

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2092481	<b>(X3) Date Survey Completed</b> 01/25/2018
<b>Name of Provider or Supplier</b> Industrial Family Day & Night Clinic	<b>Street Address, City, State</b> 6201 S Cage Blvd Suite #6, Pharr, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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. 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.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Siemens Microalbumin 2 test strips, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for the frequency of quality control testing. The findings were: 1. A review of the manufacturer's instructions for the Siemens Microalbumin 2 test strips (TN73024A, revision 10/10) under the section titled "Quality Control" revealed the manufacturer required quality control testing to be performed every 30 days. 2. A review of the laboratory's quality control records from February 2017 to November 2017 revealed the laboratory performed quality control testing on the</p>

following days: February 23, 2017 April 4, 2017 (40 days later) May 8, 2017 (34 days later) May 29, 2017 (21 days later) June 29, 2017 (31 days later) August 3, 2017 (35 days later) September 12, 2017 (40 days later) October 10, 2017 (28 days later) November 10, 2017 (31 days later) 3. The laboratory was asked to provide documentation of performing quality control testing every 30 days. No documentation was provided. 4. An interview with the technical consultant on 01/25/2018 at 1215 hours in the office - after his review of the records- confirmed the findings.

**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 the laboratory's policies, review of patient test records from 11/02 /2017 to 01/25/2018, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for repeating CBC (complete blood count) results. The findings were: 1. A review of the laboratory's policy titled "Policy for Repeating CBC Tests" (approved by the laboratory director on 06/01/2015) revealed:" In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat test when patient results are outside the following range: RBC less than 4.00 or greater than 6.00 million WBC less than 4.0 or greater than 20.0 thousand HCT less than 30% or greater than 50% HGB less than 10 or greater than 18 mg/% PLT less than 150 or greater than 450 thousand 2. A review of patient test records from 11/02/2017 to 01/25/2018 identified the following patients whose results met the laboratory's criteria for repeat testing: Date Sequence Test 11/03 3731 RBC: 3.60 11/07 3776 RBC: 3.93 11/10 3821 PLT: 107 11/30 4042 PLT: 143 12/05 4097 PLT: 120 12/05 4102 RBC: 3.25 12/11 4169 PLT: 130 12/21 4308 RBC: 3.95 12/27 65 PLT: 85 01/02 106 HCT: 58.5 01/04 143 RBC: 6.04 01/05 157 PLT: 142 01/09 205 PLT: 127 01/09 208 PLT: 99 01/09 209 PLT: 112 01/10 228 RBC: 3.99 01/15 278 RBC: 71 01/16 301 RBC: 3.99 01/19 348 PLT: 111 3. The laboratory was asked to provide documentation of repeating the identified tests as required by its policy. No documentation was provided. 4. An interview with the technical consultant on 01/25 /2018 at 1100 hours in the office - after his review of the records- confirmed the findings. Key RBC: red blood cell WBC: white blood cell HCT: hematocrit HGB: hemoglobin PLT: platelet