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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D0887476 | <b>(X3) Date Survey Completed</b><br>09/18/2018 |
| <b>Name of Provider or Supplier</b><br>Healing Hands Pllc Pharr  | <b>Street Address, City, State</b><br>105 E Polk Avenue, 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>  |
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| <b>D0000</b>              | The laboratory was surveyed on September 19, 2018 and found to be out of compliance with the CLIA regulations at: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; 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.   |
| <b>D2010</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency test records, review of patient test results, and confirmed in interview of facility personnel, the laboratory failed to test PT (proficiency testing) samples the same number of times it tests patient samples. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on January 1, 2004 stated, "PT specimens are to be treated the same as patient samples ..." 2. Review of the laboratory's policy titled, "Policy for Repeating CBC Tests" approved by the laboratory director on November 18, 2011, stated, "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following ranges: RBC less than 3.5 or greater than 7.00 million WBC less than 3.5 or greater than 20.00 thousand HCT less than 30% or greater than 46% HGB less than 10 or greater than 18MG% PLT less than 100 or greater than 450 thousand 3. Review of API proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed the following PT samples did not meet the laboratory's repeat criteria but were repeated: 2016 (event 3) ID: HEM-15 Tested: 11-17-16 @ 10:42 11-</p> |

17-16 @ 10:48 2017 (event 3) ID: HEM-12 Tested: 11-17-17 @ 12:35 11-17-17 @ 12:38 2018 (event 1) ID: HEM-02 Tested: 03-15-18 @ 10:31 03-15-18 @ 10:32 4. The findings were confirmed in interview with the technical consultant on 09/19/2018 at 0930 hours in the office. Key: CBC - complete blood count

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's policies, manufacturer's instructions, surveyor observation, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of a policy that ensured the verification of CBC (complete blood counts) results with flags. (refer to D5403)

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies, manufacturer's instructions, surveyor observation, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of a policy that ensured the verification of CBC (complete blood counts) results with flags. The findings were: 1. This is a repeat deficiency from the survey dated August 25, 2016. 2. A review of the manufacturer's instructions for the Coulter Act diff hematology analyzer (PN 4237416DA) under the section titled "Table 6.4 What Flags Mean" revealed the manufacturer identified the following flags: 1 2 3 4 M The manufacturer then listed the suggestion action to

address these flags as "Verify results according to your laboratory's protocol." 2. A review of the laboratory's policy titled "Policy for Abnormal Differentials" approved by the laboratory director on November 18, 2011 stated: "It will be the policy of this laboratory to review all abnormal differentials. A normal differential will be described as having only normal cells; lymphocytes, monocytes, basophils, eosinophils, neutrophils, and normal size and shape of RBCs and platelets." and; "If your CBC instrumentation is showing alarms (R1, R2, M3, etc.) in the differential section of the report, it will be considered an abnormal differential and should be repeated and reported to the physician/provider. Physician/provider will then determine if the CBC will be sent out for a manual differential. They will take into consideration the patient's clinical findings during the patient's medical evaluation. They physician /provider will then instruct the testing personnel on any follow up action." 3. A random review of patient results from August and September 2018 revealed the following patient results with flags. Day ID# Flag (s) 08-06-18 012152003 \* 08-13-18 008082000 3 08-29-18 010212014 M 08-29-18 008172012 2, \* 08-30-18 010122016 M 09-05-18 005112015 2, 3 09-05-18 012012010 \* 09-06-18 002062015 \* 09-06-18 012052013 2, 3 4. The laboratory was asked to provide documentation of a policy to verify flags prior to their release to the healthcare provider. No documentation was provided. 5. An interview with the technical consultant on 09/19/2018 at 0930 hours in the office confirmed the findings. She revealed the laboratory had an updated policy but it could not be located.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policy, review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory director failed to ensure flags on CBC results were resolved prior to their release to the healthcare provider. (refer to D5403) Key: CBC - complete blood count