

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1052268	<b>(X3) Date Survey Completed</b>  03/06/2018
<b>Name of Provider or Supplier</b>  Yesroon Patel Md Pa	<b>Street Address, City, State</b>  100 B Alton Gloor Suite 120, Brownsville, 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>	<p>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.</p>
<b>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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: Based on review of the laboratory's policies, review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples the same number of times it routinely tested patient samples. The findings were: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved by the laboratory director on 01/23/2016) revealed: "It will be the policy of this laboratory to rerun flagged CBC results..." 2. A review of the laboratory's policy titled "Proficiency Testing" (approved by the laboratory director on 02/08/2008) revealed: "PT specimens are to be treated the same as patient samples." 3. A review of the laboratory's American Proficiency Institute's</p>

proficiency testing records from 2016 (events 1, 2 and 3) and 2017 (events 1, 2, and 3) revealed the following proficiency samples whose results were flagged, however the laboratory failed to have documentation of repeating them: a) 2016 event 2 Sample Flag(s) HEM-06 L2, L5 HEM-07 L5 HEM-08 L5, R1 HEM-09 L5, R1 HEM-10 L5 b) 2017 event 1 Sample Flag(s) HEM-01 L5 HEM-02 L5, R1 HEM-03 L5 HEM-04 L2, L5 HEM-05 L5, R1 c) 2017 event 2 Sample Flag(s) HEM-06 L5 HEM-07 L2, L5 HEM-08 L5 HEM-09 L5 HEM-10 L2, L5 d) 2017 event 3 Sample Flag(s) HEM-11 L5, R1 HEM-12 L5 HEM-13 L5 HEM-14 L2, L5, R1 HEM-15 L5, R1 4. The laboratory was asked to provide documentation of repeating the proficiency samples with flags as it would patient samples. No documentation was provided. 5. An interview with the technical consultant on 03/06/2018 at 1245 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 December 2017 to February 2018, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for repeating CBC (complete blood count) tests. The findings were: 1. A review of the laboratory's policy titled "Revised Policy for Repeating CBC Tests" (approved by the laboratory director on 11/30/2014) revealed: "Effective 12/01/2014, in an effort to ensure accuracy inpatient CBC testing, it is the policy of this laboratory to repeat test when patient results are outside the following ranges: RBC less than 4.0 or greater than 6.00 million WBC less than 4.0 or greater than 17.0 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 December 2017 to February 2018 identified the following patients which met the laboratory's criteria for repeat testing, however the laboratory failed to have documentation of repeating the test. They were: Date ID Test 12/05 00003179 PLT: 116 12/17 00001392 PLT: 109 01/02 00003961 PLT: 133 01/11 00004126 PLT: 142 01/20 00003946 PLT: 146 02/02 00004562 PLT: 142 02/06 00004059 PLT: 148 02/24 00004567 PLT: 144 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 03/06/2018 at 1245 hours in the office - after his review of the records- confirmed the findings. Key WBC - white blood cell RBC - red blood cell HCT - hematocrit HGB - hemoglobin PLT - platelet

**D5813**

**TEST REPORT**  
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of patient test records from February 2018, review of the laboratory's "Critical Value Log", and staff interview, it was revealed the laboratory failed to have documentation of the notification of panic values. The findings were: 1. A review of the laboratory's policy titled "Reporting Panic Values" (approved by the laboratory director on 02/08/2008) revealed: "It is the policy of this laboratory to document the reporting of Panic Values. Document: - who was notified - when was the person notified - by who was the person notified 2. A review of the laboratory's policy titled "Panic Values" (approved by the laboratory director on 02/08/2008) revealed the laboratory defined its panic values as: WBC less than 2 or greater than 20 HGB less than 7.5 or greater than 18 HCT less than 25 or greater than 55% PLT less than 50 or greater than 800 3. A review of the patient test results from February 2018 identified the following patients whose results met the laboratory's criteria as a panic value: Date ID Test 02/05 00004409 WBC: 30.7 02/09 00004563 WBC: 24.0 4. A review of the laboratory's Critical Value log revealed neither results was documented as required by the laboratory's policy. 5. The laboratory was asked to provide documentation of the notification of the identified panics to the provider. No documentation was provided. 6. An interview with the technical consultant on 03/06/2018 at 1245 hours in the office - after his review of the records- confirmed the findings. Key WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet