Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468337	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Salem Family Clinic	507 N Main, Salem, AR	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Through review of proficiency test hematology result reports, the data log for the Medonic hematology analyzer, laboratory policy and procedure and interview it was determined that the laboratory tested proficiency test samples in duplicate on two of three proficiency testing events in 2018 but only tested patient samples a single time. Findings follow: A) Review of proficiency test result reports for API Hematology /Coagulation 2018 event #1 and API Hematology/Coagulation 2018 event #2 revealed that all ten specimens in the two events were tested in duplicate. B) In an interview on May 15, 2019 at approximately 02:00 PM, when asked the reason the proficiency test samples were tested in duplicate, the general supervisor, identified as number 1 on the CMS 209 form, stated that he supposed it was because the proficiency test results were abnormal. C) Review of the Medonic hematology analyzer data log for July, 2018 revealed that only seven of fifty-one complete blood cell (CBC) analyses with abnormal results were tested in duplicate. D) Review of policy and procedure for CBC testing revealed that there was no requirement for testing patients with abnormal results in duplicate. E) In an interview on May 15, 2019 at approximately 02:45 PM the general supervisor, identified as number 1 on the CMS 209 form stated that there was no policy requiring that patients with abnormal values on CBC analyses be tested in duplicate and that all samples in the proficiency testing events identified above had been tested in duplicate.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Through review of the laboratory policy and procedure manual, observation and interview it was determined that the laboratory failed to label specimens with patient name and unique patient identifier on thirty of thirty-one EDTA blood collection tube specimens observed. Findings follow: A) Review of the laboratory policy for "General Specimen Collection and Handling" revealed that "specimens must be properly labeled with the patient's complete name and secondary identifier, date and time of collection, and initials of phlebotomist". B) During a tour of the laboratory on 5/15/19 at approximately 11:00 AM thirty of thirty-one EDTA collection tube specimens were observed in a rack adjacant to the hematology analyzer labed with patient first and last name only. C) In an interview on 5/15/19 at approximately 11:15 AM the general supervisor, identified as number 1 on the CMS 209 form, confirmed that the specimens identified above had been tested, were labeled with patient first and last name only, and that he was unaware of the requirement that specimens be labeled with patient name and a secondary identifier.
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: Through observation, lack of documentation and interview it was determined that the laboratory failed to document room temperature in the laboratory room in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 5/15/19 at approximately 11:00 AM the following items with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed; 25 ea. SST BD Vacutainers lot# 9049992 experation date 2020-02-29, 15 ea. BD EDTA Vacutainers lot# 9004664 expiration date 2020-05-31, 14 ea. BD Heparin Vacutainers lot# 8276804 expiration date 2020-02-29, 200 ea. BD SST Vacutainers lot# 9030866 expiration date 2020-01-31, and 400 ea. BD EDTA Vacutainers lot# 8345595 2020-04-30. B) Upon request, the laboratory was unable to provide documentaiton of room temperature for the dates of January 1, 2018 through June 30, 2018 inclusive. C) In an interview on 5/15/19 at approximately 11:15 the general supervisor, identified as number 1 on the CMS 209 form confirmed that that the documentation of room temperature for the dates identified above was unavailable.

D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Through review of temperature records for July 1, 2018 through December 31, 2018, observation, lack of documentation and interview it was determined that the laboratory failed to take corrective action when room temperatures exceeded the maximum allowed for the storage of BD Vacutainer blood collection tubes (4 degrees C. to 25 degrees C.) on nine of one hundred and ten days of operation. Findings follow: A) During a tour of the laboratory on 5/15/19 at approximately 11:00 AM the following items with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed; 25 ea. SST BD Vacutainers lot# 9049992 experation date 2020-02-29, 15 ea. BD EDTA Vacutainers lot# 9004664 expiration date 2020-05-31, 14 ea. BD Heparin Vacutainers lot# 8276804 expiration date 2020-02-29, 200 ea. BD SST Vacutainers lot# 9030866 expiration date 2020-01-31, and 400 ea. BD EDTA Vacutainers lot# 8345595 2020-04-30. B) Review of room temperature records for July 1, 2018 through December 31, 2018 revealed that the room temperature was recorded as greater than 25 degrees C. on August 27, 2018, August 31, 2018, September 13, 2018, October 4, 2018, October 8, 2018, October 12, 2018, October 19, 2018, October 22, 2018, and October 29, 2018. C) Upon request, the laboratory was unable to provide documentation of corrective action taken when room temperature exceeded the storage requirements for BD Vacutainer blood collection tubes. D) In an interview on 5/15/19 at approximately 11:15 AM the general supervisor identified as number 1 on the CMS 209 form confirmed that temperatures were recorded as exceeding the maximum allowable for BD Vacutainer blood collection tubes and that no corrective action had been taken.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of laboratory personnel records, lack of documentation, as well as interview with staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required for four of four personnel listed as testing personnel on the CMS 209 form. Findings follow:: A. A review of personnel records,

	revealed there were no signed authorization to perform moderate complexity testing for four of four testing personnel as listed on form CMS-209. B. Upon request the laboratory could not provide a signed authorization for the testing personnel identified aove to perform moderate complexity testing. C. In the exit conference at 03:15 PM on May 15, 2019, the general supervisor identified as number 1 on the CMS 209 form confirmed that the laboratory failed to have a signed authorization for four of four personnel that perform moderate complexity testing.