

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0933840	<b>(X3) Date Survey Completed</b>  08/26/2025
<b>Name of Provider or Supplier</b>  Clinica Santa Maria	<b>Street Address, City, State</b>  3855 Southmost Road, 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>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Cell-Dyn Emerald maintenance records from January 2023 to August 2025, and staff interview, the laboratory failed to have documentation of performing semiannual maintenance for 3 of 5 occurrences. The findings included: 1. A review of the manufacturer's required maintenance for the Cell-Dyn Emerald hematology analyzer from January 2023 to August 2025 determined the laboratory was required to perform semiannual maintenance of lubricating the pistons. Further review determined the laboratory failed to have documentation of performing 3 of 5 occurrences of semiannual maintenance. Maintenance was documented on 4/2023 and 4/2024. The laboratory was missing documentation for 10/2023, 10/2024, and 4/2025. 2. Testing personnel number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 08/26/2025 at 1015 hours in the laboratory.</p>
<b>D5783</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory HDL (high density lipoprotein) quality control records from March 2025, review of patient test records from March 2025, and staff interview, the laboratory failed to have documentation of remediating 9 of 9 patients tested prior to a quality control failure. The findings included: 1. A review of the laboratory's HDL quality control records from March 2025 determined quality control testing failed on 3/13/2025. Level 1, Level 2, and Level 3 each failed. Calibration was performed and quality control was retested. The retest was successful. Thus, patients tested since the last successful quality control run (3/12/2025) were required to be remediated. 2. A review of patient test records from 3/12/25 determined the following patients were tested: Patient ID MM0000000659 99320 103590 123655 104788 MM0000000796 121803 3085100 103509 3. Testing personnel stated patients were not remediated during an interview conducted on 08/26/2025 at 1145 hours in the laboratory.