 and 2018, revealed the laboratory staff did not document semiannual checks on the centrifuge as described in paragraph 1. 3. On 1/24/2019 at 11:05 AM, TP #1 confirmed the centrifuge checks for timing and RPMs had not been performed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of Hematology calibration records, a lack of written policy and procedure by the laboratory, a review of the manufacturer's operator's manual, and interviews with the laboratory manager/owner and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to calibrate the Hematology analyzer, Sysmex XT 1800i, in 2018. The staff stated the policy was to calibrate the analyzer once each year; however the laboratory failed to have a written policy to address the frequency of calibrations for the analyzer. The findings include: 1. A review of the calibration records for the Sysmex XT 1800i (for Complete Blood Count testing) revealed calibration documentation for 3/23/2017, performed by the Sysmex representative. There was no documentation the analyzer was calibrated in 2018. 2. In an interview on 1/24/2019 at 9:32 AM, the laboratory manager stated the laboratory had no written policy for the frequency of calibrating the analyzer; although the analyzer was calibrated once per year, when the company performed the PM (Preventative Maintenance). The laboratory manager also confirmed the laboratory had no documentation the analyzer was calibrated in 2018. At 9:50 AM, TP #1 stated the calibration of the Hematology analyzer was done when the representative performed the PM, once per year. TP #1 confirmed no calibration was performed in 2018. 3. A review of the operator's manual for the Sysmex XT 1800i included the following: It is recommended the laboratory perform calibration or calibration verification, when major PM is performed or critical parts replaced; controls found to be outside acceptable limits (shifts); according to laboratory's schedule; advised by Sysmex representative; as regulatory standards require periodic calibration verifications. 4. This is a repeat deficiency.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration verification records for the Chemistry analyzer, Beckman Coulter AU 480, a review of the policies and procedures (a lack of documentation), a review of installation records, and an interview with the laboratory manager/owner and Testing Personnel (TP #1), the surveyor determined the laboratory failed to perform calibration verifications at least every six months for analytes with less than three routine calibrators. The laboratory further failed to establish a written policy to address the frequency of when these calibration verifications should occur. This affected the review period from October 2016 - date of survey (January 24, 2019). The findings include: 1. A review of the installation and calibration verification records for the AU 480 revealed calibration verifications were performed, when the instrument was installed in October of 2016; June 15, 2017 (exceeding a six month time-frame); and March 9, 2018 (about nine months after the previous calibration verification). 2. The laboratory did not perform the calibration verifications at least every six months as required for Chemistry analytes with less than three routine calibrators. 3. At 9:32 AM on 1/24/2019, the laboratory manager confirmed the laboratory had no written policy to address calibration verifications for the Beckman Coulter AU 480. At 11:05 AM, TP #1 confirmed the calibration verifications had not been performed at least every six months.
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 an electronic review of quality control (QC) records with Testing Personnel (TP #1), a review of electronic patient reports (printed), and an interview with the laboratory manager, the surveyor determined the laboratory failed to ensure at least two levels of QC were within acceptable ranges for Direct Bilirubin (dbili) on 12/21 /2018, prior to testing patient specimens and reporting the results. This affected two

	patients with dbili testing on 12/21, one day of two months of Chemistry quality control reviewed by the surveyor. The findings include: 1. At approximately 10:15 AM on 1/24/2019, TP #1 reviewed the electronic Chemistry QC for January 2019 and December 2018 with the surveyor, and confirmed only one level of QC of the usual two levels daily was within acceptable range on 12/21/2018 for dbil. 2. The laboratory's manager query of the electronic system revealed two patient specimens for dbili (12/21) had been run, and the results reported.
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 a review of personnel records, policies and procedures, quality control and quality assurance records, proficiency testing records, calibrations and calibration verifications, maintenance records, the laboratory director failed to fulfil the laboratory director's responsibilities, as evidenced by the failure to ensure a quality assurance program was established and maintained to ensure: A) the laboratory enrolled in proficiency testing for 2018; B) the laboratory participated in proficiency testing for Hematology Event #2, 2017; C) the testing personnel's competency was assessed at least semiannually the first year of employment; D) Hematology calibrations were performed; E) calibration verifications were performed at least every six months; F) policies and procedures were established to address the frequency of performing calibrations and calibration verification; G) semiannual maintenance was performed on the laboratory's centrifuges; and H) at least two levels of quality control were within acceptable limits, prior to testing patients. The findings include: 1. Refer to D6021.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records for 2016 (Event #2) - 2018, a lack of documentation, and an interview with the laboratory manager/owner, the surveyor determined the laboratory director (also the technical consultant) failed to ensure the laboratory enrolled in proficiency testing for 2018. The findings include: 1. Refer to D2000. a) An offsite review, prior to the onsite survey, revealed no data had been reported for the laboratory for proficiency testing, 2018. b) In an interview on 1/23/19 at 11:17 AM, the surveyor asked if the laboratory had participated in proficiency testing for 2018, since no data had reported to the CMS (Centers for Medicare and Medicaid) database. The laboratory manager (owner) stated the laboratory had

	problems, explained as financial; and the former responsible laboratory staff had failed to ensure enrollment in proficiency testing for 2018. The surveyor confirmed the laboratory's enrollment for 2019.
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 a review of personnel records, policies and procedures, quality control and quality assurance records, proficiency testing records, calibrations and calibration verifications, maintenance records, the laboratory director failed to ensure a quality assurance program was established and maintained to ensure: A) the laboratory enrolled in proficiency testing for 2018; B) the laboratory participated in proficiency testing for Hematology Event #2, 2017; C) the testing personnel's competency was assessed at least semiannually the first year of employment; D) Hematology calibrations were performed; E) calibration verifications were performed at least every six months; F) policies and procedures were established to address the frequency of performing calibrations and calibration verification; G) semiannual maintenance was performed on the laboratory's centrifuges; and H) at least two levels of quality control were within acceptable limits, prior to testing patients. The findings include: 1) A review of the 2017 (August - December) and 2018 quality assurance records (Standard Operating Manual) revealed monthly checklists signed by the Laboratory Director (also serving as the technical consultant) for the following monitoring: policies and procedures; calibration and calibration verification records; instrument maintenance and function checks; corrective actions plan; temperature and humidity; new staff competency training... All of the above items were check-marked; and the checklists were signed by the Laboratory Director. No problems were identified /indicated. A) Refer to D2000 and D6015 (no enrollment in proficiency testing for 2018) B) Refer to D2123 (no participation in proficiency testing) for Hematology, Event #2, 2017) C) Refer to D6053 (no semi-annual competency to testing personnel #1) D) Refer to D5437 (Hematology calibrations) E) Refer to D5439 (Chemistry calibration verifications) F) Refer to D5437 and D5439 (no written policies and procedures) G) Refer to D5435 (lack of documentation for centrifuge maintenance) H) Refer to D5481 (unacceptable quality control)
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records, a review of the policy and procedure

	manual, and an interview with Testing Personnel #1 (TP #1) and the laboratory manager, the surveyor determined the technical consultant (also serving as the laboratory director) failed to assess the competency of TP #1 at least semiannually, during the first year the employee performed patient testing of moderate complexity. This affected one of two testing personnel. The findings include: 1. A review of TP #1's personnel file revealed the employee was oriented and trained in the laboratory in October of 2017, to perform moderate complexity testing. 2. There was no documentation TP #1's competency was assessed during this first year of employment as testing personnel of moderate complexity. 3. A review of the laboratory's policy and procedure manual revealed the following: Personnel: the employee files for technical personnel contain the following; semiannual competency evaluations, supervisor evaluations. 4. On 11:17 AM on 1/23/2019, TP #1 confirmed his competency had not been assessed, since initial training in October. The laboratory manager (owner was present during this interview).