| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 35D0408215 | 12/01/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chi Lisbon Health | 905 Main St, Lisbon, ND | |

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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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory director failed to sign the attestation statements for 3 of 3 (3-2020, 1-2021, and 2-2021) immunohematology proficiency testing events reviewed. Findings include: 1. Reviewed at 1:15 p.m. on 11/30/21, the 2020-2021 proficiency testing records lacked evidence the laboratory director signed the proficiency testing attestation statements for 3-2020, 1-2021, and 2-2021 immunohematology proficiency testing events. 2. During interview at 3:45 p.m. on 11/30/21, a technical supervisor (Personnel #1) confirmed the laboratory director had not signed the attestation statements for 3-2020, 1-2021, and 2-2021 immunohematology proficiency testing events. 3. Reviewed at 11: 00 a.m. on 12/01/21, the undated policy "Proficiency Testing," stated, ". . . Procedure: . . . - After submission of the results online, the Testing Personnel must sign the attestation form. Lab director . . . must also sign the attestation form. . . ." |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for |

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| | the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy, precision, and reportable range for 1 of 2 new test methods (D-dimer) on the Quidel Triage Meter Pro in October 2019 before reporting patient results. The laboratory performed approximately 800 patient D-dimer tests on the Quidel Triage Meter Pro analyzer since implementation. Findings include: 1. Reviewed at 8:25 a.m. on 12/01/21, the laboratory's 2019 performance specification verification records for the Quidel Triage Meter Pro analyzer lacked evidence the laboratory verified performance specifications for accuracy, precision, and reportable range for D-dimer. 2. During interview at 8:50 a.m. on 12/01/21, a technical supervisor (Personnel #1) confirmed the laboratory began patient testing on the Quidel Triage Meter Pro analyzer for D-dimer in October 2019, and the laboratory did not have evidence the laboratory director and/or technical supervisor had verified the performance specifications for accuracy, precision, and reportable range. 3. Reviewed at 11:00 a.m. on 12/01/21, the policy "Clinical Laboratory Improvement Amendments (CLIA) Laboratory Director Responsibilities and Delegations," effective 08/2018, stated, "Responsibility . . . Test method verification. Approval of new instrument and /or test method validation . . . Title . . . Medical Director Technical supervisor Clinical Lab . . ." 4. Upon request on 12/01/21, the laboratory failed to provide a policy requiring verification of performance specifications for accuracy, precision, and reportable range for new test systems. |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, observation, staff interview, manufacturer's instructions review, and policy review, the laboratory failed to use the correct mean normal protime (PT) value for calculating International Normalized Ratios (INRs) for 4 of 4 weeks (October 28 through November 30, 2021) since the laboratory began using a new lot number of Innovin (thromboplastin) reagent on the Sysmex CA600 coagulation analyzer. The laboratory performed approximately 50 tests during this timeframe. Findings include: 1. Reviewed at 9:55 a.m. on 12/01/21, the 2021 coagulation lot number change records showed the mean normal PT value as 10.4 for Innovin lot number 549788. 2. Observation of the Sysmex CA600 coagulation analyzer at 10:00 a.m. on 12/01/21 revealed a mean normal PT value of 10.1 used to calculate patient INRs. 3. During interview at 10:05 a.m. on 12/01/21, a technical supervisor (Personnel #1) confirmed the laboratory did not enter the new mean normal PT value of 10.4 when the laboratory began using the new lot number of Innovin on 10/28/21. 4. Reviewed on 12/01/21, the Siemens Dade Innovin package insert, dated 05/2008, stated, ". . . Determination of INR (International Normalized Ratio) . . . 1. . . . the PT results for patients on oral anticoagulants should be recorded as INR values. . . The INR is determined according to the following equation: INR = R [powered to the ISI value], where R = Patient PT [divided by] Mean normal PT** ISI is the International Sensitivity Index of the reagent/instrument combination. . . . ** The mean normal PT is defined as the mean value of the normal range. It must be |

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| | determined specifically for each thromboplastin lot using the method used to analyze the patient samples . . ." 5. Reviewed on 12/01/21, the undated policy "Protime/INR" failed to include instructions for changing lot numbers of Innovin. |