

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1009254	(X3) Date Survey Completed 09/08/2021
Name of Provider or Supplier Jorge Mazzini Md	Street Address, City, State 765 Paredes Line Rd Suite A, Brownsville, 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	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 laboratory policy, review of the laboratory's proficiency testing records, and staff interview, it was revealed the laboratory failed to test proficiency samples in the same manner it tested patient samples. The findings were: 1. A review of the laboratory's Proficiency Testing policy approved by the laboratory director on May 20, 2003 stated: "PT specimens are to be treated the same as patient samples. The lab should document all steps taken in PT performance." 2. A review of the laboratory's Critical Values policy approved by the laboratory director on February 13, 2013 stated WBC: 2000 - 20,000 HGB: 7.5 - 18 HCT: 25 - 55 Platelets: 50,000 - 800,000 3. When the primary testing person was asked in interview on September 8, 2021 at 09:30 hours if the laboratory's routine practice was to repeat patient critical values for confirmation, she stated, "Yes." Review of instrument printouts from the Medonic M series hematology analyzer from May 2021 to September 2021 confirmed that the laboratory routinely repeated critical values for the hematology analytes WBC, HGB, HCT, and Platelets. 4. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 (events 1, 2, and 3), 2020 (events 1, 2, and 3), and 2021 (events 1 and 2) revealed the laboratory failed to test proficiency samples the same number of times it tested patient samples: 03-28-2019 HSY-01 HGB: 5.9 Not repeated 07-24-2019 HSY-08 HGB: 6.0 Not repeated 11-27-2019 HSY-12 HGB: 6.1 HCT: 18.1 Not repeated 11-27-2019 HSY-13 HGB: 18.5</p>

HCT: 57.1 03-26-2020 HSY-03 HGB: 2.1 HCT: 18.3 07-27-2020 HSY-06 HGB: 18.8
HCT: 55.4 11-24-2020 HSY-14 HGB: 6.2 HCT: 17.7 03-31-2021 HSY-02 HGB: 7.1
HCT: 20.8 03-31-2021 HSY-03 HGB: 18.2 HCT: 57.5 08-04-2021 HSY-08 HGB: 6.2
HCT: 18.8 5. An interview with the technical consultant on 09/08/2021 at 09:40 hours
in the office after his review of the records confirmed the findings. Key: PT -
proficiency testing WBC - white blood cell HGB: hemoglobin HCT: hematocrit PLT -
platelets