Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0693957	06/14/2024
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory quality control records, lack of records, and staff interviews the laboratory failed to retain manufacturer quality control (QC) package inserts for the DXH instrument used for complete blood count (CBC) and QC ranges provided by TOSOH for the TOSOH AIA 900 instrument used for patient chemistry and endocrinology testing for two years in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/14/2024 at 9: 30 am revealed a Beckman Coulter DXH 500 instrument (Serial # BD050395) used for CBC patient testing and a TOSOH AIA 900 instrument (Serial #10895907) for chemistry and endocrinology patient testing. 2. A review of the laboratory's quality control records revealed the following: CBC control lots 352315311, 362315312, 372315313 used on 10/23/2023; CBC control lots 352415911, 362415912, 372415913 used on 04/25/2024. Chemistry/Endocrinology controls for the TOSOH AIA 900 TOSOH Vitamin D Control lot 124B761 used on 10/23/2023. 3. The laboratory was unable to provide the following: Manufacturer QC package inserts for the Coulter DXH lots 352315311, 362315312, 372315313, 352415911, 362415912, 372415913. Manufacturer QC ranges provided by TOSOH for Vitamin D for lot 124B761. 4. An interview on 06/14/2024 at 3:00 pm with the technical consultant confirmed the survey findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, laboratory policy, and staff interviews, the laboratory failed to define temperature ranges that were consistent with manufacturer requirements for frozen storage of BioRad quality control (QC) materials used on the TOSOH AIA 900 instrument in 2023 and 2024. This resulted in the BioRad QC material being stored in a way that did not meet the manufacturer's requirements. The findings include: 1. Observation of the laboratory on 06/14/2024 at 9:30 am revealed a freezer used to store aliquots of the BioRad QC (Lyphocheck Immunoassay Plus Control) for the TOSOH AIA 900 instrument (Serial #10895907) used for performing chemistry and endocrinology testing. 2. A review of the manufacturer's package inserts for the BioRad QC Lyphocheck Immunoassay Plus Control revealed the storage requirements were -20 degrees () Celsius (C) to -70C when stored frozen. 3. A review of the laboratory policy titled " Quality Control" section "QC Material Storage and Stability" revealed reconstituted aliquots of QC were stored at -10C to -20C. 4. The survey findings were confirmed in an interview with the technical consultant and testing person one on 06 /14/2024 at 1:00 pm.
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 and staff interview the laboratory failed to label coplin jars that were used to stain patient slides for manual differential in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/14/2024 at 9: 30 am revealed four coplin jars on the counter. The jars were not labeled with identity, preparation date, expiration date, or strorage requirements. During the observation testing person one and the technical consultant stated the coplin jars contained stain poured from primary containers and were used to stain patient slides for manual differential. 2. An interview on 06/14/2024 at 3:00 pm with the technical consultant confirmed the survey findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interview the laboratory used QuickLink III Solution II stain after the manufacturer expiration date in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/14/2024 at 9:30 am revealed QuickLink III Solution II stain (lot #1343) stored in the laboratory with an expiration date of 10/18/2023. During the observation testing person one and the technical consultant stated the expired Solution II was used to stain patient slides for manual differential. 2. An interview on 06/14/2024 at 3:00 pm with the technical consultant confirmed the laboratory used expired Solution II in 2023 and 2024.