

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0315440	<b>(X3) Date Survey Completed</b>  09/25/2023
<b>Name of Provider or Supplier</b>  West Tn Univ Med Associates	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, laboratory procedure manual, testing personnel (TP) records, and staff interview, the laboratory failed to follow its' own policy for testing personnel (TP) assessment when the laboratory began using a new Complete Blood Count (CBC) instrument for patient testing in 2023. The findings include: 1. Observation of the laboratory on 09/26/2023 at 9:10 am revealed a Sysmex XN 330 (serial # 15879) in use for CBC patient testing (new since last survey). 2. Review of patient test reports revealed the first patient CBC for the new Sysmex XN 330 was reported on 07/25/2023 (ID # 200013887). 3. Review of the laboratory policy titled "QUALITY ASSURANCE PROGRAM" section "PERSONNEL" revealed personnel are evaluated initially, at six months, and annually. Policy further stated "Personnel will also be evaluated following the same timeline whenever new tests or methodologies are introduced." 4. Review of TP records revealed that none of the three TP had evaluation of competency for use of the Sysmex XN 330 CBC instrument prior to patient testing which began on 07/25/2023. 5. Interview on 09/25/2023 at 12:30 pm with the Laboratory Director and TP three confirmed the laboratory failed to follow its' own TP policy when it did not perform TP competency assessment prior to patient testing when the methodology for CBC changed in 2023.</p>