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| <p>Statement of Deficiencies</p> | <p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>45D2113612</p> | <p>(X3) Date Survey Completed</p> <p>07/21/2022</p> |
| <p>Name of Provider or Supplier</p> <p>Eminent Medical Center, Llc</p> | <p>Street Address, City, State</p> <p>1351 West President George Bush Hwy, Richardson, TX</p> | |
| <p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p> | | |

| <p>(X4) ID Prefix Tag</p> | <p>Summary Statement of Deficiencies</p> |
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| <p>D0000</p> | <p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> |
| <p>D3025</p> | <p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's Blood Bank policies and procedures and staff interview, it was determined the laboratory failed to have a policy in place for reporting fatal blood transfusion reactions to the Food and Drug Administration (FDA). Findings included: 1. Review of laboratory's Blood Bank policies and procedures revealed the laboratory did not have a policy in place for reporting fatal blood transfusion reactions to the FDA. 2. The laboratory was asked to provide a policy for reporting of fatal transfusion reactions to the FDA and no such policy was</p> |

available for review prior to survey exit. 3. In an interview on 07/20/2022 at 1445 hours in the laboratory, General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of laboratory's American Proficiency Institute (API) proficiency testing (PT) documents for 2020, 2021 and 2022, review of the laboratory's PT evaluation and corrective action documentation for unsatisfactory results and staff interview, it was determined the laboratory failed to document all corrective action activities for 3 of 14 PT events reviewed. Findings included: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documents for 2020, 2021 and 2022, under instructions for evaluating PT performance, revealed: "Laboratories are responsible for documenting and performing corrective action for failures..." 2. Review of the laboratory's PT evaluation and corrective action documentation for unsatisfactory results revealed the following 3 of 14 reviewed PT events had incomplete documentation of corrective action activities: 2021 Hematology / Coagulation - 2nd Event Corrective action documented by laboratory representative: "Hematology samples 7 & 8 were ran in patient mode not QC mode... Staff educated on proper running of Hematology API samples." No documentation of staff education was available for review. 2021 Hematology / Coagulation - 3rd Event Corrective action documented by laboratory representative: "Review SOP, instructed staff to double check results and entry" No documentation of staff instruction was available for review. 2021 Chemistry - Core - 3rd Event Corrective action documented by laboratory representative: "BG-14 O2 level unable to retest due to type of sample. Have staff review SOP." No documentation of staff's SOP (standard operating procedure) review was available for examination. 3. In an interview on 07/18/2022 at 1320 hours in the break room, General Supervisor number 1 (as documented on submitted Form 209) stated that she did not retain documentation of staff's education/instruction/SOP review as part of the above events' corrective actions. This confirmed the findings.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assurance (QA) policies and procedures, review of laboratory's QA documents for January of 2021 to June of 2022 and staff interview, it was determined the laboratory failed to document at least 2 of 2 twice annual quality report reviews for 2021 and 18 of 18 monthly staff meetings for 2021 and 2022 as per laboratory's policy. Findings included: 1. Review of the laboratory's

"Quality Assurance" (QA) policy (Policy Number: G.36, last reviewed April 2022) revealed: "Program Evaluation Evaluations of the Quality Assurance made in this laboratory shall be performed at least twice per year. Quality Improvement documentation data will be maintained. Staff meetings shall be held on a monthly basis, approximately, in order to keep laboratory personnel assessed of the overall status of quality expectations and summary of the quality in this laboratory and to discuss any problems and corrective actions. Minutes and list of attendees will be kept for a minimum of two years." And "Quality Improvement Program At a minimum of two times per year, the Laboratory Director will evaluate the following indicators. These indicators shall be summarized on the QIPD (Quality Improvement Plan Document) document that follows this policy. -Patient Test Management -Quality Control -Proficiency Testing -Employee Competence and In-service - Communications of Errors and Complaints -Quality Improvement Communications"

2. Review of laboratory's QA documents for January of 2021 to June of 2022 revealed: a. There was no documentation of twice annual Quality Assurance evaluation. b. There was no documentation of QIPD summary and/or Laboratory Director's QIPD evaluation. c. There was no documentation of staff meetings, staff meeting minutes or lists of attendees. 3. The laboratory was asked to provide the above QA records and no such documentation was available for review prior to survey exit. 4. In an interview on 07/21/2022 at 1245 hours in the break room, General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.

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:

A. Based on review of laboratory's policies and procedures for receiving of blood and blood components, review of the laboratory's blood product supplier's shipment documents from December of 2021 to June of 2022 and staff interview, it was determined the laboratory failed to follow its own policy for documentation of shipment temperature and visual inspection of received blood products for 7 of 15 shipments received. Findings included: 1. Review of laboratory's policy "Receiving and Storage of Blood /Blood Components and Record Retention" (Policy Number: BB.03, last reviewed March 2022) revealed: "PROCEDURE 1. Upon receipt of products from ..., units are unpacked and condition noted as visually "ok" or "quarantined" on the ...Pack list. Visually inspect each blood product upon arrival for proper labeling, abnormal appearance, and proper shipping conditions. 2. The temperature is also noted on the Pack list using the infrared thermometer. Acceptable temperature is 1-10 degrees C (Celsius) for transportation. Any deviation from this range is quarantined." 2. Review of the laboratory's blood product supplier's shipment documents from December of 2021 to June of 2022 revealed the following shipments did not contain documentation of products' visual inspection or shipment's temperature upon receipt: Ship Date: 06/27/2022 at 06:57 Pack List #: SH062722RE0018 Shipment received: 06/27/2022 at 11:30 Shipment contained 4 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature. Ship Date: 06/20/2022 at 07:06 Pack

List #:SH062022RE0020 Shipment received: 06/20/2022 at 11:00 Shipment contained 8 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature. Ship Date: 06/20/2022 at 07:14 Pack List #:SH062022RE0022 Shipment received: 06/20/2022 at 11:00 Shipment contained 14 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature. Ship Date: 05/02/2022 at 07:21 Pack List #:SH050222RE0035 Shipment received: 05/02/2022 at 11:00 Shipment contained 22 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature. Ship Date: 04/11/2022 at 07:31 Pack List #:SH041122RE0028 Shipment received: 04/11/2022 at 09:50 Shipment contained 20 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature. Ship Date: 03/22/2022 at 06:35 Pack List #:SH050222ST0020 Shipment received: 03/22/2022 at 08:00 Shipment contained 2 blood product units (refer to Pack list enclosed). Pack list did not have documentation of transport temperature. Ship Date: 03/14/2022 at 11:03 Pack List #:SH031422RE0073 Shipment received: 03/14/2022 at 15:00 Shipment contained 22 blood product units (refer to Pack list enclosed). Pack list did not have documentation of visual inspection or transport temperature.

3. In an interview on 07/20/2022 at 1135 hours in the break room, General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings. B. Based on review of laboratory's Blood Bank policies and procedures and staff interview, it was determined the laboratory failed to follow its own policy for testing for weak D antigen or confirmation of negative D antigen expression. Findings included: 1. Review of the laboratory's Blood Bank policy "ABO Forward and Reverse/D Antigen Typing" (Policy Number: BB.06, last reviewed March 2022), page 5, revealed: "13. Very weak expressions of the D antigen may not be detected. The D(VI) epitome expression of the D antigen has not been detected with this reagent. Other rare red blood cells with very low copy numbers of the D antigen may need to be tested with antiglobulin and will be negative with this reagent." And "COMMENTS ...6. In instances where confirmation of D negative antigen status is required, negative reactions obtained with MTS Anti-D (Monoclonal)(IgM) Card should be retested with an Anti-D reagent licensed for antiglobulin phase testing." 2. In an interview on 07/20/2022 at 1130 hours in the laboratory, Testing person number 1 (as described on submitted Form 209) was asked to describe the process for weak D antigen testing and negative D antigen confirmation. She stated that the laboratory does not perform testing for weak D antigen or confirmation of negative D antigen with antiglobulin phase testing, and that these samples would be sent to the Blood Center for testing. 3. Further review of the Blood Bank policies revealed there was no mention of referral of samples to the Blood Center for testing of weak D antigen, or negative D antigen confirmation. 4. In an interview on 07/20/2022 at 1130 hours in the laboratory, General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of submitted CMS form 116, a random review of a patient report for UA (urine analysis) Microscopic exam, review of the laboratory's policy/procedure for urine "Microscopic Analysis-KOVA System" (Policy Number: U.04, last reviewed April 2022) and staff interview, it was determined the laboratory failed to define how to correlate quantitative microscopic observations with the semiquantitative interpretation on the final report. Findings included: 1. Review of submitted CMS form 116 revealed the laboratory performs approximately 40 UA Microscopic exams yearly. 2. Review of a random patient report for UA Microscopic testing revealed: Patient:10953 Sample collected 07/19/2022 at 11:45 UA Microscopic results: UA WBC - Few UA RBC - Few UA bacteria - Few UA Squam Epithelial - Rare 3. Review of the laboratory's policy/procedure for urine "Microscopic Analysis-KOVA System" (Policy Number: U.04, last reviewed April 2022) revealed: "PROCEDURE 4. ...Under low (10x), note epithelial cells and casts. ...Differentiate and average the number of epithelial and casts in 10 fields. Under high (40x), count and average 10 fields for WBCs, RBCs, and Bacteria." The procedure did not explain how to correlate the observed count of cells and casts to the semiquantitative results (Few/Rare) on the patient's report. 4. The following staff interviews revealed the facility's staff was not consistent in their interpretation of the semiquantitative designations: a. On 07/19/2022 at 1555 hours in the laboratory, Testing Person number 4 (as defined on submitted Form 209) stated: "Rare" meant 0-3 "Few" meant 1-9 b. On 07/19/2022 at 1600 hours in the break room, General Supervisor number 1 (as defined on submitted Form 209) stated: "Rare" meant 0-2 "Few" meant 3-5 c. On 07/19/2022 at 1605 hours in the break room, a Facility's Provider stated: "Few" meant 1-10 5. The facility was asked to provide definitions for interpretative correlation of quantitative findings to semiquantitative results and no such documentation was available for review. 6. In an interview on 07/19/2022 at 1610 hours in the break room, General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings. Legend: CMS = Centers for Medicare and Medicaid Services WBC = White blood cells RBC = Red blood cells Squam = Squamous.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
. Based on surveyor's observations on 07/18/2022 at 1320 hours in the laboratory, review of the manufacturer instructions for use for the Sysmex XN-L Check hematology controls and staff interview, it was determined the laboratory failed to document amended expiration dates for 3 of 3 control vials in use. Findings included:
1. Surveyor's observations on 07/18/2022 at 1320 hours in the laboratory revealed the following opened/in use hematology controls stored in the refrigerator did not have documentation of amended expiration dates: Control Level 1(L1) Lot number 21551401 Unopened expiration date: 2022-09-13 Control Level 2(L2) Lot number 21551402 Unopened expiration date: 2022-09-13 Control Level 3(L3) Lot number 21551403 Unopened expiration date: 2022-09-13
2. Review of the manufacturer instructions for use for the Sysmex XN-L Check hematology controls (document R415011B) revealed: "Storage and shelf life after first opening Open vials and vials which have been sampled by cap piecing will retain their stability for 15 days if stored at 2-8 C after being re-capped."
3. In an interview on 07/18/2022 at 1320 hours in the laboratory, General Supervisor number 1 (as documented on submitted Form 209), after inspecting the vials, confirmed the findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy "Piccolo Xpress Chemistry System" (Policy Number: POC.03), review of the manufacturer's "Piccolo Xpress chemistry analyzer Operator's Manual", review of the laboratory's chemistry analyzers' maintenance records for January of 2021 to June of 2022 and staff interview, it was determined the laboratory failed to document maintenance for 2 of 2 Piccolo Xpress instruments in use. Findings included:
1. Review of the laboratory's policy "Piccolo Xpress Chemistry System" (Policy Number: POC.03, last reviewed April 2022) revealed: "Maintenance & Service The piccolo xpress ... chemistry analyzer requires minimal maintenance. Clean the exterior of the analyzer weekly with mild detergent and a soft, damp cloth. The air filter requires cleaning twice per year. Regular maintenance of the analyzer will assure reliable operation."
2. Review of the manufacturer's "Piccolo Xpress chemistry analyzer Operator's Manual"(PN: 1100-7108-1 Manual Text, Rev. E, 10/2022; 2020, Abaxis, Inc.), section 9, "Maintenance and Service", revealed: "9.1 Cleaning the Analyzer Clean the analyzer's external case and display at least weekly." And "9.3 Cleaning the Air Filter The air filter in the back of the analyzer should be cleaned at least twice per year."
3. Review of the laboratory's chemistry analyzers' maintenance records for January of 2021 to June of 2022 revealed no documentation of weekly instrument cleaning or twice annual cleaning of the air filters for 2 of 2 Piccolo Xpress analyzers in use.
4. The laboratory was asked to provide maintenance records for the two Piccolo Xpress analyzers in use and no such documentation was available for review at the time of survey exit.
5. In

an interview on 07/19/2022 at 1355 hours in the laboratory, General Supervisor number 1 (as documented on submitted Form 209) stated that the laboratory does not document maintenance for the Piccolo Xpress analyzers, confirming the above findings

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of submitted CMS form 116, a random review of a patient report for UA (urine analysis) Microscopic exam, review of the laboratory's policy/procedure for urine "Microscopic Analysis-KOVA System" (Policy Number: U.04, last reviewed April 2022) and staff interview, it was determined the laboratory failed to make available to provider "reference intervals" or "normal" values for the UA Microscopic exam. Findings included: 1. Review of submitted CMS form 116 revealed the laboratory performs approximately 40 UA Microscopic exams yearly. 2. Review of a random patient report for UA Microscopic exam revealed: Patient:10953 Sample collected 07/19/2022 at 11:45 UA Microscopic Reference Range: UA WBC - [None] UA RBC - [None] UA bacteria - [None] UA Squam (squamous) Epithelial - (space was left blank) 3. Review of the laboratory's policy/procedure for urine "Microscopic Analysis-KOVA System" (Policy Number: U.04, last reviewed April 2022) revealed: "MICROSCOPIC FINDINGS Type of Normal Sediment Findings RBC 0-3/hpf WBC 0-5/hpf Casts 0-1 (Hyaline) 0-other casts/lpf Bacteria None Seen /hpf Yeast None Seen/hpf Crystals None Seen/hpf Squamous Epithelial Cells Few/lpf Mucous Negative Trichomonas None Seen/hpf" 4. In an interview on 07/19/2022 at 1610 hours in the break room, General Supervisor number 1 (as defined on submitted Form 209) stated that there were no reference ranges for UA Microscopic exam defined within the Laboratory Information System that would be available to the provider upon viewing patient final reports. This confirmed the findings. Legend: CMS= Centers for Medicare and Medicaid hpf = high power field lpf = low power field.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Quality Assurance (QA) policies and procedures, review of laboratory's QA documents for 2021 and 2022, and staff interview, it was determined the Laboratory Director failed to ensure laboratory's Quality Assessment was maintained. Refer to D5293.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on a random review of a patient report for UA (urine analysis) Microscopic exam, review of the laboratory's policy/procedure for urine microscopic examination and staff interview, it was determined the Laboratory Director failed to ensure that reports of all test results included pertinent information required for interpretation. Refer to D5807.