Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315440	12/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
West Tn Univ Med Associates	294 Summar Dr, Jackson, 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
D0000	During a Proficiency Testing (PT) desk review survey conducted on 12/18/24, the laboratory was found out of compliance with the following CONDITIONS: 493.803 Condition: Successful participation 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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: Based on surveyor proficiency testing (PT) desk review, a review of the Centers for Medicare and Medicaid Services (CMS) Casper report 0155D (CMS 155), the laboratory's 2024 AAB-Medical Laboratory Evaluation (AAB-MLE) PT records and electronic mail (email) communication with the AAB-MLE PT program Assistant

	Technical Director, the laboratory failed to successfully participate in PT in the specialty of Hematology for the analyte White Blood Cell (WBC) Differential. The laboratory had unsatisfactory scores for 2024 Events One, Two, and Three, resulting in non-initial unsuccessful PT participation. Refer to D2130
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor PT desk review, a review of the CMS 155, the laboratory's 2024 PT records, and email communication with the AAB-MLE PT Assistant Technical Director, the laboratory failed to successfully participate in PT for the analyte White Blood Cell (WBC) Differential (WBC DIFF). The laboratory had unsatisfactory scores for 2024 Event One, 2024 Event Two, and 2024 Event Three, resulting in non-initial unsuccessful PT participation. The findings include: 1. A review of the CMS 155 revealed the following for the WBC Differential: 2024 Event One-No scores reported 2024 Event Two=8% 2024 Event Three=24% 2. A review of the laboratory's AAB-MLE PT records revealed the following for the WBC Differential: 2024 Event One: The laboratory failed to submit results for the PT Event. 2024 Event Two Cumulative Report: An overall score of 8% for the WBC Differential. 2024 Event Three Cumulative Report: An overall score of 24% for the WBC Differential for Event Three. Cumulative scores of 0% for 2024 Event One, 8% for 2024 Event Two, 24% for 2024 Event Three. 3. A review of the laboratory's 2024 Event Three PT records revealed that the reporting deadline was 09/27/24. 4. A review of the Allegation of Compliance submitted on 11/25/24 for the initial unsuccessful PT occurrence revealed that the cause of the failures for 2024 Events One and Two was not identified in a timely manner, resulting in failures for the analyte WBC Differential for 2024 Event Three. Corrective action for performance of the PT samples in the quality control (QC) mode was not performed until 10/04/24 (after the submission deadline for 2024 Event Three). 5. Email communication from the AAB-MLE PT program Assistant Technical Director, received on 12/18/24 at 10:36 a.m., confirmed the laboratory failed to confirm enrollment for 2024 and failed to submit results for 2024 Event One.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor PT desk review, a review of the CMS 155, the laboratory's AAB-MLE PT records, email communication with the AAB-MLE PT program Assistant Technical Director, and the previous Allegation of Compliance submitted in response to the initial unsuccessful PT events, the laboratory director failed to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT for the analyte WBC differential, resulting in non-

	initial unsuccessful PT occurrence (Refer to D6016) and failed to ensure corrective actions were effective in identifying and preventing future occurrences of unsuccessful PT (Refer to D6019).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor PT desk review, a review of the CMS 155, the laboratory's 2024 PT records, and email communication with theAAB-MLE PT program Assistant Technical Director, the laboratory director failed to ensure the laboratory maintained successful PT performance for the analyte WBC Differential for 2024 Events One, Two and Three, resulting in non-initial unsuccessful PT participation. The findings include: 1. A review of the CMS 155 revealed the following for the analyte WBC Differential: 2024 Event One-No scores reported 2024 Event Two=8% 2024 Event Three=24% 2. A review of the laboratory's AAB/MLE proficiency testing records revealed the following for the analyte WBC Differential: 2024 Event One: The laboratory failed to submit results for the PT Event 2024 Event Two Cumulative Report: An overall score of 8% for the WBC Differential. 2024 Event Three Cumulative Report: An overall score of 24% for the WBC Differential for Event Three. Cumulative scores of 0% for 2024 Event One, 8% for 2024 Event Two, 24% for 2024 Event Three. 3. Email communication from the AAB-MLE PT program Assistant Technical Director, received on 12/18/24 at 10:36 a.m., confirmed the laboratory failed to confirm enrollment and failed to submit results for 2024 Event One.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor PT desk review and a review of the Allegation of Compliance submitted by the laboratory on 11/25/24 for the initial unsuccessful PT, the laboratory director failed to ensure an approved corrective action plan was followed when PT results were found to be unacceptable due to failure to participate in 2024 Event One and to participate successfully in 2024 Events Two and Three. Refer to D2130