

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0694761	(X3) Date Survey Completed 05/04/2022
Name of Provider or Supplier Christian Family Medicine, Inc	Street Address, City, State 656 Kimberly Dr, Henderson, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of the laboratory procedure manual, testing personnel records, patient test reports and interview with the laboratory liaison, the laboratory failed to follow testing personnel policies when testing personnel number five performed patient testing for complete blood count (CBC) without any documented training or competency performed by the technical consultant in 2022. The findings include: 1. Review of the laboratory's personnel policy titled "COMPETENCY ASSESSMENT" revealed the following statement: "As part of their training, new testing personnel should review the policies and procedures. The current testing personnel may explain pm, QC, and routine testing of samples on the instruments and allow the new person to observe. However, no testing personnel may perform the actual duties until the technical consultant has discussed CLIA regulations and has assessed the competency of the personnel to operate and maintain any instrument or perform any actual testing." 2. Review of testing personnel records for testing personnel number five revealed the following: Testing personnel name, date of hire=March 28, 2022, training and competency assessment done 04/12/2022 by the lead testing person who is not the technical consultant. 3. Review of patient number six final patient test report for CBC revealed the CBC was performed by testing personnel number five on 05/04/2022. 4. Interview with the laboratory liaison on 05/04/2022 at 1:00 pm confirmed the laboratory failed to follow it's own testing personnel policies when testing person number five performed patient testing with no documentation that the technical consultant had performed training or competency assessment.</p>

D5787

TEST RECORDS

CFR(s): 493.1283(a)

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).

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test records and quality control records, and interview with the laboratory liaison, the laboratory failed to have a system in place to identify the person performing quality control for the Sysmex XN-330 complete blood count (CBC) instrument from 09/07/2021 until 05/04/2022. The findings include: 1. Observation of the laboratory on 05/04/2022 at 8:15 am revealed the Sysmex XN-330 CBC instrument (serial #13433) in use for patient testing. 2. Review of patient test records for patient number one revealed the first patient CBC was reported on 09/07/2021. 3. Review of the laboratory's quality control records beginning 09/07/2021 until the survey date revealed no indication of who performed the quality control testing (Lot numbers reviewed include 1183, 1267, 1351, and 2070). 4. Interview with the laboratory liaison on 05/04/2022 at 12:15 pm confirmed the laboratory was not able to identify the person performing the quality control testing since patient testing began on 09/07/2021 until the date of the survey on 05/04/22.