Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398011	12/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
La Clinica De Los Campesinos, Inc	400 S Townline Rd, Wautoma, WI	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory procedure manual and records received by the Wisconsin state agency, and interview with the laboratory director, the laboratory procedures have not been approved, signed, and dated by the current laboratory director since April 2017 when the current lab director assumed the role. Findings include: 1. Review of the laboratory procedure manual shows no evidence of review and approval of procedures by the current laboratory director. 2. Review of State Agency records show the laboratory changed the director to the current director effective April 3, 2017. 3. Interview with the laboratory director on December 27, 2018 at 11:15 AM confirms the procedures in use in the laboratory have not been approved, signed and dated by the current director.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on surveyor review of proficiency testing (PT) records and interview with the laboratory director, the laboratory director did not ensure an approved corrective action plan was developed for an unacceptable PT result for the second hematology event in 2018. Findings include: 1. Review of hematology PT records show an unacceptable platelet result for Specimen D for event two in 2018. Acceptable range was 57,000 per microliter to 97,000 per microliter. The laboratory reported 100,000 per microliter. There was no evidence of a plan of correction in the records reviewed for the unacceptable PT result for platelets. 2. Interview with the laboratory director on December 27, 2018 at 11:30 AM confirmed the laboratory director did not ensure that an approved corrective action plan was developed for the unacceptable PT result.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor review of competency evaluation records and interview with the technical consultant, the technical consultant did not document the semi-annual evaluation of competency for two of two new testing personnel during the first year the individuals performed testing. Findings include: 1. Review of competency evaluation records for testing personnel A and B shows no semi-annual evaluation of competency during the first year of testing. Initial competency evaluation was documented in November 2017 for testing personnel A, and August 2017 for testing personnel B. No additional competency evaluations were available for testing personnel A and B. 2. Interview with the technical consultant on December 27, 2018 at 10:30 AM confirms the semi-annual competency evaluations were not documented for testing personnel A and B.