| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0313772 | 08/05/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Church Health Center Of Memphis, Inc | 1350 Concourse Ave Ste 142, Floors 1 & 2, 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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual and interview with the nurse manager, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory quality assessment procedure related to testing personnel competency assessment revealed that methods used for assessing competency were not defined. The following following six criteria were not included in the procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Interview on August 5, 2021 at 4:00 pm with the nurse manager confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS). |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must |

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| | have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Citation Number One: Based on observation of the laboratory, review of laboratory records, and interview with testing personnel, the laboratory failed to perform instrument to instrument comparisons twice a year for complete blood count (CBC) instruments in 2019 and 2020. The findings include: 1. Observation of the laboratory areas on August 5, 2021 at approximately 9:00 am revealed two Beckman Coulter AcT Diff instruments in use for patient CBC testing (1st floor lab, System ID 2888238; 2nd floor lab, System ID 5615165). 2. Review of laboratory records revealed that instrument:instrument comparisons were not performed twice a year in 2019 and 2020. 3. Interview with the 1st floor lead testing person on August 5, 2021 at approximately 4:00 pm confirmed the laboratory did not perform twice a year comparisons between the two CBC instruments in 2019 and 2020. Citation Number Two: Based on observation of the laboratory, review of laboratory records, and interview with testing personnel, the laboratory failed to define criteria for acceptable difference in complete blood count (CBC) instruments in 2018, 2019, 2020 and 2021. 1. Observation of the laboratory areas on August 5, 2021 at approximately 9:00 am revealed two Beckman Coulter AcT Diff instruments in use for patient CBC testing (1st floor lab, System ID 2888238; 2nd floor lab, System ID 5615165). 2. Review of the laboratory procedure manual and the CBC instrument to instrument comparisons that were performed in 2018, 2019, 2020 and 2021 (six of six comparisons), revealed that no criteria was defined for acceptable difference between the two instruments. 3. Interview with the 1st floor lead testing person on August 5, 2021 at approximately 4: 00 pm confirmed the CBC instrument to instrument comparisons that were performed in 2018, 2019, 2020 and 2021 (six of six) did not include any defined criteria for acceptable difference between the two instruments. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of patient orders and test reports, and interview with the nurse manager, the laboratory failed to have a system in place for ensuring patient test results for wet prep, potassium hydroxide and complete blood count (CBC) are accurately entered into the final patient test report. The finding include: 1. Observation of the laboratory areas on August 5, 2021 at approximately 9 a. m. revealed a microscope in use for performing wet prep and potassium hydroxide (KOH) testing (provider performed), and Beckman Coulter AcT Diff instruments in use for performing CBCs. 2. Review of wet prep/KOH provider orders and test |

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| | reports from 2019, 2020 and 2021 revealed that the results for one of three patients for wet prep/KOH were not recorded in the final patient report destination (Patient number three, date of service 04.13.2021). 3. Interview with the nurse manager on August 5, 2021 at approximately 4 p.m. confirmed the laboratory does not have a process in place for ensuring patient test results are accurately entered into the final report destination for either the wet prep/KOH or CBC in 2021, resulting in laboratory tests for wet prep/KOH being ordered, but not resulted. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of employee competency assessment records and interview with the nurse manager, the technical consultant failed to perform competency assessments in 2019, 2020 and 2021 for 15 of 27 competency assessments performed. The findings include: 1. Review of testing personnel competency assessment records revealed that 15 of 27 competency assessments for 11 personnel who perform complete blood count (CBC) patient testing were not performed by the technical consultant. 2. Interview with the nurse manager on August 5, 2021 at approximately 4 pm confirmed that the technical consultant failed to perform competency assessments for personnel who perform complete blood count testing (15 of 27 competency assessments reviewed) in 2019, 2020 and 2021. |