

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0984680	(X3) Date Survey Completed 05/23/2022
Name of Provider or Supplier Family Medical Center	Street Address, City, State 1121 Neo Loop, Grove, OK	
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
D0000	The recertification survey was performed on 05/23/2022. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing for five of six patient reports. Findings include: (1) On 05/23/2022 at 10:00 am, the technical consultant stated the following: (a) CBC testing was performed on the Medonic M-Series hematology analyzer. (2) The surveyor reviewed the written procedures titled, "Medonic Flagged Results Policy", which stated: (a) "WBC Differential results may be flagged BD, NM, OM, and TM If the patient sample is flagged the sample is held for 5-10 minutes and the test repeated. If the flags have been removed or are still present in the same location the results are reported. At the physician's discretion the sample may be referred for further testing." (b) "If the sample volume is not sufficient for repeat analysis, another sample can be drawn OR the flagged result may not be reported in LabDaq and, if paper printouts are reviewed by the provider, the flagged results must be blacked out completely." (3) The surveyor reviewed six patient records that had been tested between 02/08/22 through 02/11/2022. For five of six patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient reported on 02/08/2022 at 09:41 am - No evidence the provider reviewed the OM flag; (b) Patient</p>

reported on 02/09/2022 at 11:27 am - No evidence the provider reviewed the BD flag; (c) Patient reported on 02/09/2022 at 12:00 pm - No evidence the provider reviewed the BD flag; (d) Patient reported on 02/09/2022 at 05:29 pm - No evidence the provider reviewed the TM flag; (e) Patient reported on 02/22/2022 at 09:52 am - No evidence the provider reviewed the OM flag; (3) The surveyor reviewed the findings with the technical consultant who stated on 05/23/22 at 10:47 am that the procedure had not been followed as indicated above.