| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0314705 | 07/14/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Consolidated Medical Practices Of Memphis, Pllc | 6799 Great Oaks Rd Suite 120, 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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| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory observation, a review of patient Complete Blood Count with automated White Blood Cell differential (CBC w/Diff) test records, a review of the Beckman Coulter DxH 900 instructions for use, a review of the laboratory procedure manual, and staff interview, the laboratory procedure for CBC w/Diff failed to include instructions for resolving issues with patient CBC w/Diff results that were flagged by the instrument for two of two patients with flagged results performed on 07/14/25. The findings include: 1. Laboratory observation on 07/14/25 at 9:00 a.m. revealed two Beckman Coulter DxH 900 instruments used for performing patient testing for CBC w /Diff. 2. A review of two patient CBC w/Diff records with instrument flags reported on 07/14/25 revealed the following: The instrument printout for patient specimen accession number 2100243 revealed "R" flags on all WBC differential parameters, with "Suspect RBC Frag/Micro" and "System High Event Rate: D." A review of the final patient test report revealed that the flags and instrument messages did not cross the interface to the final patient test report, and there was no documented review or corrective action for the flagged results. The instrument printout for patient specimen accession number 2100293 revealed "R" flag on the Platelet and MPV parameters and instrument messages of "Suspect RBC Frag/Micro" and "System RBC-PLT Overlap." A review of the final patient test report revealed the flags and instrument messages did not cross the interface to the final patient report, and there was no documented review or corrective action for the flagged results. 3. A review of the Beckman Coulter manufacturer's instructions for use revealed the following: "The DxH 900 System |

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| | Manager includes Flags, Codes, and Messages to alert you to issues with patient or control results." "Suspect messages are generated by internal algorithms to convey that a clinical condition may exist with a specimen based on an abnormal cell distribution or population." "All system messages are accompanied by R (Review) flags. Exceptions are the system messages associated with an Aspiration Error (P flag) and the Non-blood Specimen message (N flag). A system message indicates an event occurrence that may affect the operation of the system or quality of the results, or requires operator intervention." "CAUTION Risk of erroneous results." "Beckman Coulter recommends a slide review per your laboratory protocol." "Beckman Coulter recommends the review of results displaying a suspect message appropriate to your patient population and laboratory practice." Table 6.1 titled "Result Flags" listed the following for the "R" flag. "Review the result. "R flags may also indicate a System Message has occurred." Table 6.3 titled "Suspect Messages" revealed the following for RBC Frag/Micro: The specimen may contain red cell fragments and/or some microcytic red cells." Table 6.4, titled "System Messages," revealed the following for the System High Event Rate: D message: "High data event acquisition rate during Diff analysis." The RBC-PLT Overlap system message stated the possible cause was "Interference with larger platelets; may occur with the giant Platelet Suspect message." Other "Suspect Messages" included in Table 6.3 were Abnormal Hemoglobin, Cellular Interference, Dimorphic Reds, Giant Platelets, Immature Granulocytes, Left Shift, Lymphocyte, Monocyte and Neutrophil Blasts, Nucleated Red Blood Cells, Red Cell Agglutination, Sickled Cells, and Variant Lymphocytes. Table 6.4 titled "System Messages" contained approximately 67 messages that could occur with a CBC w/Diff analysis and potentially affect the final patient test results. 4. A review of the laboratory procedure for CBC w/Diff revealed that it did not include instructions for actions to take when the instrument flagged CBC w/Diff results. 5. The technical consultant confirmed the survey findings during interview on 07/14/25 at 4:00 p.m. Word Key: Frag=Fragment MPV=Mean Platelet Volume R=Review RBC=Red Blood Cell PLT=Platelet |