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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0919679 | (X3) Date Survey Completed 10/14/2019 |
| 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 | <p>The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 D6063 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's policies, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of competency assessments performed in 2018 and 2019 for 1 of 1 technical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 10/4/19) identified one technical consultant employed by the laboratory. 2. A review of the laboratory's policy titled 'New Employee Orientation, Training, and Assessment' revealed the following: "Each employee will be given an evaluation for competency at six months from hire and annually</p> |

thereafter. 3. A review of the laboratory's personnel records for the technical consultant revealed 2 forms titled 'Technical Consultant Competency Checklist'. Further review of the forms revealed the following: a) Technical Consultant Competency Checklist Conducted by: Laboratory Director Date of Inspection: 12-2-18 b) Technical Consultant Competency Checklist Conducted by: Laboratory Director Date of Inspection: 10-1-19 c) The 2 forms titled 'Technical Consultant Competency Checklist' defined the following position responsibilities: Technical Consultant's Qualifications & Experience Met: Yes/No Accessibility to laboratory: On-site, telephone or electronic consultation Met: Yes/No Review and Establish Quality Control Program Met: Yes/No Establish Protocols/Procedures to maintain accuracy and reliability of test results Met: Yes/No Establish Proficiency Testing Program: Review of proficiency testing including remedial actions for unsatisfactory results Met: Yes/No Establish Quality Assurance Program Policy Met: Yes/No Resolve test system problems for accurate patient results reporting Met: Yes/No Establish Employee Training and Competency Program Met: Yes/No Evaluate training and competency needs for staff as appropriate Met: Yes/No Review of test results, QC records, PT results and PM Met: Yes/No Assess & Solve Problems Met: Yes/No Monitor employee performance Met: Yes/No On both forms, the laboratory director did not indicate whether the position responsibilities were met or not. 4. An interview with the technical consultant on 10/14/19 at 09:50 a.m. in the office, after review of the records, confirmed the above findings. Key: QC= Quality Control PT= Proficiency Test PM= Preventative Maintenance

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, a review of patient test results, and staff interview, it was revealed that the laboratory failed to have documentation of training for 1 of 3 testing personnel on the Medonic M Series hematology analyzer prior to performing patient testing (refer to D6066).

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's personnel records and staff interview it was

revealed the laboratory failed to ensure testing personnel were qualified. Findings include: 1. The laboratory failed to have documentation of the education for 1 of 3 testing personnel in order to qualify them to perform moderate complexity testing (refer to D6065). 2. The laboratory failed to have documentation of training for 1 of 3 testing personnel on the Medonic M Series hematology analyzer prior to performing patient testing (refer to D6066).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education for 1 of 3 testing personnel in order to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 10/4/19) revealed 3 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the education for 1 of 3 testing personnel. The testing person missing the documentation of education: Testing Person #3 3. The laboratory was asked to provide the documentation of education. No documentation was provided. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 10/4/19 at 11:20 a.m. in the office, she stated, "She is from California. There, a high school diploma is not required to get certified. She was supposed to go back and get her GED but never did." This confirmed the above findings. Key: GED= General Educational Development

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, a review of patient test results, and staff interview, it was revealed that the laboratory failed to have documentation of training for 1 of 3 testing personnel on the Medonic M Series hematology analyzer prior to performing patient testing. Findings include: 1. A review of the laboratory's submitted CMS 209

form (signed by the laboratory director on 10/4/19) revealed the laboratory identified 3 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that testing person #3 did not have documentation of training on the Medonic M Series hematology analyzer prior to performing patient testing. 3. A review of patient test results revealed testing person #3 resulted 1 patient's (ID 04122012) CBC (complete blood count) test on 3/8/18. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 10/4/19 at 10:15 a.m. in the office revealed the laboratory did not have documentation of training on the Medonic M Series hematology analyzer for testing person #3. The technical consultant also stated, "She only filled in for testing person #1 while she was on a break." This confirmed the above findings.