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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D1009254 | (X3) Date Survey Completed 01/18/2023 |
| 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 | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended. |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS 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 HemoCue Hb 201 Microcuvettes, surveyor observation of microcuvettes currently in use in the laboratory, and staff interview, it was revealed the laboratory failed to have documentation of monitoring the revised expiration date of the microcuvettes once the package was opened. The findings include: 1. A review of the manufacturer's instructions for the HemoCue Hb 201 Microcuvettes (151712140726) under the section titled "Storage and Handling" revealed: "Once the seal is broken the microcuvettes are stable for three months." 2. Surveyor observation of the microcuvettes currently in use revealed the laboratory failed to have documentation of when the microcuvettes were opened or when the microcuvettes would expire based the the manufacturer's instructions. 3. An interview with the technical consultant on 01 /18/2023 at 1100 hours in the exam room - after his review of the records- confirmed the findings.</p> |
| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient</p> |

workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to ensure 1 of 3 testing personnel participated in proficiency testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 revealed 1 of 3 testing personnel did not participate in proficiency testing. They were (as listed on Form CMS 209): Testing personnel number 3 3. The laboratory was asked to provide documentation on testing personnel number 3 participating in proficiency testing. No documentation was provided. 4. An interview with the technical consultant on 01/18/2023 at 940 hours in the exam room - after his review of the records- confirmed the findings.

D2010

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(2)

The laboratory must test samples the same number of times that it routinely tests patient samples.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to test proficiency testing samples the same number of time it tested patient samples. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 (Events 1, 2, and 3) revealed the laboratory tested each proficiency sample twice. The dates and times of each were as follows: a) Event 1 Sample Date/Time HSY-1 3/24 11:20 3/24 11:33 HSY-2 3/24 11:23 3/24 11:35 HSY-3 3/24 11:24 3/24 11:37 HSY-4 3/24 11:27 3/24 11:40 HSY-5 3/24 11:30 3/24 11:42 b) Event 2 HSY-6 7/21 10:27 7/21 10:38 HSY-7 7/21 10:30 7/21 10:40 HSY-8 7/21 10:32 7/21 10:42 HSY-9 7/21 10:32 7/21 10:45 HSY-10 7/21 10:36 7/21 10:47 c) Event 3 HSY-11 11/28 18:22 11/28 18:32 HSY-12 11/28 18:24 11/28 18:33 HSY-13 11/28 18:26 11/28 18:35 HSY-14 11/28 18:28 11/28 18:37 HSY-15 11/28 18:30 11/28 18:38 2. An interview with the technical consultant on 01/18/2023 at 0935 hours in the exam room revealed the laboratory did not routinely test patient samples in duplicate. This confirmed the findings.

D3000

FACILITY ADMINISTRATION

CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such

timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's test menu, review of the laboratory's patient test logs from July 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of reporting 129 of 129 positive Covid Antigen results to the State/local authorities as required. The findings include: 1. A review of the laboratory's test menu revealed the facility started performing Covid Antigen testing utilizing the Lumira DX SARS-CoV-2 Ag test in February 2022. 2. A review of the laboratory's patient test logs from July 2022 to December 2022 revealed the laboratory had a total of 129 positive Lumira DX SARS-CoV-2 Ag results. The numbers, by month, were: July 2022 28 positive August 2022 44 positive September 2022 18 positive October 2022 10 positive November 2022 8 positive December 2022 21 positive 3. The laboratory was asked to provide documentation of positive results being reported to the State/local authorities and of a policy stating how and when positive results were to be reported. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 01/18/2022 at 1115 hours in the exam room revealed she did not have documentation of positive results being reported as required. This confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's maintenance records from January 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing 8 of 26 biweekly maintenances and 1 of 4 Three Month maintenances. The findings include: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer revealed the following maintenance was required: a) Every two weeks Clean Aspiration Probe Aspirate Sol. No.2 in PD Aspirate Diluent in PD Perform Clean Orifice x 3 Clot Prevention Run Background b) 3 Month Cleaning Hypochlorite 2% Enzymatic Cleaner Detergent Cleaner 2. A review of the laboratory's Medonic M-series maintenance records from January 2022 to December 2022 revealed the laboratory was missing documentation of the following maintenances: a) Every two weeks Missing: 3/3 4/21 6/24 8/14 9/8 10/14 12/1 12/19 b) 3 Month Cleaning Missing: November 2022 3. The laboratory was asked to provide documentation of the missing maintenance. No documentation was provided. 4. An interview with the technical consultant on 01/18/2023 at 1030 hours in the exam room - after his review of the records- confirmed the findings.