Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0294456	04/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Medical Of Naples Llc	720 Goodlette Rd N Ste 500, Naples, FL	

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	An announced CLIA validation survey was conducted at ADVANCED MEDICAL OF NAPLES LLC from 03/31/2026 to 04/01/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient 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 record review and staff interview, the laboratory failed to examine or test Proficiency Testing (PT) samples with the laboratory's regular patient workload that routinely perform the testing in the laboratory for four out of four events reviewed (2025 and 2026) for Hematology and Chemistry specialties. Findings included: 1-Review of Laboratory Personnel Report, signed and dated by the Laboratory Director (LD) on 03/06/2026 revealed that the laboratory had three Testing Personnel (TP) listed (TP#1, TP#2, and TP#3). 2-Review of the procedure titled, "PROFICIENCY TESTING POLICY", signed by the Laboratory Director on 02/18/2026, noted that: "PT samples will be rotated among the testing staff". 3-Review of American Proficiency Institute (API) PT records for the Hematology and Chemistry specialties for the following events 2025 (1st, 2nd and 3rd) and 2026 (1st event), showed that TP#2 failed to participate in PT for the period of reference. 4-During an interview on 03/31/2026 at 12:30 PM, TP#3 confirmed that TP#2 failed to participate in PT during 2025 and 1st event of 2026.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory used expired ISE Reference reagent on the Chemistry analyzer AU480 for testing at least from March 23, 2026, until March 30, 2026. The findings included: 1- During a laboratory tour on 3/31/2026 at approximately 9:50 AM, the surveyor observed that the laboratory had two bottles ISE Reference AUH1013, Lot #M306422, Expiration Date 2024-10-31 in the storage room. The same expired reagent was also observed on board the Chemistry analyzer AU480 SN 202264833, marked with open date of 03-23-2026. The laboratory technician replaced the expired reagent with a new lot at the time of the survey on 3/31/2026. 2- Review of the ISE Reference solution product instructions BAOSAUH1011 11 March 2019, stated under Storage and Stability: "1. The unopened reagents are stable until expiration date on the label when stored at 2-25C." 3- Email from practice administrator on 04-01-2026 at 10:49 AM, confirmed that the laboratory tested a total of 149 patients with expired reagents on the following dates: 3/23/2026 - the laboratory tested 18 patients 3/24/2026 - the laboratory tested 14 patients 3/25/2026 - the laboratory tested 14 patients 3/26/2026 - the laboratory tested 30 patients 3/27/2026 - the laboratory tested 20 patients 3/28/2026 - the laboratory tested 16 patients 3/29/2026 - the laboratory tested seven (7) patients 3/30 /2026 - the laboratory tested 30 patients 4- Interview on 03/31/2026 at approximately 9:51 AM with Testing Personnel #3 confirmed that the reagent on board the instrument was expired and apologized for having missed this. The Testing Personnel #3 also confirmed that the expired reagent was removed from the anlyzer and from the storage room.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review an staff interview the laboratory failed to retain instrument printouts of patient results in February 2025 and February 2026, and for quality control results in February 2025, January and February 2026 for the Triage Meter moderate complexity testing in the specialty of Chemistry. The findings included: 1. Review of random quality control log January 2025, January 2026, February 2026 revealed that the were no instrument printouts for testing of Triage control level 1 and level 2. 2. Review of random patient reports from 02-05-2025 and 02-04-2026 revealed there were no instrument printouts for the reported results. 3. Review of the Triage Meter User Manual Rev A under IMPORTANT INSTRUCTIONS FOR ALL TESTS: stated in step "e. Press the (print icon) key to make a printed copy of the results." 4. Interview on 03/31/2026 at approximately 4:59 AP with the laboratory's lead technician confirmed that the laboratory failed to retain copies of instrument printouts for the Triage Meter and that the laboratory did not have a record retention policy. Testing Personnel #3 stated that the laboratory did not keep copies after a month because the print faded and were discarded

D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to establish a policy to be onsite at least once every six months, with at least 4 months between the minimum two on-site visits and documenting the onsite visits at least since April 1 2025 through March 31, 2026. Findings included: 1. Review of the procedure manual signed by the LD on 04/01/2025 revealed that it did not specify when the LD must be onsite and document the visits. 2- During interview on 03/31 /2026 at approximately 4:59 PM, Testing Personnel #3 confirmed that there was no policy to monitor the LD visits to the laboratory and how to document the visits.