

|                                                                                                                            |                                                                                          |                                                     |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D0933273               | <b>(X3) Date Survey Completed</b><br><br>07/28/2026 |
| <b>Name of Provider or Supplier</b><br><br>Medical Associates Of Brownsville Pa                                            | <b>Street Address, City, State</b><br><br>425 E Los Ebanos Blvd Ste 100, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D5441              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's Triage Cardiac quality control records from December 2025 to June 2026, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends for 7 of 7 months. The findings included: 1. A review of the laboratory's Triage Cardiac quality control records from December 2025 to June 2026 determined the laboratory performed quality control testing for CKMB, Troponin, and Myoglobin on the Triage MeterPro on the following days: a) December 16, 2025 Level 1 - Lot: 04170 Level 2 - Lot: 04171 b) January 15, 2026 Level 1 - Lot: 04170 Level 2 - Lot: 04171 c) February 2, 2026 Level 1 - Lot: 04170 Level 2 - Lot: 04171 d) March 9, 2026 Level 1 - Lot: 04177 Level 2 - Lot: 04170 e) April 2, 2026 Level 1 - Lot: 04177 Level 2 - Lot: 04170 f) May 22, 2026 Level 1 - Lot: 04201 Level 2 - Lot: 04211 g) June 6, 2026 Level 1 - Lot: 04201 Level 2 - Lot: 04211 2. The laboratory did not have documentation of monitoring quality control results to identify any possible shifts or trends over time. 3. The technical consultant confirmed the findings in an interview conducted on 07/28/2026 at 1515 hours in the conference room.</p> |
|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Triage Cardiac quality control records from December 2025 to June 2026, review of patient test records from December 2025 to June 2026, and staff interview, the laboratory failed to have documentation of performing quality control testing each day of patient testing for 7 of 9 test days. The findings included: 1. A review of the laboratory's Triage Cardiac quality control records from December 2025 to June 2026 determined the laboratory performed quality control testing for CKMB, Troponin, and Myoglobin on the Triage MeterPro on the following days: a) December 16, 2025 Level 1 - Lot: 04170 Level 2 - Lot: 04171 b) January 15, 2026 Level 1 - Lot: 04170 Level 2 - Lot: 04171 c) February 2, 2026 Level 1 - Lot: 04170 Level 2 - Lot: 04171 d) March 9, 2026 Level 1 - Lot: 04177 Level 2 - Lot: 04170 e) April 2, 2026 Level 1 - Lot: 04177 Level 2 - Lot: 04170 f) May 22, 2026 Level 1 - Lot: 04201 Level 2 - Lot: 04211 g) June 6, 2026 Level 1 - Lot: 04201 Level 2 - Lot: 04211 2. A review of the laboratory's patient test records from December 2025 to June 2026 determined patient samples were tested on the following days without quality control testing being performed: a) December 2025 Patient ID: 55751 Test date: 12/23/2025 b) January 2026 Patient ID: 74987 Test date: 01/19/2026 Patient ID: 73913 Test date: 01/23/2026 c) February 2026 Patient ID: 6614 Test date: 02/20/2026 d) March 2026 No patients e) April 2026 Patient ID: 5946 Test date: 04/03/2026 Patient ID: 31942 Test date: 04/03/2026 Patient ID: 5297 Test date: 04/17/2026 f) May 2026 No patients g) June 2026 No patients 3. The technical consultant confirmed the findings in an interview conducted on 07/28/2026 at 1515 hours in the conference room.