Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0667196	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shamrock General Hospital	1000 South Main, Shamrock, TX	

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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing records from the proficiency testing company, American Proficiency Institute (API) and interview with facility personnel, the laboratory did not successfully participate in the specialty of hematology for the

	analyte activated partial thromboplastin time (APTT) for 2 of 3 events in 2018. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing records from the proficiency testing company, American Proficiency Institute (API) and interview with facility personnel, the laboratory did not successfully participate in the specialty of hematology for the analyte activated partial thromboplastin time (APTT) for 2 of 3 events in 2018. The findings included: 1. Based on a review of API proficiency testing results and the laboratory's self-grade findings, the laboratory received the following scores the analyte activated partial thromboplastin time (APTT) : 2018, 1st event: Score of 60 percent 2018, 2nd event: Score of 60 percent A score of less than 80 percent is unsatisfactory performance. Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. The laboratory was required to self-grade the analyte activated partial thromboplastin time (APTT) scores because API did not reach a consensus with participant scores. 2. In an interview at 10:54 hours on 2/21/2019 in the conference room, the Laboratory Manager stated the laboratory to run quality control materials as unknowns for corrective action. The results of the corrective action study were acceptable.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the quality control procedure, quality control records, patient records, and interview with facility personnel, the laboratory failed to evaluate 3 of 3 patients tested since the last acceptable control for Glucose between March 28, 2018 and March 29, 2018. The findings included: 1. Based on review of the laboratory procedure "VITROS QUALITY CONTROL", approved by the Lab Director on 5/15 /2017, under Daily QC Decisions, the document states the following: "Quality Control rules are applied to the data of the 2 levels of quality-control fluid individually and together. If there are no flags, proceed with patient testing. If any analyte is flagged with F2 or F3, do not continue with patient testing until investigating. The F2 flag describes a situation where one control value for any of the two levels of control is outside the mean plus/minus 2SD. Evaluate: if both levels of control for a single analyte have an F2 flag both values are outside the 2SD limit and troubleshooting is

	needed; if only one level for an analyte has an F2 flag, check QC values from the previous run: if either level of the analyte has an F2 flag, troubleshooting is needed.; If there are no other F2 flags for the analyte, proceed with patient testing. The F3 flag describes a situation where one control value for any of the two levels of control is outside the mean plus/minus 3SD. System behavior may have changed and troubleshooting is needed. Troubleshoot: * Rerun control. *Make a new bottle of control and repeat. Follow reconstitution instructions. *Check analyte slides to see how long the slides have been on the Vitros ad if it is within the On Analyzer Stability Time. Replace if needed. *Check last calibration. Recal if needed. *Call Vitros Customer Service for help. Patient results can be reported only when the controls used in the repeat assay do not have F2 or F3 flags." The procedure did not describe a process to identify all patient test results obtained in the unacceptable test run and since the last acceptable test run to be evaluated to determine if patient test results have been adversely affected. 2. Based on a review of quality control records and corrective action records, the high control was unacceptable on March 29, 2018 for Glucose: Glucose control U5612 Lab stated mean: 279.00 Lab stated plus/minus 2SD range: 269.56 to 288.44 On 3/29/2018 at 06:38 hours, Glucose value was 268.6 with a flag of F2 indicating this value was outside of 2 standard deviations from the mean of 279.0. The control was repeated at 08:02 hours on 3/29/2018 and corrective action stated "Reran QC fluid". This value was 267.1, flagged with F2 indicating this value was outside of 2 standard deviations from the mean of 279.0. The control was repeated at 08:15 hours on 3/29/2018 and corrective action stated "Fresh QC fluid". This value was 266.9, flagged with F2 indicating this value was outside of 2 standard deviations from the mean of 279.0. At 10:38 hours on 3/29/2019, the Glucose analyte was recalibrated and the value was 281.7, within acceptable limits. The corrective action was documented as "Post Calibration QC". 3. The previous acceptable quality control (prior to the corrective actions taken above) was a value of 270.4 on 3/28/2018 at 07:56 hours. Based on a review of patient records, no patients were tested during the time period of the troubleshooting (06:38 - 10:38 hours on 3/29/18). Three (3) patients were tested between the troubleshooting and the last acceptable quality control value on 3/28/2018. Patient: 84259, Reported at 08:53 hours on 3/28/2018 Glucose: 107 mg/dL Laboratory Normal Range: 74 - 106 Patient: 84291, Reported at 15:59 hours on 3/28/2018 Glucose: 401 mg/dL Laboratory Normal Range: 74 - 106 Patient: 84307, Reported at 16:35 hours on 3/28/2018 Glucose: 108 mg/dL Laboratory Normal Range: 74 - 106 4. In an interview at 15:55 hours on 2/21/2019 in the laboratory, the Laboratory Manager stated the laboratory did not have an established protocol for assessing patients since the last acceptable control when corrective actions required significant interventions like recalibration of an assay. Key: SD-standard deviation QC - Quality Control mg/dL - milligrams per deciliter
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 review of proficiency testing records, corrective action records, and interview with facility personnel, the Laboratory Director failed to provide overall

	management and direction of the laboratory. The laboratory received unsatisfactory scores for 2 of 3 consecutive events for first and second events of 2018 for the analyte activated partial thromboplastin time (APTT). Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing records, corrective action records, and interview with facility personnel, the Laboratory Director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. The laboratory received unsatisfactory scores for 2 of 3 consecutive events for first and second events of 2018 for the analyte activated partial thromboplastin time (APTT). Refer to D2130.