| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 28D0679413 | 07/10/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chi Health St Elizabeth | 555 South 70th Street, Lincoln, NE | |

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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to follow manufacturer's instructions for interpretation of results. Findings: 1. Manufacturer's instructions for the Logix Smart Coronavirus Disease 2019 (COVID-19) test kit state "Once controls have passed, the unknown samples can be interpreted based on three possible outcomes: Positive, Negative, Invalid... An Invalid result refers to situations when any of the controls fail...." 2. The "PP Test Nebraska Result Reporting" policy and |

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| | procedure states: "If IPC is twice negative, report as Inconclusive" 3. Confirmed during interview with Personnel #4 on June 1, 2020 at approximately 11 AM. 4. Approximately 64,000 patients have been tested for COVID-19 since May 6, 2020. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure (P&P) "Correction of Incorrect Laboratory Results" and confirmed during interview, the Correction of Incorrect Laboratory Results P&P was not approved, signed, and dated by the LD prior to testing patient samples. Findings: 1. Review of the laboratory's procedure manual revealed the LD did not review and sign the P&P prior to performing patient testing for COVID-19. 2. Confirmed during interview with Personnel #4 on June 1, 2020 at approximately 11 AM. 3. Approximately 64,000 patients have been tested for COVID-19 since May 6, 2020. |