

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0717959	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Memorial Hospital	Street Address, City, State 209 N W 8th St, Seminole, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Review of laboratory records and interview facility personnel found that the laboratory used expired CVP (calibration verification product) to verify the performance of the Gem Premier blood gas analyzer in October 2017. The findings included: 1. Review of CVP sample reports for 2017 found that the laboratory used expired CVP in one of 12 months. The laboratory used CVP lot 1826 with an expiration date of September 2017 on October 18, 2017 to verify the performance of the analyzer. 2. Review of patient test records found that the laboratory tested 12 patient specimens between October 1 and November 1, 2018 when lot 1834 was placed into use. 3. Interview the technical consultant conducted on August 14, 2018 at 9:27 AM confirmed that the expired CVP material was used to verify the accuracy of the machine.</p>
D6114	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(1)</p> <p>The technical supervisor is responsible for selection of the test methodology that is appropriate for the clinical use of the test results.</p> <p>This STANDARD is not met as evidenced by: Observations, review of operators guides and package inserts and interview facility personnel found that the technical supervisor failed to select the appropriate blood</p>

glucose monitoring system for use in the emergency room, nursery, operating room and nurses unit. The findings included: 1. Observations made during the tour the facility found four Contour Next blood glucose monitoring devices in use. Emergency room- Contour next blood glucose monitoring device serial number 84635987358 with blood glucose test strips lot DW8APEF088 expiration January 31, 2020. Nursery- Contour Next blood glucose monitoring device serial number 84636657358 with blood glucose strips lot DW8CPEG 11B expiration March 31, 2020. Nursing unit - Contour Next blood glucose monitoring device serial number 84635027358 with blood glucose strips lot DW8CPEG 11B expiration March 31, 2020. Operating room - Contour Next blood glucose monitoring device serial number 80704427358 with blood glucose test strips lot DW7H PEG14A expiration August 31, 2019. 2. Review of the operator's guide for the Contour Next blood glucose monitoring system found under the heading indications for use: "The contour next blood glucose monitoring system is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and is for single patient use only, and should not be shared. The system is intended for self testing outside the body (in vitro diagnostic use) and is to be used as an aid to monitor the effectiveness of diabetes control. The contour next blood glucose monitoring system is not intended for the diagnosis or screening for diabetes mellitus and is not intended for use on neonates." Review of the package insert for the Contour Next blood glucose test strips found under the heading intended use: "Contour Next test strips are an over-the-counter (OTC) product and are intended for self testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples. The Contour Next blood glucose monitoring systems are not intended for the diagnosis of or screening for diabetes mellitus." Under the heading caution: "the meter in Lansing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!" 3. Review of patient test records found 66 patient specimens tested in the nursery and 23 patients tested in the emergency room using the Contour Next blood glucose monitoring device. Patient test records for the operating room were requested but not provided. 4. Interview of the laboratory director and technical supervisor conducted on August 16, 2018 at 11:10 AM confirmed that the laboratory director and technical supervisor were not consulted in the choosing of the blood glucose meters. It was confirmed that when the hospital built the new ER and labor and delivery in early 2018 these meters were purchased and placed into use without their knowledge.