

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0495521	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier El Campo Memorial Hospital	Street Address, City, State 303 Sandy Corner Road, El Campo, 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
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: An unannounced revisit was performed on 3/22/2022 to 3/24/2022. Based on review of the manufacturer's instructions for the Siemens Dimension Lactic Acid Flex reagent cartridge, review of patient test records from January 2022 to March 2022, and staff interview, it was revealed the laboratory failed to ensure manufacturer's instructions were followed for specimen handling (refer to D5311).</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: An unannounced revisit was performed on 3/22/2022 to 3/24/2022. *****New</p>

Deficiency**** Based on review of the manufacturer's instructions for the Siemens Dimension Lactic Acid Flex reagent cartridge, review of patient test records from December 2021 to February 2022, and staff interview, it was revealed the laboratory failed to ensure 113 of 571 (19.7%) specimens were centrifuged within 15 minutes of collection as required by the manufacturer. The findings include: 1. A review of the manufacturer's instructions for the Siemens Dimension Lactic Acid Flex reagent cartridge (Ref DF16, Issue Date 2015-01-30) under the section titled "Specimen Collection and Handling" revealed: "...followed by immediate chilling of the specimen and separation of the cells within 15 minutes." 2. An interview with testing personnel number 4 (as listed on Form CMS 209) on 03/23/2022 at 1645 hours in the laboratory revealed the facility received samples for lactic acid testing from the hospital floors and outpatient facilities. He stated that all samples were received on ice and not spun. 3. A review of patient test records from December 1, 2021 to February 28, 2022 revealed 113 of 571 samples (19.7%) were received more than 15 minutes from the time of collection and thus, could not have been separated from the cells within 15 minutes from collection (see patient alias list). Examples are: Order number: 5358923 Collection: 01/31/2022 06:08 Receipt: 01/31/2022 06:34 Elapsed Time: 26 minutes Order number: 5363016 Collection: 02/06/2022 22:37 Receipt: 02/06/2022 23:18 Elapsed Time: 41 minutes Order number: 5363693 Collection: 02/07/2022 17:30 Receipt: 02/07/2022 17:58 Elapsed Time: 28 minutes Order number: 5361905 Collection: 02/03/2022 15:42 Receipt: 02/03/2022 16:25 Elapsed Time: 43 minutes Order number: 5364252 Collection: 02/08/2022 10:45 Receipt: 02/08/2022 11:52 Elapsed Time: 77 minutes Order number: 5362627 Collection: 02/06/2022 06:53 Receipt: 02/06/2022 07:27 Elapsed Time: 34 minutes Order number: 5372433 Collection: 02/22/2022 03:50 Receipt: 02/22/2022 04:37 Elapsed Time: 47 minutes Order number: 5372722 Collection: 02/22/2022 04:30 Receipt: 02/22/2022 05:08 Elapsed Time: 38 minutes Order number: 5374494 Collection: 02/24/2022 05:49 Receipt: 02/24/2022 06:16 Elapsed Time: 27 minutes 4. An additional interview with testing personnel number 4 (as listed on Form CMS 209) on 03/23/2022 at 1650 hours in the laboratory revealed the facility did not know samples for lactic acid testing were required to be centrifuged within 15 minutes of collection. This confirmed the findings.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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.

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 3/22/2022 to 3/24/2022. NEW citation Based on review of the laboratory and patient test records from January to March 2022 and confirmed in interview, the laboratory failed to document corrective actions when coagulation quality control for Protime and Partial thromboplastin time was outside of acceptable range for ten of forty days reviewed. Findings included: 1. Review of the QC Cumulative report from January 2022 to March 2022 revealed the following ten of forty days outside of the acceptable ranges (QC Invalid) with no

documentation of the corrective action: PT (protime) lot N0806642, exp 8/31/2023 Level 1 acceptable range 10 - 13 seconds 2/26/2022: 13.1 seconds 2/24/2022: 13.6 seconds 2/22/2022: 13.2 seconds 2/06/2022: 13.2 seconds 3/21/2022: 13.1 seconds 3/19/2022: 13.6 seconds PTT (Partial thromboplastin time) lot N0806642, exp 8/31/2023 Level 1 acceptable range 25-34 seconds 2/28/2022: 34.1 seconds 2/23/2022: 51.1 seconds 2/13/2022: 34.1 seconds 2/15/2022: 34.7 seconds 2. A review of the laboratory's patient test records revealed the laboratory reports an estimated 9,000 coagulation tests annually. 3. An interview with the laboratory manager on 3/23/2022 at 1310 hours in his office confirmed the above findings.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 3/22/2022 to 3/24/2022. Based on a review of laboratory preanalytic and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D5311, D5411-I, II.