

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0919679	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Clinica Hispana Ii	Street Address, City, State 9720 Jones Rd, #240, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and records and confirmed in interview, the laboratory failed to follow its own policy to verify flags generated by the Medonic M-series hematology analyzer. Findings were: 1. Review of the laboratory policy Medonic Series M Hematology Analyzer reviewed 12/10/15 revealed under Sample Review System information messages result when instrument detects circumstances that require the attention of the operator. NOTE: If parameter or system information messages are generated, refer to user manual section 9. Following flags cover abnormalities in the WBC differential and indicate a possible problem with accuracy of the results. OM **Flags generated by the system will be verified before reporting to physicians. Sample will be rerun. Upon repeat if flag persists, sample will be sent out to Reference lab to validate the lab results. Physician may ask patient for a follow up visit based on clinical history and symptoms or until results are validated. Patient management and treatment is at physicians' discretion. Upon receiving the reference lab result, it will be scanned along with lab result on patient chart accordingly. Result</p>

will be then filed in the lab binder called "Medonic Abnormal Flag Verification - Patient Reports" 2. Random review of the laboratory patient test records from June 2017 - December 2017 revealed 2 of 10 flagged sample results that had no documentation of results from a reference to validate the lab results. Date Sample ID Flags 06/05/17 06101983 OM 07/10/17 02161954 OM 3. Interview with the technical consultant and testing person #1 on 01/25/18 at 1045 hours in the laboratory confirmed the above findings. Testing person #1 acknowledged that the above specimens should have been sent to the reference lab. OM - only one blood population found

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and records and confirmed in interview, the laboratory quality assessment policy failed to identify flags generated by the Medonic M-series hematology analyzer were not sent to the reference lab for verification of lab results. Refer to D5401

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and records and confirmed in interview, the laboratory director failed to ensure the laboratory follow its own policy to verify flags generated by the Medonic M-series hematology analyzer. Refer to D5401