Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507420	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Methodist Hospital Levelland	1900 S College Avenue, Levelland, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, patient test records and interview of facilty personnel found that the laboratory failed to define corrective actions to be taken when quality control results failed to meet their established acceptable limits in their own quality control procedure. The findings included: 1. Review of the laboratory's own procedure titled Quality Control found no direction to testing personnel for corrective actions to be taken when quality control results fail to meet the laboratory's own criteria of acceptability. 2. Interview of Technical Consultant 2 on the CMS Report 209 conducted on June 20, 2018 confirmed the

	laboratory failed to include the corrective actions to be taken when quality control results do not meet the laboratory's own criteria of acceptability.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Review of verification records for the Vitamin D and Microalbumin, and interview of facility personnel found that the laboratory failed to evaluate the data for accuracy, precision and reportable ranges to ensure the results met the performance specifications as defined by the manufacturer. The findings included: 1. Review of the verification studies for the Vitamin D and Microalbumin procedures tested on the Dimension EXL (in use 01/2018) found that the data had not been evaluated to ensure it met the performance specifications as defined by the manufacturer. 2. Interview of the Technical Consultants on June 19, 2018 at 3:23 PM confirmed that the laboratory had not evaluated the data against the manufacturer's claims to ensure the assays met the manufacturer's specifications.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of the laboratory's Individual Quality Control Plans (IQCP), quality control worksheets, patient test records and interview of facility personnel found that the laboratory failed to follow it's own IQCP for testing external quality control materials when using the AmniSure ROM and Crypto/ Giardia test kits. The findings included: 1. AmniSure ROM - a. Review of the laboratory's written IQCP found that the laboratory had defined a frequency of testing external quality control materials with each new lot, shipment and every 30 days. b. Review of the quality control records for the AmniSure ROM found that the laboratory tested external quality control materials seven times in 6 months between the months of January and December 2017. I. January 1, 2017 lot 551011560 II. April 29, 2017 lot 551011560 III. July 8, 2017 lot 551011560 IV. August 22, 2017 lot 551011560 V. September 28, 2017 Lot 557011197 VI. November 9, 2017 Lot 557011197 VII. November 25, 2017 Lot

	557011197 c. Review of patient test records found that the laboratory tested seven patient specimens in 2017, one on each day they tested and documented external quality control testing. d. Interview of the Technical Consultants conducted on June 20, 2018 at 3:48 PM confirmed that they did not test external quality control materials once every 30 days as per their own IQCP. 2. Cryptosporidium/Giardia Antigen Detection a. Review of the laboratory's IQCP found that the laboratory had defined a frequency of testing external quality control materials "with each new lot or monthly, whichever is more frequent." b. Review of quality control records found that the laboratory tested external quality control materials in 10 0f 12 months during 2017. I. January 1, 2017 lot 0816263 II. February21, 2017 lot 08161341 III. April 5, 2017 lot 081613411 IV. May 23, 2017 lot 08161341 V. June 23, 2017 lot 08161341 VI. July 25, 2017 lot 08161341 VII. August 30, 2017 lot 08171190 VIII. October 5, 2017 lot 08171190 IX. November 11, 2017 lot 08171190 X. December 4, 2017 lot 08171190 c. Review of patient test records found that the laboratory tested 6 patient specimens in the month of September 2017 without testing external quality control materials at least monthly. I. September 1, 2017 - patient LU01104631 II. September 2, 2017 - patient LU01069571 III. September 7, 2017 - patient LU01083800 IV. September 21, 2017 - patient LU00928934 V. September 22, 2017 - patient LU01099341 VI. September 27, 2017 - patient LU00966876 d. Interview of the Technical Consultants conducted on June 20, 2018 at 3:48 PM confirmed that they did not test external quality control materials monthly as per their own IQCP.
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: Review of the laboratory's own procedure, quality control records and interview of facility personnel found that the laboratory failed to document quality control results each day of patient testing when using the Rapid Plasma Reagin (RPR) test kit. The findings included: 1. Review of the laboratory's own procedure found on page 3 of 4 under the heading Quality Control- " Controls must give expected results (reactive, weakly reactive and nonreactive) in order to report out any patient. Controls are to be run with each batch of patients daily. When controls do not react as expected no patient results may be released and kit should not be used for further testing." 2. Review of patient test records for June 2018 found that quality control is recorded as pass or fail. The laboratory did not record the results of the negative, weakly reactive and reactive controls tested each day of patient testing. 47 patient specimens were tested between June 1 and June 20, 2018. 3. Interview of Technical Consultant 2 listed on the CMS report 209 Laboratory Personnel report conducted on June 21, 2018 at 10: 35 AM confirmed that the laboratory did not document the results of the three controls each day and documented only that the passed.
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 a review of the laboratory's policies and procedures, quality control records, patient test records, and interview of facility personnel, the laboratory failed to evaluate forty six (46) patients tested since the last acceptable quality control values between October 23, 2017 and October 24, 2017 for the analyte Glucose. The findings included: 1. Review of the laboratory's procedure titled QUALITY CONTROL found on page 1 under the heading GENERAL and IMMUNO CHEMISTRY: "INVESTIGATION OF QUALITY CONTROL FAILURES - All QC failures are to be investigated for cause and documented either through the computer system or on worksheets. Investigation for resolution of the problem may include, but are not limited to : 1. Technical Error 2. Reagent Failure (dating, need for calibration, improper preparation, etc) 3. Instrument Malfunction 4. need for recalibration or calibration error. When all aspects of test performance have been evaluated and the failure still occurs, the appropriate companies Technical Service will be notified for additional assistance." Further review found on page 2 -" For the Siemens Dimension EXL, 2 levels of control (normal and High) material are performed for each 24 hour period of operations. Booth levels of control material must be within performance range in order for patient results to be reported." 2. Based on review of the laboratory's quality control records for the BIO-RAD MultiQual quality control materials levels 1 and 3 (tested on Dimension 1), the laboratory defined the following ranges of acceptability (2SD) for the analyte Glucose: Lot 47950 (level 1) 56.52 - 64.12 mg/dl Lot 47950 (level 3) 332.05 - 362.17 mg/dl 3. Review of the laboratory quality control records for Dimension 1 found that quality control results for Glucose failed to meet the laboratory's acceptable limits as follows: a. October 23, 2017 - quality control tested at 12:20 AM Lot 47950 (level 1) 65.00 mg/dl (high). This result was accepted with the 1-2S(W) flag) Lot 47950 (level 3) 357.00 mg/dl b. October 24, 2017- quality control tested at1:14 AM Lot 47950 (level 1) 65.00 mg/dl (high). This result was rejected with the 2-2SI flag. Comments included "Actions - Rerun with fresh control (KL - 10/24/2017 1:08 AM)" Lot 47950 (level 3) 358.00 mg/dl Further review of quality control records found additional quality control materials tested 10 /24/2017 at 1:21 AM Lot 47950 (level 1) 65.00 mg/dl (high). This result was accepted with the 2-2SI flag. Comments included "Actions -Blow a well and rerun (KL - 10/24 /2017 1:23 AM)" Additional repeated qualit control testing for level 1 at 1:30 AM: Lot 47950 (level 1) 65.00 mg/dl (high). This result was rejected with the 2-2SI flag. Comments included "Actions - Put nnew flex and rerun (KL - 10/24/2017 1:30 AM)" Lot 47950 (level 1) 64.00 mg/dl Accepted This result was accepted at 2:35 AM. 4. Review of patient test records found 46 patient samples tested on Dimension 1 between October 23, 2017 between 7:10 AM and 9:46 PM without assessment of results to determine if erroneous values had been reported: Patient ID LA 0082598707 Patient ID LA0082598715 Patient ID LA0082598731 Patient ID LA0082598740 Patient ID LA0082598766 Patient ID LA0082598774 Patient ID LA0082598782 Patient ID LA0082598791 Patient ID LA0082598804 Patient ID LA0082598898 Patient ID LA0082598901 Patient ID LA0082598863 Patient ID LA0082598936 Patient ID LA0082598944 Patient ID LA0082598979 Patient ID LA0082599053 Patient ID LA0082599061 Patient ID LA0082599070 Patient ID LA0082599088 Patient ID LA0082598952 Patient ID LA0082599134 Patient ID LA0082599142 Patient ID LA0082599185 Patient ID LA0082598952 Patient ID LA0082599282

	Patient ID LA0082599291 Patient ID LA0082599312 Patient ID LA0082599347 Patient ID LA0082599347 Patient ID LA0082599339 Patient ID LA0082599398 Patient ID LA0082599410 Patient ID LA0082599428 Patient ID LA0082599444 Patient ID LA0082599380 Patient ID LA0082599517 Patient ID LA0082588540 Patient ID LA0082599495 Patient ID LA0082599436 Patient ID LA0082599576 Patient ID LA0082599631 Patient ID LA0082599703 Patient ID LA0082599703 Patient ID LA0082599711 Patient ID LA0082599738 Patient ID LA0082599754 Patient ID LA0082599819 Patient ID LA0082599827 5. Interview of the General Supervisor conducted on June 20, 2018 at 4:20 PM confirmed that the laboratory did not assess patient specimens tested since the last acceptable quality control results obtained on October 22, 2017 12:43 AM
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Review of verification studies for the Vitamin D and Microalbumin assays performed on the Dimension EXL Chemistry analyzer (in use 01/2018) found that he data had not been evaluated against the manufacturer's claims to ensure the methods met the manufacturer's specifications. (see D 5421)
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Review of the laboratory's own IQCP's, quality control records, patient test records, and interview of facility personnel found that the laboratory director failed to ensure that the quality control program had been established and maintained. The laboratory failed to test external controls at least once every 30 days for the AmniSure ROM test kit as written in their own IQCP. (see D 5445) The laboratory failed to test external controls at least once each month when using the Cryptosporidium/ Giardia Antigen test kit.(see D5445) The laboratory failed to assess patient glucose results tested on October 23, 2017 (using Dimension 1) since the last acceptable quality control run. (see D5783)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Review of the laboratory's own IQCP's, quality control records, patient test records, and interview of facility personnel found that the laboratory director failed to ensure that the quality control program had been established and maintained. The laboratory failed to test external controls at least once every 30 days for the AmniSure ROM test kit as written in their own IQCP. (see D 5445) The laboratory failed to test external controls at least once each month when using the Cryptosporidium/ Giardia Antigen test kit.(see D5445)
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: The laboratory failed to assess patient glucose results tested on October 23, 2017 (using Dimension 1) since the last acceptable quality control run. (see D5783)
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Review of the laboratory's own procedure, quality control records and interview of facility personnel found that the Technical Consultant failed to ensure that testing personnel documented quality control results on the quality control worksheets for each day of patient testing when using the Rapid Plasma Reagin (RPR) test kit. (see D5481)