Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408215	11/25/2025
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to report the results from the Laboratory Information System (LIS) or testing personnel worksheets to American Proficiency Institute (API) for 3 of 3 Immunology /Immunohematology events (3rd Event 2024,1st Event 2025, and 2nd Event 2025) reviewed from 2024 and 2025. Findings include: 1. Review of API proficiency testing records on the afternoon of 11/24/25 showed the 3rd Event 2024, 1st Event 2025, and 2nd Event 2025 Immunology/Immunohematology proficiency testing records lacked evidence of testing personnel worksheets showing agglutination results for ABO, Rh, Compatibility Testing, and Unexpected Antibodies. 2. During interview at 5:30 p.m. on 11/24/25, a Technical Supervisor (Personnel #1) confirmed testing personnel do not document proficiency testing agglutination results on a blood bank log or into the LIS. 3. Review of 2nd Event 2025 Immunology/Immunohematology proficiency testing records on the afternoon of 11/24/25 showed the following: - Testing personnel marked "Group O" for ABO sample RED-10 on the API report form - API Comparative Evaluation report showed "Group A" was reported to API 4. During interview at 5:30 p.m. on 11/24/25, a Technical Supervisor (Personnel #1) confirmed the results documented for the 2nd Event 2025 was not the result reported to API. 5.

	Reviewed the afternoon of 11/25/25, the policy "Blood Band Identification System," last revised 11/25/25, stated, "CHI Lisbon Health is subscribed to the API Proficiency Testing program. All samples are treated like patient samples. . . ."
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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: Based on record review, staff interview, and policy review, the laboratory failed to ensure testing personnel signed the attestation statement for 1 of 15 (2nd Event 2025 Chemistry Core) American Proficiency Institute (API) proficiency testing events reviewed from 2024 and 2025. Findings include: 1. Reviewed at 2:26 p.m. on 11/24 /25, the 2nd Event 2025 Chemistry Core API proficiency testing records failed to include attestation statements signed by the Testing Personnel. 2. During interview the afternoon of 11/24/25, a Technical Supervisor (Personnel #1) confirmed testing personnel had not signed the attestation statements for the 2nd Event 2025 Chemistry Core API proficiency testing. 3. Reviewed the afternoon of 11/24/25, the policy "Proficiency Testing," effective 08/27/24, stated, "After submission of the results online, the Testing Personnel must sign the attestation form."
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to retain instrument printouts for 1 of 3 American Proficiency Institute (API) proficiency Chemistry Core events (1st Event 2025) reviewed from 2024 and 2025. Findings include: 1. Reviewed at 2:57 p.m. on 11/24/25, the 1st Event 2025 Chemistry Core proficiency testing records lacked evidence of Siemens Dimension EXL 200 analyzer printouts. 2. During interview at 3:18 p.m. on 11/24/25, a Technical Supervisor (Personnel #1) confirmed the chemistry proficiency testing results were not interfaced with the laboratory information system (LIS) and the Siemens Dimension EXL 200 (Dimension EXL) analyzer printouts were not available. 3. The laboratory failed to provide Dimension EXL analyzer printouts or LIS results for 1st Event 2025 Chemistry Core proficiency testing. 4. Reviewed on 11/24/25, the policy "Proficiency Testing" effective 08/27/24, stated, "Results are recorded on report forms, all instrument printouts are saved along with a copy of completed report form."
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy of results for 2 of 2 regulated analytes (Total Bilirubin and Gram Stain Morphology) the American Proficiency Institute (API) assigned as not graded. The laboratory performed 1465 Total Bilirubin patient tests and 16 Gram Stain patient tests over the past year. Findings include: 1. Reviewed on 11/24/25, the 2nd Event 2025 Chemistry Core proficiency testing showed Total Bilirubin samples CH-07, CH-09, and CH-10 as not graded and 3rd Event 2025 Chemistry Core proficiency testing showed Total Bilirubin samples CH-12 and CH-15 as not graded. The laboratory failed to evaluate the not graded results. 2. Reviewed on 11/24/25, the 2nd Event 2025 Microbiology proficiency testing showed Gram Stain Morphology sample GS-09 as not graded. The laboratory failed to evaluate the not graded results. 3. During interview the afternoon of 11/24/25, a Technical Supervisor (Personnel #1) confirmed the laboratory failed to evaluate the 2nd Event 2025 Total Bilirubin, 3rd Event 2025 Total Bilirubin, and 2nd Event 2025 Gram Stain Morphology not graded results. 4. Reviewed on 11/24/25, the policy "Proficiency Testing " effective 08/27/24, stated, ". . . Ungraded or educational ungraded results will be self-graded with follow up as needed . . ."
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 record review and staff interview, the laboratory failed to verify the accuracy of results for 3 of 3 (1st Event 2025, 2nd Event 2025, and 3rd Event 2025) American Proficiency Institute (API) serum HCG proficiency testing verification events reviewed in 2025. The laboratory performed 24 serum HCG patient tests over the past year. Findings include: 1. Reviewed on 11/24/25, the 1st Event 2025, 2nd Event 2025, and 3rd Event 2025 proficiency testing serum HCG records failed to show the laboratory documented verification of accuracy of serum HCG. 2. During interview the afternoon of 11/24/25, a Technical Supervisor (Personnel #1) confirmed the laboratory did not document review of the 2025 serum HCG proficiency testing verification events. 3. The laboratory failed to provide a policy regarding verification proficiency testing.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review, staff interviews, and policy review, the Technical Supervisor failed to evaluate and document the competency at least semiannually for 1 of 1 new

	testing personnel (Testing Personnel #4) hired in March 2025. Findings include: 1. Reviewed at 11:35 a.m. on 11/24/25, Testing Personnel #4's competency evaluation records lacked evidence of six-month competency evaluations for serum Human Chorionic Gonadotropin (HCG) and manual differential in September 2025. 2. During interview at 11:48 a.m. on 11/24/25, a Technical Supervisor (Personnel #1) confirmed Testing Personnel #4 was hired in March 2025 and did not have six-month competency evaluations completed for the serum HCG and manual differential. 3. During interview at 11:52 a.m. on 11/24/25, Testing Personnel #4 confirmed she has reported patient serum HCG and manual differential test results. 4. Reviewed the afternoon of 11/24/25, the policy "Competency Assessment," effective 02/12/18, stated, "Assessment Determination . . . Six Month Assessment This follows the initial assessment."
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the Technical Supervisor failed to evaluate and document the competency for 4 of 4 testing personnel (Testing Personnel #1, #2, #3, and #5) requiring annual competency evaluations in 2024. Findings include: 1. Reviewed at 10:47 a.m. on 11/24/25, the competency evaluation records lacked evidence of annual competency evaluations in 2024 as follows: - Testing Personnel #1 - K-Check Ketone testing (Ketones), blood culture identification and sensitivities, sedimentation rate MiniiSED analyzer (MiniiSED), gram stain procedure (gram stain), and manual differential procedure (manual differential) - Testing Personnel #2 - Ketones, MiniiSED, gram stain, and manual differential - Testing Personnel #3 - Ketones, gram stain, and manual differential - Testing Personnel #5 - Ketones, MiniiSED, blood bank procedure, gram stain, and manual differential 2. During interview at 1:15 p.m. on 11/24/25, a Technical Supervisor (Personnel #1) confirmed Testing Personnel #1, #2, #3, and #5 did not have all annual competency evaluations completed in 2024. 3. Reviewed the afternoon of 11/24/25, the policy "Competency Assessment," effective 02/12/18, stated, "Assessment Determination . . . Annual Competency . . . This is performed after 6-Month Assessment and annually for all staff."