Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2127194	08/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Walnut Ridge Family Medical Clinic	1045 West Main Street, Suite C, Walnut Ridge, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through review of proficiency testing attestation forms and interview it was determined that the laboratory director did not attest that the proficiency testing was performed in the same manner as patient testing in one of nine events reviewed and testing personnel did not sign the attestation on two of nine events reviewed. Survey findings follow: A) Review of API proficiency testing Hematology/Coagulation second event 2019 revealed the laboratory director and the testing personnel did not sign the attestation statement attesting that testing was performed in the same manner as patient testing . B) Review of API proficiency testing Microbiology second event 2019 revealed the testing personnel did not sign the attestation statement attesting that testing was performed in the same manner as patient testing . C) In an interview at approximately 04:45 PM on 8/22/19, the technical consultant, identified as number three on the CMS 209 form, confirmed that the signatures were not present on the proficiency testing event attestations identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Through observation made during a tour of the laboratory,interview with laboratory staff , calibration records for the Vitros chemistry analyzer and patient result reports it was determined that the laboratory had one of three boxes of Vitros Triglyceride reagents available for use after its date of expiration and expired reagents had been used to perform and report triglyceride assays on patients in July 2019 . Findings follow: 1. The laboratory had one of three boxes of expired triglyceride reagent. A) During a tour of the laboratory on 8/22/19 at approximately 04:00 PM one of three boxes of Vitros Triglyceride reagent lot number 0734-3427-6783 with expiration date of 7/6/19 was observed in the chemistry reagent storage freezer. B) In an interview on 8/22/19 at approximately 04:00 PM laboratory staff members, identified as numbers three and seven on the CMS 209 form, confirmed that the reagent identified above had expired and was available for use. 2. The laboratory used expired reagent to perform triglyceride assays on patients in July 2019. A) Review of calibration records for the Vitros chemistry analyzer revealed that Vitros Triglyceride reagents, lot number 0734-3427-6783 expiration date 7/6/19, were in use until 8/8/19. B) Review of patient result reports for the dates of 7/12/19 through 7/18/19 inclusive revealed that triglyceride assays were performed and reported on forty-nine patients. C) In an interview on 8/22/19 at approximately 4:45 PM, the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the triglyceride reagent identified above expired on 7//6/19 and had been used to perform and report triglyceride assays on patients after 7/6/19 until 8/8/19.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Through a review of the manufacturer's requirements, documentation of calibrations, and interview with laboratory staff, it was determined the laboratory failed to perform calibration with at least the frequency recommended by the manufacturer. Survey findings follow: A. The manufacturer of the Viitros 350 chemistry analyzer requires calibration at least every six months. B. Calibration of the Vitros 350 chemistry analyzer was documented on 10/24/18 and not again until 8/8/19 (approximately three months late). C. In an interview at approximately 4:45 PM on 8/22/19, the laboratory staff member, identified as number three on the CMS 209 form, confirmed the calibration of the Vitros 350 chemistry instrument was not performed on time.
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: Through review of the manufacturer's manual for the Beckman Access Immunochemistry instrument, laboratory temperature and humidity level records, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to take corrective actions on three of twenty-three days of operation in January 2019 when laboratory humidity level was below the instrument's operational requirement. Findings follow: A) Review of the manufacturer's manual for the Beckman Access immunochemistry analyzer revealed that the instrument had an operating humidity requirement of 20% to 80%. B) Review of the laboratory's room temperature and humidity records revealed that room humidity was recorded as below 20% on January 29th through January 31st, 2019 inclusive. C) Upon request, the laboratory was unable to provide documentation of corrective action when humidity levels were below required levels on the dates identified above. D) In an interview on 8/22/19 at approximately 03:45 PM, the laboratory staff member identified as number three on the CMS 209 form, confirmed that humidity levels on the dates identified above were below required levels and no corrective action had been initiated.