Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2029915	02/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Compassionate Family Care, Llc	15900 College Boulevard, Ste 100, Lenexa, KS	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records for 2020, 2021, and interview with office manager, the laboratory failed to establish means to verify the accuracy of wet prep testing twice a year. Findings: 1. Review of laboratory records for 2020, 2021 revealed the laboratory failed to verify the accuracy twice a year for wet prep testing. 2. Interview with the office manager on 2/18/22 at 2:50 p.m. confirmed, the laboratory failed to verify the accuracy of the non-regulated wet prep testing twice annually for 2020, 2021.
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 the lack of available on-site procedure for wet prep and interview with staff revealed the laboratory failed to have written, approved procedures available to, and followed by, laboratory personnel. Findings: 1. No procedure for vaginal wet prep was on site for use by laboratory personnel at the time of survey. 2. Office manager stated the procedure was at the laboratory director's residence. 3. Request was made

	for information on what liquid was placed into the unlabeled specimen collection tubes in patient exam rooms. (see D5415) 4. Interview with testing personnel #2 on 2 /18/22 at 2:10 p.m. revealed sterile water was placed into specimen collection tubes. 5. Office manager had the procedure emailed to surveyor for review. Review of emailed procedure revealed saline should be used in sample collection. 6. Interview with office manager on 2/18/22 at 2:20 p.m. confirmed, the laboratory failed to have written, approved procedures available to, and followed by, laboratory personnel.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of patient examination rooms, laboratory testing area, and interview with office manager, the laboratory failed to identify the contents and expiration dates of the reagents used for the collection of wet prep patient samples and failed to ensure reagent used in KOH examinations had not exceeded the expiration date. Findings: 1. Observation of patient examination rooms showed 5 unlabeled containers with no content labeling or expiration dates. 2. Observation of laboratory testing area showed one bottle of KOH solution with an expiration date of 1/6/22. 3. Interview with office manager on 2/18/22 at 2:20 p.m. confirmed the laboratory failed to identify the contents and expiration dates of the reagents used for the collection of wet prep patient samples and failed to ensure reagent used in KOH examinations had not exceeded the expiration date.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the lack of documentation, and interview, the laboratory failed to establish a maintenance protocol and perform maintenance on their microscope. Findings: 1. Request was made to review the microscope maintenance protocol and records. No documentation was available at the time of survey. 2. Interview with office manager on 2/18/22 at 3:05 p.m. confirmed, the laboratory failed to establish a maintenance protocol and perform maintenance on their microscope.