

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0910401	<b>(X3) Date Survey Completed</b> 11/06/2023
<b>Name of Provider or Supplier</b> Family Care Center	<b>Street Address, City, State</b> 1610 South Jefferson Ave, Mount Pleasant, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite survey conducted 10/26/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory quality control (QC) records, patient test reports, and confirmed in interview the laboratory failed to ensure that QC met the laboratory's acceptability criteria before testing and reporting 87 of 87 patients when CBC QC for the Sysmex XP-300 hematology analyzer did not meet the acceptable criteria in April 2023. The findings included: 1. Review of the laboratory policy titled "Family Care Center CBC Procedure", section "Quality Control" had the following statement: "Every parameter of QC must have at least two levels within range. If not, control must be repeated ...No patient results will be reported until all parameters of quality control are within the determined ranges for two levels." Subsection "QC Documentation": "2. ... The acceptable SD and mean for each lot is entered into the analyzer so that parameters that are out of range flag on the analyzer. If any of the parameters are out of range, corrective action must be implemented and documented." The surveyor queried what the flags looked like to alert personnel that QC was out of range and testing personnel (TP) 1 stated that the analyzer would flag a + or - next to the result out of range. 2. Review of laboratory QC records for April 2023 had the following four days where QC was flagged unacceptable for one or more parameters for two or more levels: 4/06/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 70.0 fL - [ + ] MCHC: 32.3 g/dL [ - ] Level 2: Lot 30810711, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 82.5 fL [ + ] MCHC: 35.7 g</p>

/dL [ - ] Level 3: 30810712, exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 86.8 fL [ + ] 23 patients had CBC's performed on 4/06/2023 when QC was out for two or more levels for MCV and MCHC, including the following five: Sample ID: 1003988966 1003988525 1003987729 1003987664 1003987977 4/10/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 70.4 fL [ + ] Level 2: Lot 30810711, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 82.5 fL [ + ] 18 patients had CBC's performed on 4/10/2023 when QC was out for two or more levels for MCV, including the following five: Sample ID: 1004011015 1004010611 1004011363 1004010170 1004010157 4/13/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 70.2 fL - [ + ] Level 3: 30810712, exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 86.5 fL [ + ] 21 patients had CBC's performed on 4/13/2023 when QC was out for two or more levels for MCV, including the following five: Sample ID: 1004047051 1004046959 1004046921 1004046885 1004045608 4/19/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 70.0 fL - [ + ] RDW-CV: 46.4 fL [ + ] Level 2: Lot 30810711, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 83.0 fL [ + ] RDW-CV: 34.6 fL [ + ] Level 3: 30810712, exp 6/28/2023 Analyte: Result - [ Flag ] RDW-CV: 10.4 Fl [ + ] 25 patients had CBC's performed on 4/19/2023 when QC was out for two or more levels for MCV and RDW-CV, including the following five: Sample ID: 1004100834 1004100328 1004099485 1004100115 1004100332 3. In an interview on 10/26/2023 at 12:40 hours, in the conference room, TP 1 confirmed that two or more levels of QC were out for the above days and that patient testing had proceeded. Key: CBC: complete blood count MCV: mean corpuscular hemoglobin. MCHC: mean corpuscular hemoglobin concentration. RDW-CV: Red Blood Cell Distribution Width - CV

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on a review of laboratory policy, laboratory quality control (QC) records, patient test reports, and confirmed in an interview the laboratory failed to document corrective action for five of six days where hematology QC had been outside of the laboratory's acceptability criteria, for the Sysmex XP-300 hematology analyzer, reviewed in April 2023. The findings included : 1. Review of the laboratory policy titled "Family Care Center CBC Procedure", section "Quality Control", subsection "QC Documentation" had the following statement: "2. ... The acceptable SD and mean for each lot is entered into the analyzer so that parameters that are out of range flag on the analyzer. If any of the parameters are out of range, corrective action must be implemented and documented. Actions taken to correct unacceptable results and justification of acceptance of out of range QC results must also be documented in the QC notebook on the day's print out that correlates with the action. 3. When unacceptable QC is obtained, patient test results since the last acceptable QC run must be reevaluated to determine if there is any clinical discrepancy that requires correction

of the patient's results due to unacceptable or inaccurate results. 4. All corrective actions are logged on the daily XP-300 maintenance log located on top of the analyzer." 2. A review of laboratory QC records for April 2023 had the following six days where QC was flagged by the Sysmex XP-300 hematology analyzer to be out of acceptability, and corrective action was not documented when QC came into acceptability. 4/8/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 70.5 fL [ +]; ran at 08:19 AM MCV: 69.8 fL; ran at 08:48 AM, within acceptability. No documentation of corrective actions. Level 2: Lot 30810711, Exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 82.7 fL [ +]; ran at 08:17 AM RDW-SD: 34.7 fL [ +] ran at 08:17 AM MCV: 82.2 fL; at 08:49 AM, within acceptability. No documentation of corrective actions. RDW-SD: 34.1 fL; at 08:49 AM, within acceptability. No documentation of corrective actions. Level 3: 30810712, exp 6/28/2023 Analyte: Result - [ Flag ] MCV: 86.8 fL [ +]; at 08:21 AM MCV: 85.9 fL; at 08:51 AM, within acceptability. No documentation of corrective actions. 13 patients had CBCs performed since the last acceptable QC on 4/7/2023 to include the following five: Sample ID: 1003991935 1003992301 1003991940 1003991921 1003991935 4/11/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] HCT: 16.1 % [ +]; at 08:04 AM MCV: 70.0 fL [ +]; at 08:04 AM HCT: 16.0 %; at 08:05 AM, within acceptability. No documentation of corrective actions. MCV: 69.6 fL; at 08:05 AM, within acceptability. No documentation of corrective actions. 18 patients had CBCs performed since the last acceptable QC on 4/9/2023 to include the following five: Sample ID: 1004005200 1004005741 1004005247 1004005861 1004005000 4/13/2023 Level 2: Lot 30810711, Exp 6/28/2023 Analyte: Result - [ Flag ] HCT: 36.8 % [ +]; at 08:18 AM MCV: 82.5 fL [ +]; at 08:18 AM HCT: 36.6 %; at 08:19 AM, within acceptability. No documentation of corrective actions. MCV: 82.1 fL; at 08:19 AM, within acceptability. No documentation of corrective actions. 25 patients had CBCs performed since the last acceptable QC on 4/12/2023 to include the following five: Sample ID: 1004029026 1004035840 1004035696 1004034923 1004035263 4/27/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] RDW-SD: 47.0 fL [ + ]; at 08:11 AM RDW-SD: 45.7 fL; at 08:12, within acceptability. No documentation of corrective actions. 19 patients had CBCs performed since the last acceptable QC on 4/26/2023 to include the following five: Sample ID: 1004164236 1004163135 1004162901 1004164225 1004161735 4/29/2023 Level 1: Lot 30810710, Exp 6/28/2023 Analyte: Result - [ Flag ] HCT: 16.3% [ + ]; at 07:58 AM HCT: 15.7%; at 08:07 AM, within acceptability. No documentation of corrective actions. Level 3: 30810712, exp 6/28/2023 Analyte: Result - [ Flag ] LYM#: 6.6 x10<sup>3</sup> /uL [ + ]; at 08:10 AM LYM#: 6.0 x10<sup>3</sup>/uL; at 08:11 AM, within acceptability. No documentation of corrective actions. The following five patients had CBCs performed since the last acceptable QC on 4/28/2023: Sample ID: 1004182773 1004182167 1004181252 1004180789 1004180256 3. In an interview on 10/26/2023 at 12:30 hours, in the conference room, testing person (TP)1 confirmed that corrective action for the above flagged QC failures, by the Sysmex SP-300 analyzer, had not been documented. Key: CBC: complete blood count HCT: hematocrit HGB: hemoglobin MCV: mean corpuscular hemoglobin. RDW-SD: Red Blood Cell Distribution Width - SD LYM#: Lymphocyte absolute number