Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0910401	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Care Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute proficiency test records from 2019 to 2021, and confirmed in interview, the laboratory failed to test the proficiency testing samples the same manner as it tests patient specimens for one of six PT events reviewed. Findings included: 1. Review of the laboratory policy Proficiency Survey Policies under Receipt of Surveys revealed "testing personnel will test the specimen in the same manner as any other patient specimen." 2. Review of 2019 to 2021 API test events revealed one of six test events when the laboratory repeated PT samples days after the initial run--unlike a patient sample. 2019 Hematology/Coagulation 3rd test event Sample HSY11, analyzed on 11/18/19, and repeated on 11/21/19 Sample HSY12, analyzed on 11/18/19, and repeated on 11/21

	/19 Sample HSY13, analyzed on 11/18/19, and repeated on 11/19/21 sample HSY14, analyzed on 11/18/19, and repeated on 11/19/19 Sample HSY15, analyzed on 11/18 /19, and repeated on 11/19/19 3. An interview with the laboratory manager on 9/8/21 at 1120 hours in the conference room confirmed the above findings. She acknowledged that they do not repeat a patient sample a day or so after the initial run.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing reports from 2019 to 2021 and confirmed in an interview, the laboratory failed to document the self-evaluation of proficiency testing results returned ungraded by the proficiency testing agency for 1 of 6 API test events reviewed. Findings included: 1. A review of the API user guide under Grading Standards for Not Graded analytes revealed the following: "Whenever a result is not graded, you should perform a self-evaluation. To do this, you would compare your result to the expected result(s). If your result falls within the expected range, you may conclude that your lab obtained the correct response. If your result does not fall within the expected range, you may want to troubleshoot to determine the cause. In most cases, the expected result is printed on your evaluation next to your reported result for each sample. If the expected result is not printed on your evaluation, to find the result or range of results that is the most appropriate for you to use for comparison." 2. Review of the API test records from 2019 to 2021 revealed 1 of 6 test events with "not graded" 2019 Hematology/Coagulation 1st event Urine Sediment US-02 - not graded Vaginal Wet Preparation (KOH) VKP-01 - not graded 3. Review of the laboratory records available revealed no self-evaluation of the above test event. 4. An interview with the laboratory manager on 9/8/21 at 1120 hours in the conference room confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of Sysmex XP-300 Instruction for use, review of the laboratory's maintenance records, patient records, and confirmed in an interview revealed the laboratory failed to document the required maintenance procedures for six of thirty-five weekly maintenance from January to August 2021 for Sysmex XP-300. The findings were: 1. Review of Sysmex XP-300 Instruction for use (Code No: AU553517, Date of Last Revision: February 2013, Software Version: 00-10 and onwards) under Chapter 12 Cleaning and Maintenance revealed "To ensure proper

	functioning of the instrument, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below and record the results in the Maintenance checklist." Weekly Clean SRV tray 2. Random review of the laboratory's maintenance records revealed the laboratory had no documentation of performing the required maintenance procedures on Sysmex XP-300 (SN# A3957) for six of thirty-five weekly maintenance from January to August 2021. Weekly: 1/24/21-1/30/21 4/11/21-4/17/21 5/23/21-5/29/21 5/30/21-6/5/21 6/27/21-7/3/21 7/25/21-7/31/21 3. Random review of patient records from 1/1/21-8/31/21 revealed the following 14 patient testing without required maintenance procedures performed on Sysmex XP-300 (SN# A3957). 1/28/21 Sample ID: 1000058372 1/28/21 Sample ID: 1000058428 4/15/21 Sample ID: 1000109608 4/15/21 Sample ID: 1000109643 4/15/21 Sample ID: 1000109552 4/16/21 Sample ID: 1000110452 4/16/21 Sample ID: 1000110479 5/28/21 Sample ID: 1000214375 5/28/21 Sample ID: 1000214101 5/30/21 Sample ID: 1000216646 6/27/21 Sample ID: 1000289387 6/27/21 Sample ID: 1000289484 7/26/21 Sample ID: 1000369157 7/26/21 Sample ID: 1000367475 4. An interview with testing person #1 (TP#1) on 7/9/21 at 11:30 am in the conference room confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory and patient test records from July 2020 to August 2021, and confirmed in interview, the laboratory failed to document corrective actions for 22 of 22 days reviewed when temperature was outside of acceptable range for storage of hematology quality control (Sysmex Eightcheck 3WP X-TRA) for CBC (complete blood count) testing on the Sysmex XP-300 hematology analyzer. Findings included: 1. Review of the Sysmex XP-300 hematology analyzer manual under Quality Control revealed " Eightcheck 3WP X-TRA-N, Eightcheck 3WP X-TRA-L, and Eightcheck 3WP X-TRA -H are to be stored at 2-8C before and after opening." 2. Review of the Sysmex Eightcheck 3WP X-TRA package insert under storage and shelf life after first opening revealed "opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C after being recapped." 3. Random review of the laboratory quality control records from July 2020 to August 2021 revealed the laboratory stored and used the following six lots of quality control in their whirlpool refrigerator. Sysmex Eightcheck 3WP X-TRA lot 10550710, exp 6/2/21 lot 10550711, exp 6/2/21 lot 10550712, exp 6/2/21 lot 01690710, exp 9/23/20 lot 01690711, exp 9/23/20 lot 01690712, exp 9/23/20 4. Random review of the whirlpool refrigerator logs from July 2020 to August 2021 revealed 22 of 22 days with temperature outside of the acceptable range of 2-8 C with no documentation of corrective action. 7/30/2020: Min 0 C 8/16/2020: Min 0 C 9/30/2020: Min 1 C 10/2/2020: Min 0 C 10/30/2020: Min 1 C

	11/10/2020: Min 0 C 11/30/2020: Min 1 C 12/04/2020: Min -1 C 1/01/2021: Min 1 C 1/19/2021: Min 1 C 2/10/2021: Min 1 C 3/16/2021: Min 1 C 3/27/2021: Min 1 C 4/17/2021: Min 1 C 5/07/2021: Min 1 C 5/28/2021: Min 1 C 6/05/2021: Min 1 C 6/25/2021: Min 1 C 7/02/2021: Min 1 C 7/24/2021: Min 1 C 8/02/2021: Min 1 C 8/12/2021: Min 1 C 5. Review of the CMS116 revealed the laboratory performed 32364 hematology testing annually. 6. An interview with the laboratory manager on 9/8/21 at 1145 hours in the conference room confirmed the above findings.