Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0991906	07/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Filosa Childrens Clinic	1240 Business 83 Suite B, Mission, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure expired test kits were not available for use in patient testing. Findings: 1. During a tour of the laboratory on 07/26/2021 at 11:00 am, the surveyor observed the following on a shelf: 1 bottle of McKesson Strep A Dipstick; Lot #STA9072001; expiration date 06/30/2021 2. Review of manufacturer's package insert revealed: "STORAGE AND STABILITY ... Do not use beyond the expiration date." 3. The laboratory performed 2 patient tests from 07/01/2021 through

	07/26/2021 when the test strips were expired. See patient alias list. The laboratory failed to ensure expired test kits were not available for use in patient testing. 4. During an interview on 07/26/2021 at 11:05 am, Testing Person-1 confirmed the test kit was expired.
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 review of laboratory policy, quality control (QC) records, and confirmed in interview, the laboratory failed to follow their own written policy for corrective action for unacceptable QC for 9 of 57 QC runs in 2021 (April-June). Findings: 1. Review of the laboratory's policy "OUT OF RANGE CONTROL POLICY" revealed: "IT IS THE POLICY OF THIS LABORATORY TO DO THE FOLLOWING WHEN CONTROLS ARE NOT WITHIN RANGE: 1. ENSURE THAT ALL SPECIMENS AND REAGENTS ARE AT THE RIGHT TEMPERATURE. 2. ENSURE THAT CONTROLS ARE NOT EXPIRED. 3. VERIFY THAT CONTROL RANGERS ARE CORRECT AND THAT THE CORRECT CONTROL SAMPLE; IF IT FAILS THEN, 4. OPEN A NEW VIAL OF CONTROLS AND RUN; IF CONTROLS FAIL THEN, 5. ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HASBEEN [sic] CLEARED AND CONTROLS ARE IN RANGE. 6. DEPENDING ON THE UNIT, DO A BACKGROUND OR CLEAN THE ORFICES THEN RERUN THE THREE CONTROLS; IF THE CONTROL STILL FAIL THEN 7. EVALUATE MAINTENANCE SCHEDULE, ENSURE THAT ALL OF MANUFACTURERS RECOMMNEDATIONS ARE FOLLOWED AND THAT MAINTENANCE PROCEDURES LIKE BLEACHING OR CLEANING OF THE APERATURES ARE BEING DONE AS REQUIRED. PERFORM BLEACHING OR CLEANING OF THE APERATURES AND RERUN ALL THREE CONTROLS, IF CONTROLS FAIL THEN, 8. EVALUATE CALIBRATION; IF NECESSARY, RECALIBRATE UNIT AND RUN CONTROLS; IF CONTROLS FAIL THEN, 9. CALL TECHNICAL SUPPORT FOR HELP; 10. ENSURE THAT ALL REMEDIAL ACTION STEPS ARE DOCUMENTED. MOST IMPORTANTLY, ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HAS BEEN CLEARED AND CONTROLS ARE IN RANGE." 2. Review of Medonic M-Series QC records revealed the laboratory failed to follow their own written policy for troubleshooting unacceptable QC on the following dates for the following analytes in 2021: QC low level control lot #22100231; expiration date: 07/13/2021 QC normal level control lot #2210232; expiration date: 07/13/2021 QC high level control lot #2210233; expiration date: 07/13/2021 04/30/2021 High control 09:33 am - QC failed for HGB and was not repeated 05/05/2021 Normal control 09:33 am - QC failed for HGB and was not repeated 05/14/2021 Low control 12:05 pm - QC failed for PLT and was not repeated High control 12:04 pm - QC failed for HGB and was not repeated 05/19/2021 Normal control 2:44 pm - QC failed for HGB and was not repeated 05/21/2021 Normal control 10:02 am - QC failed for HGB and was not repeated High control 10:03 am - QC failed for HGB and was not repeated 05/29/2021 High control 10:12 am - QC failed for HGB and was not repeated 05/30/2021 High control 10:19 am - QC failed for HGB and was not repeated 06/01/2021 Low control 10:46 am - QC failed for RBC

	and was not repeated High control 10:14 am - QC failed for MCV, HCT, HGB, MCH, WBC, LYM and was repeated 10:42 am - QC failed for HGB and was not repeated 06 /02/2021 High control 10:09 am - QC failed for HGB and was not repeated The laboratory failed to follow their own written policy for verifying if specimens and reagents were at the correct temperature, verifying expiration dates of QC material, verifying control ranges, verifying if correct control level of the control being run was correct, remixing and rerunning QC material, and using a new vial of QC material. 3. During an interview on 07/26/2021 at 10:47 am, the Technical Consultant confirmed the above findings. Word Key: HGB - hemoglobin PLT - platelet RBC - red blood cell MCV - mean corpuscular volume HCT - hematocrit MCH - mean corpuscular hemoglobin WBC - white blood cell LYM - lymphocyte
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory policy, environmental logs, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within the laboratory's defined temperature range for 5 of 27 days in 2020 (10/2020) and 15 of 24 days in 2021 (01/2021). Findings: 1. Review of the laboratory's policy "INSTRUMENT OPERATION AND MAINTENANCE" revealed: "Temperature readings of all temperature control devices will be made daily and documented. Temperature Log Sheets should state the name of the appliance, the date of the reading, and the operating temperature range for the appliance ..." 2. Review of the laboratory's environmental logs from 10/2020 through 06/2021 revealed the laboratory had an established an acceptable room temperature range for the laboratory of 72-77F. 3. Further review of the laboratory's environmental monitoring records from 10/2020 through 06/2021 revealed the following 5 of 27 days in 10/2020 and 15 of 24 days in 01/2021 when the temperature was out of the acceptable range of 72-77F: Date: 10/08 /2020; Temperature: 71.3 F Date: 10/10/2020; Temperature: 71.8 F Date: 10/23/2020; Temperature: 70.7 F Date: 10/26/2020; Temperature: 71.5 F Date: 10/28/2020; Temperature: 71.2 F Date: 01/12/2021; Temperature: 71.2 F Date: 01/13/2021; Temperature: 71.1 F Date: 01/14/2021; Temperature: 70.7 F Date: 01/15/2021; Temperature: 71.8 F Date: 01/16/2021; Temperature: 71.9 F Date: 01/18/2021; Temperature: 70.7 F Date: 01/19/2021; Temperature: 70.4 F Date: 01/20/2021; Temperature: 70.9 F Date: 01/21/2021; Temperature: 70.8 F Date: 01/22/2021; Temperature: 70.5 F Date: 01/23/2021; Temperature: 70.8 F Date: 01/25/2021; Temperature: 70.8 F Date: 01/28/2021; Temperature: 70.5 F Date: 01/29/2021; Temperature: 71.2 F Date: 01/30/2021; Temperature: 70.4 F 4. During an interview on 07/26/2021 at 11:27 am, the Technical Consultant 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 review of laboratory policy, manufacturer's instructions, review of maintenance logs, and confirmed in interview the laboratory failed to perform monthly maintenance for 2 of 2 months in 2021 (05/2021, 06/2021) as required by the manufacturer for the Medonic M-Series hematology analyzer. Findings: 1. Review of the laboratory's policy "INSTRUMENT OPERATION AND MAINTENANCE" stated the following: "Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacture's recommendations. Document all maintenance performed on the test systems in use. Also document repairs and remedial action on all test system." 2. Review of Medonic M-Series hematology analyzer maintenance guide revealed the following: "Medonic M-Series Maintenance ... Monthly Cleaning Procedure (~10 minutes) 1. Fill a cup with 10 mL 2% hypochlorite from Boule Cleaning Kit (White Cap). 2. Fill another cup with 18 mL diluent. The diluent can be obtained by using the dispense function of the M-Series. To dispense diluent: a. Press [Dispense] from Main Menu. b. Hold empty cup under Pre-Dilute probe (1:200 probe on right side). c. Press 1:200 Start plate behind probe. d. Discard first dispense. e. Repeat steps b-c four times to achieve 18 mL of diluent. f. Press [Cancel] to exit the dispense function. 3. Aspirate the hypochlorite (White Cap) as a Pre-dilute sample (1: 200 probe) twice. *Note: Pre-dilute mode has intentional delay. Press and hold start plate to start cycle (keep probe submerged in hypochlorite solution until the screen displays "Now Analyzing"). 4. Aspirate the clean diluent obtained is [sic] step 2e as a Pre-dilute Sample. Repeat. Discard results. 5. Perform a background check in the Pre-dilute mode by aspirating the remaining clean diluent obtained in step 2e. Verify all values are within specifications. 6. Continue to the clot prevention procedure. Clot Prevention Procedure (~15 minutes) This procedure should be done once a month or every 1000 samples processed by the Medonic M-Series. You will not be able to run samples for approximately 15 minutes once the clot prevention cycle has started. 1. Fill a cup with 5 ml of Enzymatic Cleaner (Blue Cap) from the Boule Cleaning Kit. 2. If you have the Cap Pierce or Autoloader option, fill a clean standard 4.0-5.0 ml tube half full with the Enzymatic Cleaner (Blue Cap) as well. 3. From the Main Menu press [Advanced], then [Maintenance] and then [Clot Prevention]. (Do NOT press [OK] yet) 4. If you have the Open Tube configuration of the M-Series proceed to Step 7. If you have the Cap Pierce proceed to step 5. If you have an Autoloader proceed to Step 6. 5. If you have the optional Cap Pierce place the filled cleaner tube into Cap Pierce (Cap Down - same as a normal sample analysis). Close the door to continue to step 7. 6. If you have the optional Autoloader configuration place the filled cleaner tube into position number one on the wheel, lock the wheel in place, and continue to step 7. 7. Hold the cup (with 5 ml cleaner) under the Open Tube probe, submerged in cleaner, press [OK] to begin clot prevention cycle. Do not remove container (with cleaner) for at least 5 seconds after the aspiration has stopped. 8. The system will then perform the cleaning process for all analysis modes simultaneously. This will take 15 minutes. 9. Once the clot prevention cycle is completed perform a background check. Verify all values are within specifications." 3. A review of Medonic M-Series hematology analyzer's maintenance log revealed the following months in 2021 monthly maintenance was not performed: May June The laboratory failed to perform monthly maintenance as required by the manufacturer. 4. During an interview on 07 /26/2021 at 10:57 am, the Technical Consultant confirmed the above findings.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Medonic M-Series quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 3 of 3 patients in 2021 (May). Findings: 1. Review of the laboratory's policy "OUT OF RANGE CONTROL POLICY" revealed: "IT IS THE POLICY OF THIS LABORATORY TO DO THE FOLLOWING WHEN CONTROLS ARE NOT WITHIN RANGE: 1. ENSURE THAT ALL SPECIMENS AND REAGENTS ARE AT THE RIGHT TEMPERATURE. 2. ENSURE THAT CONTROLS ARE NOT EXPIRED. 3. VERIFY THAT CONTROL RANGERS ARE CORRECT AND THAT THE CORRECT CONTROL SAMPLE; IF IT FAILS THEN, 4. OPEN A NEW VIAL OF CONTROLS AND RUN; IF CONTROLS FAIL THEN, 5. ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HASBEEN [sic] CLEARED AND CONTROLS ARE IN RANGE ... MOST IMPORTANTLY, ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HAS BEEN CLEARED AND CONTROLS ARE IN RANGE." 2. Review of Medonic M-Series QC records revealed QC was not within acceptable range before reporting patient test results for the following day in May 2021: QC normal level control lot #2210232; expiration date: 07/13/2021 QC high level control lot #2210233; expiration date: 07/13/2021 Complete Blood Count (CBC) acceptable ranges: Normal control HGB (hemoglobin): 11.2-12.0 g/dL High control HGB: 15.6-16.6 g/dL 5/21/2019 Normal control QC 10: 02 am HGB: 12.3 g/dL; QC failed and was not repeated High control QC 10:03 am HGB: 17.0 g/dL; QC failed and was not repeated The results for HGB for both the normal and high level of control were not within acceptable range and 3 patients were tested and reported: Patient Seq #: 363, 365, 366 The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results. 3. During an interview on 07/26/2021 at 10:47 am, the Technical Consultant 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 laboratory policy, hematology quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for 21 of 57 runs that included failures in 2021 (04/2021-06/2021). Findings: 1. Review of the laboratory's policy "OUT OF RANGE CONTROL POLICY" revealed: "IT IS THE POLICY OF THIS LABORATORY TO DO THE FOLLOWING WHEN CONTROLS ARE NOT WITHIN RANGE: 1. ENSURE THAT ALL SPECIMENS AND REAGENTS ARE AT THE RIGHT TEMPERATURE. 2. ENSURE THAT CONTROLS ARE NOT EXPIRED. 3. VERIFY THAT CONTROL RANGERS ARE CORRECT AND THAT THE CORRECT CONTROL SAMPLE; IF IT FAILS THEN, 4. OPEN A NEW VIAL OF CONTROLS AND RUN; IF CONTROLS FAIL THEN, 5. ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HASBEEN [sic] CLEARED AND CONTROLS ARE IN RANGE. 6. DEPENDING ON THE UNIT, DO A BACKGROUND OR CLEAN THE ORFICES THEN RERUN THE THREE CONTROLS; IF THE CONTROL STILL FAIL THEN 7. EVALUATE MAINTENANCE SCHEDULE, ENSURE THAT ALL OF MANUFACTURERS RECOMMNEDATIONS ARE FOLLOWED AND THAT MAINTENANCE PROCEDURES LIKE BLEACHING OR CLEANING OF THE APERATURES ARE BEING DONE AS REQUIRED. PERFORM BLEACHING OR CLEANING OF THE APERATURES AND RERUN ALL THREE CONTROLS, IF CONTROLS FAIL THEN, 8. EVALUATE CALIBRATION; IF NECESSARY, RECALIBRATE UNIT AND RUN CONTROLS; IF CONTROLS FAIL THEN, 9. CALL TECHNICAL SUPPORT FOR HELP; 10. ENSURE THAT ALL REMEDIAL ACTION STEPS ARE DOCUMENTED. MOST IMPORTANTLY, ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HAS BEEN CLEARED AND CONTROLS ARE IN RANGE." 2. Review of Medonic M-Series QC records revealed the laboratory failed to document corrective actions for QC failures in 2021 on the following dates and times: QC low level control lot #22100231; expiration date: 07/13/2021 QC normal level control lot #2210232; expiration date: 07/13/2021 QC high level control lot #2210233; expiration date: 07/13/2021 04/24/2021 Normal control 10:37 am QC failed for RBC, HCT, HGB, WBC, LYM, PLT 10:39 am QC was repeated and failed for RBC 10:41 am QC was repeated and failed for RBC, HGB 10:50 am QC was repeated and passed 04/28/2021 High control 9:33 am QC failed for RBC, HCT, HGB, 9:39 am QC was repeated and passed 05/03/2021 Low control 09: 49 am QC failed for RBC 09:54 am QC was repeated and passed 05/07/2021 Normal control 9:33 am QC failed for RBC, HGB, 9:36 am QC was repeated and failed for RBC 9:37 am QC was repeated passed 05/15/2021 Low control 9:59 am QC failed for RBC, HGB, WBC 10:04 am QC was repeated and passed 05/22/2021 Normal control 9:42 am QC failed for RBC 9:44 am QC was repeated and passed High control 9:39 am QC failed for HGB 09:40 am QC was repeated and passed 05/28/2021 Low control 9:28 am QC failed for MCH, LYM 9:30 am QC was repeated and passed Normal control 9:32 am QC failed for RBC, HGB 9:34 am QC was repeated and failed for RBC 9:36 am QC was repeated and failed for RBC 9:38 am QC was repeated and failed for RBC 9:41 am QC was repeated and passed High control 9:43 am QC failed for HGB 9:45 am QC was repeated and passed 06/01/2021 High control 10:14 am QC failed for MCV, HCT, HGB, MCH, WBC, LYM 10:42 am QC was repeated and failed for HGB 06/07/2021 Low control 10:24 am QC passed 10:52 am QC was repeated and passed 10:58 am QC was repeated and failed for PLT 11:07 am QC was repeated and passed Normal control 10:28 am QC failed for RBC 11:10 am QC was repeated and passed High control 10:27 am QC passed 10:54 am QC was repeated and failed for RBC 11:08 am QC was repeated and passed 06/09/2021 Normal control 10:09 am QC failed for WBC 10:11 QC was repeated and passed 06 /10/2021 Normal control 9:28 am QC failed for RBC, HGB 9:31 am QC was repeated and passed High control 9:27 am QC failed for RBC 9:30 am QC was repeated and

	passed 06/12/2021 Low control 9:59 am QC failed for HGB 10: 14 QC was repeated and passed High control 9:57 am QC failed for HGB 10:00 am QC was repeated and failed for RBC, HCT, HGB 10:12 am QC was repeated and passed 06/14/2021 Normal control 10:15 am QC failed for PLT 10:17 am QC was repeated and passed 06 /15/2021 High control 10:55 am QC failed for RBC 12:17 pm QC was repeated and passed 06/16/2021 Normal control 10:21 am QC failed for RBC, HGB 10:25 am QC was repeated and passed High control 10:18 am QC failed for RBC, HGB 10:23 am QC was repeated and failed for HGB 10:26 am QC was repeated and passed 06/21 /2021 Low control 9:52 am QC failed for RBC, HGB 9:53 am QC was repeated and passed High control 9:47 am QC failed for HGB 9:49 am QC was repeated and passed 6/22/2021 High control 9:31 am QC failed for HGB 9:35 am QC was repeated and failed for HGB 9:51 am QC was repeated and passed 06/23/2021 Normal control 10: 07 am QC failed for HGB 10:10 am QC was repeated and passed 06/24/2021 High control 10:12 am QC failed for HGB 10:14 am QC was repeated and failed for HGB 10:16 am QC was repeated and passed 06/29/2021 High Control 9:14 am QC failed for RBC, HGB, WBC, PLT 9:20 am QC was repeated and failed for RBC 9:23 am QC was repeated and failed for RBC 9:26 am QC was repeated and failed for RBC 9: 43 am QC was repeated and passed 06/30/2021 Normal control 9:25 am QC failed for RBC 9:28 am QC was repeated and failed for RBC 9:34 am QC was repeated and failed for RBC 9:47 am QC was repeated and failed for RBC 9:49 am QC was repeated and failed for passed The laboratory failed to document corrective action for the above QC failures. 3. During an interview on 07/26/2021 at 10:47 am, the technical consultant stated that testing persons were to document corrective action log for QC failures on a log. He provided a copy of the log and it was blank, this confirmed the above findings. Word Key: RBC - red blood cell HCT - hematocrit HGB - hemoglobin PLT - platelet MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin WBC - white blood cell LYM - lymphocyte