Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2106196	10/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
My Family Healthcare, Llc	1708 Delivery Lane, Durant, 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 10/02/2020. The findings were reviewed with the technical consultant and clinic manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. 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 CBC quality control procedures for 3 of 6 days; and failed to follow the written policy for verifying flagged results for 2 of 3 patient records. Findings include: QUALITY CONTROL (1) On 10/02/2020 at 10:00 am, the technical consultant stated to the surveyors CBC (Complete Blood Count) was performed on the Medonic M-Series analyzer; (2) Surveyor #2 reviewed written QC procedure titled, "QUALITY CONTROL GUIDELINES" which stated, (a) "7.1 3 levels of Quality Control (QC) materials should be tested in both modes each day of patient testing prior to testing patient samples." (b) "7.2 The QC material used for the Medonic M-Series is the CDS Boule Con-Diff, provided in 3 levels (Low, Normal, and High)." (c) "7.3 QC may be analyzed via any of the sample modes. At this facility, all 3 levels of QC will be performed in the Open Tube/Closed Tube AND the Micro Capillary mode each day of patient testing. The Micro Capillary mode utilizes the Micro Pipette Assembly (MPA)." (d) "7.4 Results of QC testing must be acceptable for two of the three levels tested before patient test results can be reported." (3) Surveyor #2 reviewed 6 days of QC records between 09/02/2020 and 09/11/2020. For 3 of 6 days QC records there

	was no indication the laboratory staff followed their written procedure as follows: (a) MC (Micro Capillary) QC on 09/08/2020 (i) QC Low Control (lot# 2200521) tested at 09:50 am failed (aa) RBC (Red Blood Cell) (ii) QC Normal Control (lot# 2200522) tested at 09:46 am failed (aa) RBC (bb) Hematocrit (cc) Hemoglobin (dd) WBC (White Blood Cell) (ee) Platelets (iii) 6 patients test results were reported with 1 level of MC QC within acceptable range (aa) Patient tested at 11:52 am (bb) Patient tested at 12:59 pm (cc) Patient tested at 02:11 pm (dd) Patient tested at 03:56 pm (ee) Patient tested at 04:27 pm (ff) Patient tested at 04:32 pm (b) MC QC on 09/10/2020 (i) QC Low Control (lot# 2200521) tested at 09:24 am failed (aa) RBC (ii) QC High Control (lot# 220053) tested at 09:25 am failed (aa) Hemoglobin (iii) 6 patients test results were reported with 1 level of MC QC within acceptable range (aa) Patient tested at 09: 36 am (bb) Patient tested at 10:55 am (cc) Patient tested at 12:50 pm (dd) Patient tested at 02:15 pm (ee) Patient tested at 02:48 pm (ff) Patient tested at 02:53 pm (c) MC QC on 09/11/2020 (i) QC Low Control (lot# 2200521) tested at 10:02 am failed (aa) RBC (ii) QC Normal Control (lot# 220052) tested at 09:59 am failed (aa) Hemoglobin (iii) QC High Control (lot# 220053) tested at 09:54 am failed (aa) RBC (bb) Hematocrit (cc) Hemoglobin (dd) WBC (ee) Lymphocytes (ff) Platelets (iv) 1 patient test result was reported with no level of MC QC within acceptable range (aa) Patient tested at 10:08 am (3) Surveyor #2 reviewed the findings with the technical consultant who stated on 10/02/2020 at 01:00 pm that the QC procedure had not been followed as indicated above before testing patients. FLAGGED RESULTS (1) On 10 /02/2020 at 10:00 am, the technical consultant stated to surveyor #1 the laboratory performed CBC (Complete Blood Count) testing using the Medonic M Series analyzer; (2) Surveyor #1 reviewed the manufacturer's instructions for verifying flagged results obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) BD - "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." (b) OM - "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." (3) Surveyor #1 then reviewed the laboratory's written policy and procedure for verifying flags which stated: (a) "Performing a slide review or referring the specimen for further study is required when flags are attached to the differential WBC for the OM and TM flags." (3) Surveyor #1 randomly reviewed 3 patient records which contained flagged results from CBC testing performed during September 2020. For 2 of the records, there was no evidence the laboratory followed their written instructions for verifying the flags. The findings for the 2 records were: (a) Patient testing was performed on 09/21/20 at 03:32 pm, with BD flags obtained; (b) Patient testing was performed on 09/30/2020 at 05:06 pm, with OM flags obtained. (4) Surveyor #1 reviewed the records with the technical consultant, who stated on 10/02 /2020 at 11:53 am that the laboratory failed to follow their policy for verifying the flags obtained for the above 2 patients.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions and interview with the technical consultant and testing person #1, the laboratory failed ensure quality control materials were not used beyond open vial stability. Findings include: (1) On 10/02/2020 at 10:

	00 am, the technical consultant stated to surveyor #1 the laboratory performed CBC (Complete Blood Count) testing using the Medonic M Series analyzer; (2) Surveyor #1 observed the following control material stored in the laboratory refrigerator, that had not been dated when opened: (a) Boule Con-Diff Tri-Level control materials: (i) 1 bottle of low control lot# 22008-31 (ii) 1 bottle of normal control lot# 22008-32 (iii) 1 bottle of high control lot# 22008-33 (3) Surveyor #1 asked the technical consultant and testing person #2 to explain what the controls were used for. The technical consultant explained the following: (a) Boule Con-Diff Tri-Level controls were used to perform quality control procedures for CBC testing performed on the Medonic M Series analyzer. (4) Surveyor #1 reviewed the manufacturer's open date stability instructions, which required the following: (a) Boule Con-Diff Tri-Level controls - Open vial stability 14 days after opening when returned to refrigerator after each use. (5) Surveyor #1 reviewed the instructions and the lack of dates on the control bottles with the technical consultant and testing person #1, who stated on 10/02/20 at 10:00 am the controls had not been dated with the open vial expiration date; (6) Since the bottles had not been dated, surveyor #1 could not determine if they had been used beyond their open vial expiration dates.