Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1038709	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Letreise D Winkfield Md	4829 S Jackson Rd, Edinburg, 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	The laboratory was surveyed on October 18, 2018. The facility was not in compliance with the following CLIA Conditions at 42 CFR part 493: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2015 and 2016, and staff interview, it was revealed the laboratory failed to have documentation of rotating proficiency testing among all testing personnel. The findings were: 1. This is a repeat deficiency from the survey dated September 7, 2016. 2. A review of the laboratory's submitted Form CMS-209, signed by the laboratory director on October 16, 2018, revealed the laboratory identified 2 testing personnel. 3. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1 and 2) revealed testing personnel #1 as listed on Form CMS-209 performed proficiency testing for 5 of 5 testing events. 4. An interview with testing personnel one (as listed on Form CMS 209) on 10/18/2018 at 14:30 hours in the physician's office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policies, review of calibration records, review of maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to resolve flags on CBCs prior to their release to the healthcare provider (this is a repeat deficiency). (refer to D5405) 2. The laboratory failed to ensure centrifuge calibrations were performed at the designated times and failed to ensure the centrifuge was calibrated according the laboratory's policy (this is a repeat deficiency). (refer to D5435) 3. The laboratory failed to ensure calibrations on the Abbott Cell-Dyn 1800 hematology analyzer were performed according to manufacturer's instructions. (refer to D5437)
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CELL DYN 1800 System Operator's Manual, random review of patient test records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for assessing flags on hematology results. The findings were: 1. This is a repeat deficiency from the survey dated November 7, 2016. 2. Review of the laboratory's policies revealed a laboratory policy approved by the laboratory director on January 8, 2016 stated: "The director of the laboratory approves the use of the entire contents of the Cell-Dyn System Operator's Manual provided by Abbott Laboratories, as the procedure used for performing all hematology procedures." 3. A review of the CELL DYN 1800 System Operator's Manual (9140390A, March 2003) Section 10 "Troubleshooting and Diagnostics" within the table titled "DATA Problems" listed the following flags and required corrective action(s) to take: LYM R2 Re-run specimen after 20 minutes of collection: redraw if necessary. If flag persists, check stained smear to confirm differential. Check specimen for clots or agglutination. MID R2 or RM Re-run specimen after 20 minutes of collection: redraw if necessary. If flag persists, check stained smear to confirm differential. Check specimen for clots or agglutination. MID R3 or RM Re-run specimen after 20 minutes of collection: redraw if necessary. If flag persists, check stained smear to confirm differential. Check specimen for clots or agglutination. LYM R0 or RM Re-run specimen after 20 minutes of collection: redraw if necessary. If flag persists, check stained smear to confirm differential. Check reagents (See Section 9: Service and Maintenance, Subsection: As-required Maintenance.) Massage and reseat tubing in Lyse Normally Closed Valve. Check specimen for clots or agglutination. LYM R1 Re-run specimen after 20 minutes of collection: redraw if necessary. If flag persists, check stained smear to confirm

	differential. Check specimen for clots or agglutination. 4. A random review of patient test results from October 18, 2018 (the day of the survey) revealed the following patient results with flags. The manufacturer's instructions to resolve flags were not performed. Sequence Number: 107 Flag: R1 Sequence Number: 109 Flag: R1 Sequence Number: 111 Flag: R1 Sequence Number: 114 Flag: R3 Sequence Number: 116 Flag: R3 Sequence Number: 120 Flag: R3 5. An interview with testing personnel one (as listed on Form CMS 209) on 10/18/2018 at 16:00 hours in the physician's office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 surveyor observations, review of laboratory policies, maintenance records, and interview with the facility personnel, the laboratory failed to establish a maintenance protocol to ensure centrifuge performance that is necessary for accurate and reliable in urinalysis testing for 1 of 1 centrifuges. The findings included: 1. This is a repeat deficiency from the survey dated November 7, 2016. 2. At 16:00 hours on 10/18/2018 in the laboratory, the surveyor observed the following 1 of 1 centrifuges used for processing specimens. -The dial used to adjust the speed was in the position marked "Urine." -The centrifuge had a sticker dated "1/17" and "Next Check: 1/18)." -The centrifuge had a sticker labeled "RPM: 3005." 3. The elapsed time since the centrifuge was last checked was approximately 21 months. 4. Review of the laboratory's policy titled, "Urine Microscopy" signed by the laboratory director on July 20, 2016, stated, "4. Centrifuge sample at 1500 rpm for 5 minutes." 5. The speed marked on the sticker failed to ensure the speed matched the laboratory's policy. 6. In an interview at 16:45 hours on 10/18/2018 in the laboratory, Testing Person 1 (as listed on Form CMS 209) confirmed the findings. He stated those were the only records the laboratory had. Key: CMS - Centers for Medicare and Medicaid Services
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 review of the laboratory's policies, review of manufacturer's instructions, review of calibration records for the Abbott Cell-Dyn hematology analyzer, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of the following the manufacturer's instructions for performing calibrations. The findings were: 1. Review of the laboratory's policies revealed a laboratory policy approved by the laboratory director on January 8, 2016 stated: "The director of the laboratory approves the use of the entire contents of the Cell-Dyn System Operator's Manual provided by Abbott Laboratories, as the procedure used for performing all hematology procedures." 2. Review of the manufacturer's instructions for the Abbott Cell-Dyn 1800 hematology analyzer (9140390A, March 2003) under, "Calibration Procedures" it stated, " ...Calibration is indicated following service adjustments (e.g. major component changes.) Calibration is necessary when indicated by the results of Quality Control procedures. Calibration is also required following component replacement, software upgrade, preventative maintenance, or reagent changes ..." 3. Review of the laboratory's calibration records for 2017 revealed calibrations were performed as follows: May 30, 2017 July 6, 2017 August 24, 2017 4. The laboratory failed to have documentation of the data to support performing a calibration for each of the 3 of 3 calibrations in 2017. 5. An interview of testing personnel one (as listed on Form CMS 209) on October 18, 2018 at 16:30 hours in the physician's office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test records, and confirmed in interview of facility personnel, the laboratory failed to ensure normal ranges were available to the ordering healthcare provider. The findings were: 1. Review of patient test reports from July 2018 revealed 5 of 5 patient test results reviewed did not have normal ranges available to the ordering healthcare provider. 2. The laboratory was asked to provide documentation of providing normal ranges to the ordering healthcare provider. No documentation was provided. 3. Interview of testing personnel one (as listed on Form CMS 209) on 10/18/2018 at 16:00 hours in the laboratory director's office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D6054	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 annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of laboratory personnel job descriptions, review of the laboratory's personnel records and confirmed in interview of facility personnel, the technical consultant failed to ensure annual competency assessments were complete for 2 of 2 testing persons in 2017. The findings were: 1. Review of the laboratory's job description, "Technical Consultant Responsibilities" signed by the laboratory director on May 2012, stated, "-Review competency of all testing personnel." 2. Review of the laboratory's personnel records for testing personnel one and testing personnel two (as listed on Form CMS 209) revealed the competency assessments for both testing persons in 2017 had an area for the technical consultant to sign. It stated, "Signature of Person completing the Assessment." The forms for both testing persons was dated, but not signed by the technical consultant. 3. An interview with testing personnel one (as listed on Form CMS 209) on 10/18/2018 at 13:30 hours in the physician's office confirmed the findings. He agreed the forms were not signed by the technical consultant. Key: CMS - Centers for Medicare and Medicaid Services