

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1009254	(X3) Date Survey Completed 04/08/2025
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
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Casper Report 155 Individual Laboratory Profile, proficiency testing records for 2024 and interview of facility personnel, the laboratory failed to participate in one of three proficiency testing events for the specialty of Hematology. The findings include: 1. Review of the Casper Report 155 Individual Laboratory Profile found the laboratory received a score of 0% in the 2024 third testing event for Hematology. 2 A review of the American Proficiency Institute (API) proficiency testing records found no documentation of corrective actions for the missed event. 3. During interview of testing person one on the CMS Report 209 Laboratory Personnel Report conducted April 8, 2025 at 1:34 PM she confirmed that the results were not submitted to the PT agency for grading prior to the final submission.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:

Based upon review of the laboratory's proficiency testing records and interview of facility personnel found the laboratory failed to document the review of proficiency testing results for three of three Hematology proficiency testing events in 2024 The findings included: 1. Review of the 2024 American Proficiency Institute proficiency testing records found the laboratory failed to document the review of three of three Hematology testing events. 2. During interview of the technical consultant conducted April 8, 2025 at 1:29 PM he confirmed that he had not documented his review of the proficiency results.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

A. Based upon review of policies and procedures, quality control records and interview of facility personnel, the laboratory failed to document corrective actions when Hematology quality control results failed to meet the laboratory's acceptable criteria on 7 of 28 days in February 2025. The findings included: 1. Review of the CONTROL POLICY (signed by the laboratory director 5-29-14) found : "Controls results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. Use the "QC Out of Limits Log Sheet" to record controls and remedial actions when controls are outside the expected range. Additionally, use the Daily Control Sample Troubleshooting Checklist" found in this section, to help you resolve daily control problems. All control records and Remedial Action Sheets will be reviewed, signed/initialed, and dated monthly by the Laboratory Technical Consultant." 2. Review of Hematology data logs for February 2025 found quality control results failed to meet the laboratory's acceptable criteria on the following dates: 02/03/2025 13:10 - 2240931 - RBC exceeded acceptable limits 13:19 - 2240933 - RBC exceeded acceptable limits 02/04/2025 10:22 - 2241232 - RBC exceeded acceptable limits 02/05/2025 10:10 - 2241233 - RBC and MCH exceeded acceptable limits 02/06/2025 09:09 - 2241231 - HGB exceeded acceptable limits 02/10/2025 09:26 - 2241231 - HGB and WBC exceeded acceptable limits 09:30 - 2241232 - HGB exceeded acceptable limits 02/12/2025 10:15 - 2241232 - HGB and WBC exceeded acceptable limits 10:17 - 2241231 - HGB and WBC exceeded acceptable limits 10:20 - 2241233 - HGB and WBC exceeded acceptable limits 02/13/2025 10:19 - 2241232 - HGB exceeded acceptable limits 10:53 - 2241231 - HGB, MCH and MCHC exceeded acceptable limits Continued review of quality control records found no documentation of corrective actions taken when quality control results failed to meet the laboratory's acceptable limits for the dates listed. 3. During interview of the Technical Consultant conducted April 8, 2025 at 2:44 PM, he confirmed testing personnel did not document corrective actions when quality control results failed to meet the acceptable criteria as defined in the laboratory's own written policy. B. Based upon review of policies and procedures, quality control records and interview of facility personnel, the laboratory failed to ensure at least two levels of Hematology quality control materials met the laboratory's acceptable limits before reporting patient results on 3 of 28 days in February 2025. The findings included: 1. Review of the

CONTROL POLICY (signed by the laboratory director 5-29-14) found : "Patients testing must not be performed or reported when controls results are outside of the expected range for two of three controls per analytes." All control records and Remedial Action Sheets will be reviewed, signed/initialed, and dated monthly by the Laboratory Technical Consultant." 2. Review of Hematology data logs for February 2025 found the laboratory failed to have at least two of three acceptable quality control results on the following dates and reported six patient CBC results: 02/10/2025 09:26 - 2241231 - HGB and WBC exceeded acceptable limits 09:30 - 2241232 - HGB exceeded acceptable limits The laboratory tested and reported results for patients 87394 and 85776 without two levels of acceptable quality control results for Hemoglobin (HGB). 02/12/2025 10:15 - 2241232 - HGB and WBC exceeded acceptable limits 10:17 - 2241231 - HGB and WBC exceeded acceptable limits 10:20 - 2241233 - HGB and WBC exceeded acceptable limits The laboratory tested and reported results for patients 84564 and 74309 without two levels of acceptable quality control results for Hemoglobin (HGB) and White Blood Cells (WBC). 02/13/2025 10:19 - 2241232 - HGB exceeded acceptable limits 10:53 - 2241231 - HGB, MCH and MCHC exceeded acceptable limits The laboratory tested and reported results for patients 82721 and 82358 without two levels of acceptable quality control results for Hemoglobin (HGB). Continued review of quality control records found no documentation of remedial actions for patient results reported when quality control results failed to meet the laboratory's acceptable limits for the dates listed. 3. During interview of the Technical Consultant conducted April 8, 2025 at 2:44 PM, he confirmed testing personnel did not document corrective actions when quality control results failed to meet the acceptable criteria as defined in the laboratory's own written policy.