Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1006973	01/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
D&F Med, Pllc Dba Groveton Family Medical Clinic	180 N Magee Lane, Groveton, 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. 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.
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 Medonic M- Series User's Manual, a review of the laboratory's policies, review of patient records, and confirmed in staff interview, the laboratory failed to follow its own policy for resolution of flags on four of six CBC (complete blood count) results reviewed with flags from March 2021. The findings included: 1. A review of the Medonic M- Series User's Manual (Article no. 1504472, 02/2016) revealed the following flags: "BD, NM, OM, TM flags - Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2.

	A review of the laboratory's policy titled 'Troubleshooting Patient Samples with Abnormalities' approved by the laboratory director on June 29, 2021 stated the following: Step 1: Follow manufacturer's instructions. Locate indicator flag in Medonic user manual in section 9.2 System Information Messages. Review system message, description, and complete recommended action. Step 2: Re-test sample after troubleshooting is completed. Review sample to ensure that indicator flag is no longer present. If indicator remains, complete recommended manufacturer action again and re-test sample. Mark through any analyte result that is flagged prior to provider seeing the result. Step 3: If the analyte being flagged is needed for diagnostic purposes, indicate on PT report that the sample would be sent to a reference lab for testing. 3. Review of patient records found the following four of six patient samples for CBC that had flags and no verification was performed to resolve the flags: Date: 03/09 /2021 Sequence #: 8086 Flag: BD - WBC Diff: High interference between populations Date: 04/27/2021 Sequence #: 8945 Flag: BD - WBC Diff: High interference between populations Date: 07/02/2021 Sequence #: 9077 Flag: OM Only one WBC population found; slide review advised Date: 10/21/2021 Sequence #: 104 Flag: BD - WBC Diff: High interference between populations a. The laboratory failed to follow its own policy to repeat samples with flags according to the laboratory's own policy. b. The laboratory failed to follow its own policy to invalidate analytes with flags according to the laboratory's own policy. c. The laboratory failed to follow its own policy to send out samples with unresolved flags according to the laboratory's own policy. 4. An interview with the laboratory's executive administrator on January 26, 2022 at 15:30 hours in her office, after review of the records, confirmed the findings. Key: PT - patient WBC - white blood cell