Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2113612	06/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Eminent Medical Center, Llc	1351 West President George Bush Hwy, Richardson, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert, patient final reports and confirmed in interview, the laboratory failed to follow manufacturer's instructions in reporting gender-specific reference intervals on patient reports for the Piccolo Xpress Comprehensive Metabolic Panel test for one of 14 analytes reviewed in 2022 and 2023. Findings include: 1. Review of the manufacturer's package insert titled "Piccolo Comprehensive Metabolic Panel" version PN: 400-7139-1 Rev. P stated: "Table 4: Piccolo Reference Intervals Alkaline Phosphatase (ALP), Male 55-128 U/L Alkaline Phosphatase (ALP), Female 42-141 U/L" 2. A random review of patient final reports determined the laboratory failed to follow manufacturer's instructions to include gender-specific reference intervals for ALP in 2022 and 2023 : a) Patient ID: 11253 Collection Date: 08/29/2022 Gender: Male Result: 76 U/L Reference Range: 42-141 U /L b) Patient ID: 11413 Collection Date: 09/30/2022 Gender: Male Result: 59 U/L Reference Range: 42-141 U/L c) Patient ID: 11473 Collection Date: 10/04/2022 Gender: Male Result: 72 U/L Reference Range: 42-141 U/L d) Patient ID: 12088 Collection Date: 02/28/2023 Gender: Male Result: 49 U/L Reference Range: 42-141 U /L e) Patient ID: 12798 Collection Date: 06/21/2023 Gender: Male Result: 41 U/L

	Reference Range: 42-141 U/L 3. The technical supervisor confirmed the findings during an interview on 06/11/2024 at 1520 hours in the office. Key: U/L - Units per Liter
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: I. Based on surveyor observation, American Proficiency Institute (API) Proficiency Testing (PT) 2024 Immunohematology 1st event, and confirmed in interview, the laboratory failed to have documentation of the Laboratory Director (or designee) attesting to the routine integration of proficiency samples into the patient workload for one of one Immunohematology events in 2024. Findings Included: 1. During a tour of the laboratory on 06/11/2024 at 09:35 AM revealed the laboratory performed gel Immucor immunohematology (blood bank) testing. 2. Review of API instructions provided to the laboratory by the PT agency for Immunohematology 1st Event in 2024, revealed the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." Further review of laboratory API PT Immunohematology 1st Event in 2024, revealed the Laboratory Director or designee failed to sign the attestation statement. The surveyor requested documentation of the Laboratory Director or designee signing the attestation statement on 06/11/2024 at 12:15 PM, and no documentation was provided. 3. In an interview on 06/11/2024 at 12:15 PM in the laboratory break room, the Technical Supervisor (TS-1) confirmed the laboratory failed to have documentation of the Laboratory Director (or designee) attesting to the routine integration of proficiency samples into the patient workload for one of one Immunohematology events in 2024. II. Based on surveyor observation, American Proficiency Institute (API) Proficiency Testing (PT) 2023 Immunohematology 1st, 2nd and 3rd events, and confirmed in interview, the laboratory failed to have documentation of testing personnel attesting to the routine integration of proficiency samples into the patient workload for one of three Immunohematology events in 2023. Findings Included: 1. During a tour of the laboratory on 06/11/2024 at 09:35 AM revealed the laboratory performed gel Immucor immunohematology (blood bank) testing. 2. Review of API instructions provided to the laboratory by the PT agency for Immunohematology 3rd Event in 2023, revealed the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." Further review of laboratory API PT Immunohematology 3rd event in 2023, revealed Testing Person (TP-2) performed the PT event and failed to sign the attestation statement. The surveyor requested documentation of TP-2 signing the attestation statement on 06/11/2024 at 12:17 PM, and no documentation was provided. 3. In an interview on 06/11/2024 at 12:15 PM in the laboratory break room, the Technical Supervisor (TS-1) confirmed the laboratory failed to have documentation of testing personnel attesting to the routine integration of

	proficiency samples into the patient workload for one of three Immunohematology events in 2023.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, patient final reports and confirmed in interview, the laboratory failed to follow their own policy for reference ranges on patient final reports for one of one analytes on the i-STAT Troponin-I cartridge reviewed in 2022 and 2023. Findings include: 1. Review of the laboratory policy titled "i-STAT Test Cartridges" approved by the laboratory director on 05/03/2022 stated: "Test Name Acronym Units of Measure Reference Range Troponin I cTNI ng/mL 0.0-0.08" 2. Review of patient final reports determined the reference ranges for Troponin-I did not match the laboratory's policy for the following: a) Patient ID: 11724 Collection Date: 11/11/2022 Result: 0.01 ng/mL Reference Range: 0.00-0.03 ng/mL b) Patient ID: 11889 Collection Date: 01/20/2023 Result: 0.02 ng/mL Reference Range: 0.00-0.03 ng/mL c) Patient ID: 12202 Collection Date: 03/01/2023 Result: 0.01 ng/mL Reference Range: 0.00-0.03 ng/mL d) Patient ID: 13458 Collection Date: 10/10/2023 Result: 0.00 ng/mL Reference Range: 0.00-0.03 ng/mL e) Patient ID: 13083 Collection Date: 11/09/2023 Result: 0.00 ng/mL Reference Range: 0.00-0.03 ng /mL 3. The technical supervisor confirmed the findings during an interview on 06/13 /2024 at 1520 hours in the office. Key: ng/mL - nanograms per milliliter
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records and confirmed in interview, the laboratory failed to have documentation of the technical supervisor performing competency assessments on two of three high complexity testing personnel in 2023. Findings Included: 1. Review of CMS-209 form provided at time of survey, 06/11/2024 at 09:35 AM, the surveyor reviewed three testing personnel (TP-1, TP-2, TP-3) performing high complexity testing. 2. Review of laboratory personnel records in 2023 revealed the following: a. Personnel Competency: TP-1 Performed by: TP-2 Performed: 02/23/2023 b. Personnel Competency: TP-2 Performed by: TP-1 Performed: 07/13/2023 3. In an interview on 06/11/2024 at 12:15 PM in the laboratory break room, the Technical Supervisor (TS-1) confirmed the laboratory failed to have documentation of the

	technical supervisor performing competency assessments on two of three high complexity testing personnel in 2023.