

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2176164	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Vanderbilt University Medical Center DbA	Street Address, City, State 64 Belinda Parkway, Suite 200, Mount Juliet, 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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, the laboratory's quality control records and interview with the technical consultant, the laboratory failed to maintain records that identified the testing personnel who performed complete blood count (CBC) quality control testing from the date patient testing began on 02/22/2022 until the date of the survey on 08/10/2022. The findings include: 1. Observation of the laboratory on August 10, 2022 at 8 am revealed the Sysmex XN-330 in use for performing patient testing for CBC. 2. Review of patient test records revealed patient testing began on 02/22/2020. 3. Review of the laboratory's quality control records for the dates of 02/22/2020, 08/17/2020, 05/21/2021, 02/21/2022, and 06/16/2022, when patient testing was performed revealed the identity of the person who performed the quality control testing could not be determined. 4. Interview with the technical consultant on August 10, 2022 at 11 am confirmed the laboratory failed to identify the person who performed quality control testing for five of five selected dates in 2020, 2021 and 2022. She further confirmed the laboratory did not have a process in place to identify the person who performed CBC quality control from the first date of patient testing on 02/22/2020 until the date of the survey on 08/10/2022.</p>