Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508911	01/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Winkler County Memorial Hospital	821 Jeffee Dr, Kermit, 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: Based on review of laboratory procedures, laboratory references, surveyor observations, and interview with facility personnel, the laboratory failed to establish and follow a step-by-step procedure for urine sediment microscopic examinations. The findings included: 1. Based on review of the laboratory's procedure "Microscopic Examination of the Urine", (last revised 11/96), the procedure states the following: "C. Procedure 1. Using a disposable pipette, transfer one drop of the spun down, stained, well-mixed sediment to a clean test chamber on the standardized slide or on the glass slide with coverslip. Place each patient sample in a different test chamber

	(up to six on one slide) or two patients on aslide with coverslips.". Procedures must include: (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. The procedure did not state step-by-step instructions for how to prepare the urine specimen for centrifugation, the time, speed or force, or how to decant and re-suspend the urine sediment. Under part D. Reference of the procedure, the laboratory listed the following reference: Susan King Strasinger, URINALYSIS AND BODY FLUID, Edition 3, 1992. 2. Based on review of the laboratory's cited reference, Susan King Strasinger, URINALYSIS AND BODY FLUID, Edition 3, 1992, under Methodology, the reference states the following: "2. A standard amount of urine, usually between 10 and 15 mL, is centrifuged in a conical tube. This will provide an adequate volume from which to obtain a representative sample of the elements present in the specimen. The use of a 12 mL volume is considered idea because the multi-parameter reagent strips can be totally immersed in this volume and yet the tube i not filled to the point that leakage occurs when the cap is applied. 3. The speed of the centrifuge and length of time the specimen is centrifuged should be consistent. Centrifugation for 5 minutes at a relative centrifugal force (RCF) of 450 will produce an optimum amount of sediment with the least change of damaging the elements." The surveyor was notified by email on 2/4/2019 the laboratory had another urinalysis procedure, "Urinalysis SOP", last revised March 2017. This procedure, provided by email, stated the following: "14. Place the specimen tube in the centrifuge with a counterbalance and spin for 5 minutes at 2115 RPM. 15. After completion of the centrifugation, remove the specimen from the centrifuge and decant." In an email received at 14:50 hours on 2/4/2019, the lab manager stated the following: "9 cm. was the radius we used to compute for RPM before. I spoke to Drucker diagnostics technical support to ask for the specific radius of the 614v centrifuge and its 4.25 inches or around 10.8 cm. which will bring us to 1931 RPM. We will update our urinalysis policy to include the correct centrifuge RPM speed." 3. At 10:24 hours on 1/31/2019 in the laboratory, the surveyor observed that the centrifuge used for processing urine specimens was set at 2500 RPM on the inside black scale, which was consistent with the black tube holders in use in the centrifuge. Based on review of the Drucker Model 614V operator's manual, on page 10, the RCF conversion chart indicated that a speed of 2500 RPM would correlate with a relative RCF between 700 and 800. 4. In an interview at 10:20 hours on 1/31 /2019 in the laboratory, the Laboratory Manager stated the laboratory had spent some time trying to determine the appropriate force to spin urines in the past and was able to see on the RCF conversion chart that a speed between 1750 and 2000 RPM would correlate with the laboratory's reference of 450 RCF. Based on review of documentation provided by the laboratory, the laboratory performs approximately 1, 942 urinalysis examinations annually.
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:
A. Based on review of the laboratory's policies and procedures, manufacturer's instructions, verification studies performed by the laboratory and interview of facility personnel, the laboratory failed to follow manufacturer's instructions for verifying the precision, reference range, reportable ranges and accuracy of the PT (using Innovin lot5393878) and APTT(using Actin lot 547493).) tested on the Sysmex CA 620 coagulation analyzer installed in October, 2017. The findings included: Precision Verification Based on review of the laboratory's policies and procedures, Siemens CA 620 coagulation analyzer manufacturer's instructions, precision verification study, and confirmed in interview with facility personnel, the laboratory failed to follow manufacturer's instructions for verifying the between run precision for PT and APTT upon installation of the CA 620 analyzer October 2017. 1. The laboratory had not written a separate policy / procedure for the use of the Sysmex CA 620 coagulation analyzer , using the manufacturer's Operator Guide as its own procedure 2. Review of the manufacturer's instruction guideline titled "Precision Verification" (1/2013), states the following: on page III-1 "Between-run precision measure the degree of imprecision over time and requires testing over a minimum of five days." on page III-2 "The laboratory should determine Between Run Precision over a minimum of 5 days using 4 replicates of each level of control More runs and days will increase confidence in the results. Record results on the appropriate Precision Worksheet." Further review of instructions found on page III-2, "5. The laboratory should determine Between Run Precision over a minimum of 5 days using 4 replicates of each level of control. More runs and days will increase confidence in the results. Calculation of Precision 1. Calculate the Mean, SD, and %CV for controls. 2. Calculate the acceptable limits of error. Regulated analytes are PT, APTT & Fibrinogen. according the the manufacturer, the acceptable limit for within run precision is: PT + 2% APTT + 2%" 3. Based on a review of the verification studies for the Sysmex CA 620, the laboratory performed within run precision studies, but did not assess between run precision for PT (using Innovin lot 5393878) and APTT(using Actin lot 547493). 4. Interview of the General Supervisor conducted on January 31, 2019 at 11:07 AM confirmed the laboratory did not evaluate the data for the within run precision, and did not assess the between run precision over a minimum of 5 days as required by the manufacturer. Method Verification 1. Review of the manufacturer's instructions for Method verification found the following instructions to the laboratory on page IV-1: "Performance of a method verification study defines the relationship between a system currently in use and a new system. Accuracy is closeness to the true value. The PT and APTT are screening tests with no recognized reference method to determine accuracy. Best results for method verification studies require a minimum of 40 patient samples (20 normal and 20 abnormal). Range should be from below to substantially above the expected reference range. Studies should be performed over several days. Samples should be tested on the current system, followed immediately, but by no more than 1/2 to 1 hour later by testing on the new system. Clotting factor activity can deteriorate over time affecting APTT values and to a lesser extent, the PT. Run Tests as appropriate following the recommended operating procedure (see application sheets). Record results on worksheets. Perform regression analysis." 2. Review of the laboratory's own method verification found no documentation of review. 3. Interview of the General Supervisor conducted on January 31, 2019 at 11:07 AM confirmed the laboratory did not evaluate the data for the method verification for acceptability. Reference Interval 1. Based on a review of the manufacturer's instructions titled "Reference Interval" (1/2013), the document states the following: "A reference interval must be established for Fibrinogen, Prothrombin Times, APTT's, D-Dimer's and Thrombin Times by each institution. Some tests, such as factor assays, do not require that each individual lab perform a reference interval study, as clinical

investigations have established reference values that are widely accepted by the medical community. Requirements: Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) Donors should not take any medications, including aspirin. A minimum of 20 donors with a reasonable even distribution of males and females should be included. Donors should span the adult age range. (NOTE: a separate range should be established for pediatric populations). The FDA defines pediatric as up to 21 years of age. Testing should be performed over a period of several days and by different people, if possible to allow for day to day variation. A minimum of 4-6 specimens should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing of patient plasma samples. The test result from the donors should be analyzed statistically and verification of the mean (plus/minus) 2 SD or 95 percent confidence limit should be calculated. Software that performs this calculation can be used to verify the Laboratory or the IFU (instructions for use) reference interval. Note: Because the reference interval is defined with a plus/minus 2SD, values falling outside this range may or may not be normal and should be further evaluated. Statistically, a certain percentage of these patients will be normal. However, by defining the normal ranges in this manner, patients' who are abnormal will be less likely to go undetected. (See CLSI document C28-A.)." 2. Review of the laboratory's own reference interval studies found that the laboratory had defined a reference interval of 9.3 - 11.4 seconds for Prothrombin Time (PT) (using Innovin lot 5393878) and 24.5 - 32.8 seconds for Activated Partial Thromboplastin (using Actin lot 547493) . 3. Review of patient final results from January 28, 2019 found that the laboratory defined the reference ranges as follows: PT 9.2 - 10.6 seconds PTT 21.8 - 28.0 seconds Review of patient reports from September 3, 2017 (prior to installation of new analyzer) found that the laboratory defined the reference ranges as follows: PT 9.2 - 10.6 seconds PTT 23.2 - 29.0 seconds Interview of the General Supervisor conducted on January 31, 2019 at 11:29 AM confirmed that the reference ranges established by the laboratory were not the ranges on the current final report. He went on to say he did not know where the reference ranges in the final report came from. Reportable Range 1. Review of the manufacturer's instructions titled Reportable Range found on page VI-1 found the following instruction to the laboratory: "Reportable range determination is addressed both in CLIA requirements and CLSI Guidelines. While CLIA requires the laboratory to verify the Reportable Range, the method used is not explicit, and leaves this up to the individual laboratories." 2. Review of the records provided for the verification of the Sysmex CA 620 found no documentation of reportable range verification. 3. Interview of the Laboratory Director conducted on January 31, 2019 at 11:29 AM confirmed that the laboratory had not verified the reportable ranges for PT and APTT using the Sysmex CA 620 coagulation analyzer. 36342 B. Based on review of the laboratory's Sysmex hematology analyzer verification studies, the Sysmex hematology analyzer's operator's manual, patient records, and interview with facility personnel, the laboratory failed to verify that the manufacturer's reference ranges were appropriate for the patient population prior to putting the instrument into service on July 17, 2018. The findings included: 1. The laboratory placed a Sysmex XN-Series hematology analyzer into service for patient testing on 7/17/2018. In Section 3 of the Method Verification Manual (Document Number 1251-LSS, Rev.2), the manual states the following: "The CAS is to verify that the analyzer meets manufacturer's performance claims by performing the following studies: Reportable Range Study Carryover Study It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation studies (CAS assists) Sensitivity Study (see resource manual) Reference Range Verification (See Resource Manual). 2. Based on review of the Sysmex

	Application Manual (Document Number 1252-LSS, Rev. 2), under Reference Range study, the document states the procedure to follow for verifying reference ranges. The manufacturer provided reference ranges can be found on page 5-17 of the XN-550 /XN-450/XN-350 General Information operator's manual. 3. Based on a random review of patient specimens, the laboratory's in-use reference ranges correlated with the manufacturer provided ranges from page 5-17 of the operator's manual. B. Based on a review of the verification studies performed, the laboratory verified the manufacturer's claims of accuracy, precision, and reportable range. The laboratory did not have documentation of performed the reference range verification study as described in the Application Manual. 4. In an interview at 10:15 hours on 1/31/2019 in the laboratory, the Laboratory Manager stated the laboratory had adopted the manufacturer's reference ranges but had not performed a study to verify the manufacturer's ranges were appropriate prior to performing patient testing on the new Sysmex hematology analyzer. This is a REPEAT deficiency. Citations at 493.1253 Standard: Establishment and verification of performance specifications (D5421) were cited on the previous survey conducted on 6/14/2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the MTS diluent dispenser instructions for use, laboratory maintenance records, and interview with facility personnel, the laboratory failed to accurately perform required weekly maintenance procedures for 2 of 2 repetitive dispensers for of 4 of 4 weekly cleaning events in 2019. The findings included: 1. Based on review of the Ortho MTS Dispenser Repetitive Dispenser of 0.5 or 1.0 mL Instructions for Use (Pub. No. J33098_EN), on page 3 of 5, the document states the following: "Cleaning: The dispenser should be cleaned on a weekly basis as follows: 1. Remove the dispenser from the diluent bottle. Dispense diluent until the outlet line is empty. 2. Rise and decant the inside of the cap with 70 percent Isopropyl Alcohol. 3. Rinse and decant the inside of the cap with copious amounts of deionized or distilled water. 4. Aspirate with 70 percent Isopropyl Alcohol a minimum of 15 times through the dispenser into a waste receptacle. 5. Remove the dispenser from the 70 percent Isopropyl Alcohol solution. 6. Dispense into the waste receptacle the remained 70 percent Isopropyl Alcohol that is left in the tubing until the outlet line is empty. 7. Wipe the inlet tubing with a soft cloth so as not to contaminate the deionized or distilled water with the 70 percent Isopropyl Alcohol solution. 8. Flush the dispenser with freshly drawn deionized or distilled water a minimum of 20 dispenses into a waste receptacle. 9. Remove the dispenser from the deionized or distilled water. 10. Dispense into a waste receptacle the remained water that is left in the tubing until the outlet line is empty. 11. Wipe dry the inlet tubing wand outer dispenser surface with a soft, clean cloth. 12. If ready for use, prime line a minimum of one time, with appropriate diluent to be dispensed. If the dispenser will not be used for a while, store dry." 2. Based on review of laboratory maintenance records "ID-MTS Quality Control Record", MTS Dispenser Weekly Cleaning was documented as being performed on the following dates in 2019: 1/3/2019 1/10/2019 1/16/2019 1/24 /2019 3. In an interview at 13:22 hours on 1/31/2019 in the laboratory, when asked to describe how weekly maintenance was performed on the MTS diluent dispensers, the

	Laboratory Manager stated the outside of the dispenser tube was wiped with an alcohol swab and then followed up with water. In a separate interview at 13:34 hours on 1/31/2019 in the laboratory, Testing Person 4 (as listed on the CMS-209 laboratory personnel report) described the same maintenance procedure as the laboratory manager by stating the testing personnel would wipe the dispenser with an alcohol swab, but did not perform the maintenance procedure as described in the instructions for use.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the K-Check instructions for use, laboratory quality control records, patient testing records, and interview with facility personnel, the laboratory failed to test control materials of a similar matrix as patient specimens for 7 of 7 serum patient specimens for the K- Check serum ketone analysis. The findings included: 1. Based on review of the laboratory's procedure "K-CHECK", adopted 04 /2016, under quality control, the procedure states: "Use known positive and negative controls are recommended by your institutional guidelines. This could vary from daily to weekly quality control. At least a positive and negative control must be run each tie a new bottle of K-Check is opened. A positive control can be prepared by diluting 50 microliters (one drop) of acetone to 40 mL of distilled water. The preparation should be comparable to the "small" on the color chart." The procedure states K-Check is for urine, serum, plasma, or Whole Blood Ketone determination. 2. In an interview at 10: 45 hours on 1/31/2019 in the laboratory, the Lab Manager stated the quality control material use for the serum K-Check reagent was a commercially available urinalysis control and the laboratory did not use a serum control material. 3. Based on a review of the laboratory worksheet "SERUM KETONES" for the month of August 2018, seven (7) of seven patients were tested between 8/24/2018 and 10/29/2018. Quality control was documented each date of patient testing; the quality control used was a Quantimetrix Dipper Urinalysis Dipstick control and not of a similar matrix as serum patient specimens. Date: 8/24/2018 Patient 1 Result: Negative Date: 9/5/2018 Patient 2 Result: Negative Date: 9/9/2018 Patient 3 Result: small Date: 9/12/2018 Patient 4 Result: Negative Date: 10/16/2018 Patient 5 Result: Negative Date: 10/24/2018 Patient 6 Result: Small Date: 10/29/2018 Patient 7 Result: Negative