Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1042724	09/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clinica Familiar San Jose Pa	8030 N Fm 1015 Ste B, Mercedes, 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	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended. The laboratory ceased moderate complexity bacteriology testing and therefore, this specialty will be removed from the facility's CLIA certificate.
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 review of laboratory policy, review of manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy to resolve abnormal CBC (complete blood count) results with flags. The findings were: 1. This is a repeat deficiency from the survey conducted June 11, 2019. 2. Review of laboratory's policy titled, "Policy for Abnormal Differentials" approved by the laboratory director on March 18, 2014 revealed the policy was written for the facility's previous analyzer. The policy stated, "It will be the policy of this laboratory to send out abnormal differentials to the reference lab based on the Laboratory Directors [sic] discretion. The Laboratory Director will determine if an abnormal differential is required post evaluating CBC results and assessing the patient's clinical findings..." 3. Review of the manufacturer's instructions for the Sysmex XP-300 (Code No. AU553517, Revision: July 2017) under "8.3 Histogram flags" it stated, "AG: Correction: 1) Check smear, etc." The table went on to list further flags, their probable cause, and correction. 4. Random review of 10 patient results from August 2021 and September 2021 found the following 3 of 3 patient reports that flags were not resolved prior to their release to the healthcare provider.

	See patient alias list 5. The laboratory was asked to provide documentation of resolving abnormal results prior to their release to the provider. No documentation was provided. 6. An interview with the Technical Consultant on September 20, 2021 at 14:30 hours in the office confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor observation, review of patient results, and confirmed in interview of laboratory personnel, the laboratory failed to ensure at least two unique patient identifiers were available on 2 of 10 patient final reports reviewed. The findings were: 1. This is a repeat deficiency from the survey conducted on June 11, 2019. 2. Review of patient records from August and September 2021 revealed the following 3 of 10 patient results were finalized with one or less unique identifiers. Sample ID 1st name only 07-15-2019 Sample ID Room 2 Date of birth not legible Sample ID 10-08-2015 3. An interview with the primary testing person on September 20, 2021 at 14:50 hours in the office confirmed the findings. She agreed that without at least two patient identifiers, she would not know the correct chart to scan results to.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory policies, and confirmed in interview of facility personnel, the laboratory's quality assurance plan failed to identify and correct that instrument records were incomplete due to poor printer quality. The findings were: 1. Review of the laboratory's Quality Assurance Plan approved by the laboratory director on July 3, 2007 stated, "2. Identify problems in our laboratory and apply corrective actions..." 2. Review of quality control records over time from May 2021 to August 2021 were incomplete due to poor printer quality. The complete record was not legible. 3. Review of patient records from August and September 2021 were not legible due to poor printer quality. 4. An interview with the primary testing person and the technical consultant on September 20, 2021 at 15:00 hours confirmed the findings. They stated that the drum had been replaced but it did not fix the problem and that most likely a new printer was needed.