Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2071889	04/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
West Cancer Center	1727 Kirby Pkwy Ste 100, Memphis, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the laboratory director, the testing person and laboratory director failed to sign attestation statements for two of twelve proficiency testing events in 2020 and 2022. The findings include: 1. Review of the laboratory's proficiency testing records revealed the attestation statements for 2020 hematology event three and 2022 core chemistry event one were not signed by the lab director or testing person. 2. Interview with the lab director on 04/05/22 at approximately 5 p.m. confirmed the lab director and testing person failed to sign attestation statement for two of twelve PT events in 2020 and 2022.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS

	may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory participation in two of three proficiency testing events for the aspartate aminotransferase (AST) analyte (Refer to D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Casper report 155, the laboratory's 2021 and 2022 proficiency testing (PT) performance evaluation reports, and interview with the laboratory director, the laboratory failed to maintain satisfactory performance for the aspartate aminotransferase (AST) analyte for two of three PT events resulting in the first unsuccessful PT occurrence for the AST analyte. The findings include: 1. Review of the CMS Casper report 155 revealed a score of 60% for the AST analyte for 2021 event two and 2022 event one. 2. Review of the laboratory's 2021 and 2022 PT performance evaluation reports revealed the following: 2021 event two: Sample numbers CH-06 and CH-09 scored as unacceptable resulting in an overall score of 60% for the AST analyte. 2022 event one: Sample numbers CH-04 and CH-05 scored as unacceptable resulting in an overall score of 60% for the AST analyte and the first unsuccessful PT occurrence. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to maintain satisfactory participation in PT for the AST analyte in two of three PT events.
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 review of laboratory records and interview with the laboratory director, the laboratory failed to retain 15 of 27 quality control assay range package inserts for two years in 2022. The findings include: 1. Review of laboratory records revealed the following quality control assay range package inserts were not retained: 15991, 15992, 15993 (chemistry controls) in use on 08/27/20 1351 (Levels 1, 2, and 3) (Complete Blood Count (CBC) QC) in use on 01/20/22 1015 (Levels 1, 2, and 3)

	(CBC QC) in use on 03/08/21 1183 (Levels 1, 2, and 3) (CBC QC) in use on 09/22/21 0297 (Levels 1, 2, and 3) (CBC QC) in use on 11/17/20 2. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to retain quality control assay limit package inserts for two years (15 of 27 lots) reviewed.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to evaluate non-graded proficiency testing (PT) scores for unregulated analytes (Refer to D5213), failed to evaluate non-graded PT scores for regulated analytes (Refer to D5215), failed to verify the accuracy of unregulated analytes twice a year (Refer to D5217), and failed to follow the quality assessment plan for performing corrective action for unacceptable and unsatisfactory proficiency testing results (Refer to D5291).
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to evaluate non-graded PT scores for cholinesterase in 2021 (three of three test events/15 of 15 PT results). The findings include: 1. Review of the laboratory PT records revealed the following: 2021 Chemistry-Core-1st Event: Cholinesterase results scored as "Not Graded" for CH-01, CH-02, CH-03, CH-04, CH-05. 2021 Chemistry-Core-2nd Event: Cholinesterase results scored as "Not Graded" for CH-06, CH-07, CH-08, CH-09, CH-10. 2021 Chemistry-Core-3rd Event: Cholinesterase results scored as "Not Graded" for CH-11, CH-12, CH-13, CH-14, CH-15. None of the results had been evaluated to determine the accuracy of the results. 2. Interview with the lab director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to evaluate non-graded PT scores for accuracy for the cholinesterase test in 2021 for all three test events / 15 of 15 PT results).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to evaluate non-graded PT results for 2021 Event One for Alanine aminotransferase (ALT). The findings include: 1. Review of the laboratory's PT performance evaluation reports revealed the following un-graded scores that were not evaluated to determine accuracy: 2021 Chemistry-Core-1st Event-- ALT 2. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to evaluate the accuracy of non-graded proficiency testing results for 2021 Chemistry-1st event for ALT.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of patient test records, the laboratory's proficiency testing (PT) records, and staff interview, the laboratory director failed to verify the accuracy of unregulated analytes twice a year in 2021. The findings include: 1. Review of patient test records revealed the laboratory began patient testing for quantitative Rheumatoid Arthritis Factor (RA) (patient account number 863) on 04/27/21, and Hepatitis C Antibody (Anti-HCV) on 12/14/20 (patient chart # 460203). 2. Review of the laboratory's proficiency testing records revealed no participation in proficiency testing for 2021 event one or 2021 event two for the Anti-HCV. No participation in 2021 event two for RA. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. revealed the laboratory participates in proficiency testing to verify the accuracy of its' tests. The lab director confirmed the laboratory failed to verify the accuracy of the Anti-HCV and quantitative RA test twice a year in 2021.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, proficiency testing records and staff interview, the laboratory failed to follow the quality assessment plan for corrective action for unacceptable and unsatisfactory proficiency testing results in 2021 and 2022. The findings include: 1. Review of the laboratory's quality assessment plan under the section for proficiency testing revealed the following statements: "The director will evaluate any unacceptable or unsatisfactory test results in order to identify the cause of failure." "The results of our proficiency testing will be evaluated by the laboratory director within one month." 2. Review of the laboratory's

	proficiency testing records revealed the following: 2021 Chemistry-Core-1st Event: Direct Bilirubin sample number CH-04 scored as unacceptable with no corrective action performed, calculated Low Density Lipoprotein (LDL) cholesterol scored as unacceptable with no corrective action performed, 25-OH Vitamin D scored as unacceptable with no corrective action performed. 2021 Chemistry-Core-2nd Event: aspartate aminotransferase (AST) with an unsatisfactory score of 60% with no corrective action performed. 2021 Chemistry-Core-3rd Event: AST sample number CH-13 scored as unacceptable with no corrective action performed. 2022 Chemistry-Core-1st Event: AST with an unsatisfactory score of 60% with a comment of "results were wrong" with no corrective action performed. Total Protein unacceptable result for sample CH-03 with a comment of "results were wrong" with no corrective action performed. 2021 Hematology-2nd Event had not been reviewed by the laboratory director. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to follow the quality assurance policy as it relates to proficiency testing and investigation of unacceptable and unsatisfactory results in 2021 and 2022.
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: The laboratory procedures were not approved by the laboratory director (Refer to D5407) and the laboratory failed to follow the analytic quality assessment policy /procedure (Refer to D5791).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure manual, and staff interview, the laboratory director failed to approve, sign and date laboratory procedures. The findings include: 1. Observation of the laboratory on 04/05/22 at approximately 10 a.m. revealed the following moderately complex test systems in use for patient testing: Sysmex XN 550 (serial # 19081) for complete blood count Ortho Vitros 7600 (serial # 76000410) for general chemistry, endocrinology and immunology Ortho Vitros ECI (serial number J30005654) for general chemistry, endocrinology and immunology 2. Review of the laboratory's procedure manual revealed no signature or date indicating approval by the laboratory director. 3. Interview with the lab director on 04/05/22 at approximately 5 p.m. confirmed the laboratory's procedures had not been signed, dated, and approved by the laboratory director.

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: Based on observation of the laboratory, laboratory validation studies, and interview with the laboratory director, the laboratory failed to verify manufacturer normal values were appropriate for its' patient population in 2020 (three of three instrument platforms). The findings include: 1. Observation of the laboratory on 04/05/22 at approximately 10 a.m. revealed the following moderately complex test systems in use for patient testing: Sysmex XN 550 (serial # 19081) for complete blood count Ortho Vitros 7600 (serial # 76000410) for general chemistry, endocrinology and immunology Ortho Vitros ECI (serial number J30005654) for general chemistry, endocrinology and immunology 2. Review of the validation studies performed for each of the three instruments revealed no documentation that the patient normal range had been verified. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. revealed the following: Patient testing on the instrument platforms began in 2020. The laboratory uses the manufacturer normal range for its' patient normal range. The laboratory had not verified the manufacturer normal range for use in its' patient population. The laboratory director confirmed the laboratory had not verified the manufacturer normal range for three of three test platforms in 2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, requests for documentation, and staff interview, the laboratory failed to follow established policies and procedures for review of quality control in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's quality assessment and quality control plan revealed the following: "Quality control forms in the laboratory should include the date, initials of the person performing the test, lot number of controls, acceptable range, control results, and comments. The QC forms should be intitialed and dated to indicate they have been reviewed by the laboratory director." "Quality control results will be reviewed by the laboratory director periodically throughout the month. For documentation, the quality control results and Levy-Jennings charts will be printed and kept monthly and kept for 2 years." The quality control section for the Sysmex XN550 revealed the following: "The following reports should be reviewed at regular intervals according to the laboratory's policy: Insight Report, Detailed Daily Verification Report, and

	Continuous Calibration Verification Certificate." "The supervisor reviews the following QC reports at the following intervals:" Monthly-Insight, exception and summary reports; Every 3 months-continuous calibration verification certificate, calibration certifications-each calibration performed, quarterly: detailed daily verification report, parameter report, traceability report. 2. Request on 04/05/22 at approximately 4:00 p.m. for documentation of laboratory director quality control reviews revealed no documentation was present. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory failed to follow its' own quality assessment and quality control plan when it did not document review of quality assessment activities including quality control. The laboratory began patient testing in 2020 until current date.
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: Based on observation of the laboratory, review of validation studies, and interview with the laboratory director, the laboratory director failed to review and approve validation studies for the Sysmex XN550 complete blood count instrument and the Ortho Vitros ECI chemistry, endocrinology and immunology instrument in 2020 (two of three instrument platforms). The findings include: 1. Observation of the laboratory on 04/05/22 at approximately 10 a.m. revealed the following moderately complex test systems in use for patient testing: Sysmex XN 550 (serial # 19081) for complete blood count Ortho Vitros 7600 (serial # 76000410) for general chemistry, endocrinology and immunology Ortho Vitros ECI (serial number J30005654) for general chemistry, endocrinology, and immunology 2. Review of the validation studies for the Sysmex XN550 and Ortho Vitros ECI revealed the studies had not been reviewed or approved by the laboratory director. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the validation studies for two of three test systems (Sysmex XN550 and Ortho Vitros ECI) has not been reviewed or approved by the laboratory director. The laboratory began testing on the instruments in 2020.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by:

	Based on review of patient test records, the laboratory's proficiency testing (PT) records, and staff interview, the laboratory director failed to ensure enrollment in PT for regulated analytes in 2021 (events one and two). The findings include: 1. Review of patient test records revealed the laboratory began patient testing for Human Immunodeficiency Virus (HIV) on 12/14/20, and testing for Hepatitis B Surface Antigen, Hepatitis B Core IgM antibody and Hepatitis A IgM antibody (patient chart # 471379) on 12/15/20. 2. Review of the laboratory's proficiency testing records revealed no enrollment or participation in proficiency testing for 2021 event one or 2021 event two for the HIV, Hepatitis B Surface Ag, Hepatitis B Core IgM antibody and Hepatitis A IgM antibody. 3. Interview with the laboratory director on 04/05/22 at approximately 5 p.m. confirmed the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for regulated analytes in 2021.