Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0693957	03/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
West Tennessee Healthcare Henry County Dba West Tn	305 Tyson Avenue, Paris, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, employee personnel records for 2021 and 2022 and the competency assessment form, and interview with the laboratory supervisor, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency and failed to include re-assessment of competency when test methodology changes. The findings include: 1) Review of the laboratory procedure manual revealed the procedure for assessing testing personnel competency did not include evaluation of problem solving skills, monitoring the recording and reporting of test results, review of intermediate test results or worksheets and maintenance records, and did not require re-evaluation of competency when test methodology changes. 2) Review of the 2021 and 2022 testing personnel records and the form used for documenting competency revealed no documentation of, or a process in place, that included blind testing, record review, monitoring of recording and reporting of test results or problem solving skills to be included in competency assessment evaluations. 3) Interview on 03/06/23 at 4:15 p.m. with the laboratory supervisor confirmed the testing personnel competency procedure did not include all six required criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS) and did not include re-assessment of competency when test methods change.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of control manufacturer instructions for use, and interview with the laboratory supervisor, the laboratory failed to label nine of nine controls observed on the date of the survey (03/06/23) with corrected expiration date after the controls were opened or prepared. The findings include: 1. Observation of the laboratory on 03/06/23 at 8:15 a.m. revealed multiple controls in use for performing quality control on the Beckman Coulter DxH520 complete blood count (CBC) instrument (three levels), the Ortho Vitros 350 chemistry instrument (two levels) and the Tosoh A1A900 chemistry/endocrinology instrument - immunoassay-two levels and vitamin D-two levels. All nine controls were labeled with an open date but no corrected expiration date. 2. Review of the control manufacturer package inserts revealed the following: CBC controls for the Coulter DxH520 are to be stored at 2-8 degrees Celsius (C) and are good for 16 days after opening. Performance Verifier I and II used on the Orthos Vitros 350 chemistry instrument as follows: When stored at 2-8 degrees C: Reconstituted Stability 7 days; "Stable for 3 days: ALKP, ALKP(XT), ALT2, ALT2(XT), ALTJ, ASTJ(XT), BuBc, Ca, Ca(XT), CK, TBIL, TBIL (XT)." Immunoassay Plus used on the Tosoh A1A900 instrument for general chemistry and endocrinology quality control revealed the following: "After reconstituting and storing tightly capped at 2 to 8 degrees (C), this product will be stable as follows: -All analytes: 7 days Except -Folate and PSA (Total): 3 days Vitamin D control used on the Tosoh A1A900 revealed the following: The reconstituted control is stable for 1 day at 18-25 degrees C, 14 days at 2-8 degrees C, and 60 days at -20 degrees C. 3. Interview with the laboratory supervisor on 03/06 /23 at 4:15 pm confirmed the laboratory controls in use had expiration dates that changed after opening or reconstitution and the laboratory failed to label the controls with the corrected expiration dates on the date of the survey (03/06/23) for nine of nine controls observed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control

	materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer instructions for use, calibration verification records and interview with the laboratory supervisor, the laboratory failed to perform calibration verification for the Prostate Specific Antigen (PSA) at least every six months in 2021 for two of six calibration verification records reviewed. The findings include: 1. Review of the manufacturer instructions for use for PSA performed on the Tosoh A1A900 revealed that calibration is performed using two points. 2. Review of calibration verification records revealed that calibration verification for the PSA was not performed at least every six months in 2021 as follows: Calibration verification was performed August 25, 2020 and was not performed again until March 22, 2021 (six month requirement not met). Calibration verification was performed March 22, 2021 and was not performed again until November 19, 2021 (six month requirement not met) 3. Interview with the laboratory supervisor on 03/06/23 at 4:15 p.m. confirmed the laboratory failed to performed calibration verification for the PSA analyte at least every six months in 2021 (two of six calibration verification records reviewed.)
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of a patient report, lack of documentation and interview with the laboratory supervisor, the laboratory failed to compare results between the automated White Blood Cell (WBC) differential and the manual WBC differential in 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 03/06/23 at 8:15 a.m. revealed a Beckman Coulter DxH 520 instrument on the counter in use for performing patient testing for CBC with automated WBC differential and a microscope used for performing manual WBC differentials. 2. Review of patient 62172 performed on 02/02/23 revealed both an automated WBC differential and a manual WBC differential performed on the same patient. 3. There was no documentation of comparison studies to evaluate the results obtained between the automated WBC differential and the manual WBC differential from 2021, 2022 and 2023. 3. Interview with the laboratory supervisor on 03/06/23 at 4:15 p.m. confirmed the laboratory did not perform comparisons between the automated WBC differential and the manual WBC differential in 2021, 2022, and 2023.