Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0954859	12/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lakeview Clinic	110105 Pioneer Trail, Chaska, MN	

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
D0000	The Lakeview Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on December 28, 2023. The following condition-level deficiencies were cited: 493.1250 Analytic Systems The following standard-level deficiencies were cited: 493.801 Enrollment and testing of samples (Proficiency testing) 493.1236 Evaluation of proficiency testing performance 493.1251 Procedure Manual 493.1254 Maintenance and function checks 493.1289 Analytic systems quality assessment 493.1407 Laboratory director responsibilities 493.1413 Technical consultant responsibilities .
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 document review and interview with laboratory personnel, the Laboratory Director (LD) failed to attest to the integration of proficiency testing samples into the routine patient workload on ten of ten occasions in 2021, 2022, and 2023. In addition, Testing Personnel (TP) failed to do the same on two of ten occasions in the same time period. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The Laboratory performed proficiency testing using the American Academy of Family Practitioners (AAFP) proficiency testing provider in 2021 and 2021 and the American Proficiency Institute (API) in 2023. 3. The LD's signature and the TP's signature were required on the attestation statements for all PT events as indicated in the Proficiency Testing Policy found in the Policy and Procedure Manual. 4. The Laboratory Director

	failed to sign the attestation statement for ten of ten PT events reviewed from 2021, 2022, and 2023. See below. AAFP events 2021-C 2022-A 2022-B 2022-C API events 2023 Hematology - 1 2023 Microbiology - 1 2023 Hematology - 2 2023 Microbiology - 2 2023 Hematology -3 2023 Microbiology 3 5. The TP failed to sign the attestation statement for two of ten PT events reviewed from 2021, 2022, and 2023. See below. AAFP event 2021-C API event 2023 Microbiology - 1 5. In an interview at 1:08 p.m. on 12/28/23, the TC confirmed the above finding. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document review of proficiency testing (PT) results for nine of ten PT events completed in 2021, 2022, and 2023. In addition, the laboratory failed to evaluate four unacceptable PT results in the same time period. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The Laboratory performed proficiency testing using the American Academy of Family Practitioners (AAFP) proficiency testing provider in 2021 and 2021 and the American Proficiency Institute (API) in 2023. 3. The results from the following AAFP and API events did not include documented review: AAFP events 2021-C 2022-A 2022-B 2022-C API events 2023 Hematology - 1 2023 Microbiology - 1 2023 Hematology - 2 2023 Microbiology - 2 2023 Microbiology 3 4. The following unacceptable results were not evaluated by the laboratory: AAFP events Sample Test 2021-C TC-11 Throat culture 2022-B CM-15 Vaginal wet preparation API event Sample Test 2023 Hematology-1 HEM-01 Granulocytes 2023 Hematology-2 HEM-06 Monocytes 5. In an interview at 1:08 p.m. on 12/28/23, the TC confirmed the above finding. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of laboratory policies and procedures, patient testing and quality control logs, direct observation, and interview with laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to follow a Microbiology written procedure. See D5401 2. The laboratory failed to ensure one of four testing procedures included all required elements. See D5403 3. The laboratory director failed to approve three of four testing procedures prior to use. See D5407 4.

	The laboratory failed to establish a thermometer maintenance protocol and perform and document thermometer function check activities. See D5433 .
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: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow a Microbiology written procedure in 2021, 2022, and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. Media plates and a Boekel incubator were observed as present and in use during the tour. The laboratory performed Throat Cultures testing using these items. 3. Throat cultures were read after 18 hours and results were reported after 20 hours as established in the ID of Group A Beta-hemolytic Streptococcus by Culture procedure found in the Policy and Procedure manual. 4. Upon inquiry by surveyor, the TC indicated throat cultures set up on Friday were not read until the following Monday. The clinic was not open on Saturday or Sunday. 5. The laboratory performed approximately 409 Microbiology tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 1:38 p.m. on 12/28/23, the TC confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel,

	the laboratory failed to ensure one of two Hematology testing procedures included reference ranges (normal values). Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 12/28/23 at 10:15 a.m. 2. An Alcor miniiSED Erythrocyte Sedimentation Rate (ESR) analyzer was observed as present and available for use during the tour. 3. The ESR Procedure found in the Policy and Procedure Manual did not include ESR normal values. The ESR normal values were not found in other laboratory records. 4. In an interview at 1:50 p.m. on 12/28/23, the TC confirmed the above finding. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve three of four written testing procedures in use by the laboratory. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Microbiology -Olympus CH30 microscope (Vaginal Wet Preparation) -Boekel incubator (Throat cultures) Hematology -Beckman Coulter AcT diff2 (Complete Blood Count) 3. Laboratory Director approval of the following procedures was not found during review on date of survey: ID of Group A Beta-hemolytic Streptococcus by Culture Wet Mount Preparation Procedure Beckman Coulter AcT diff Operator's Guide (in use as procedure) 4. In an interview at 1:40 p. m. on 12/28/23, the TC confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to establish a thermometer maintenance protocol and perform and document thermometer function check activities for three of three thermometers in 2021, 2022, and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12 /28/23. 2. The following thermometers were observed in the laboratory as present and available for use during the tour: Type Location Serial number Calibration expiration

	Min/Max Thermometer Refrigerator 160820533 10/04/18 Alcohol thermometer Boekel incubator H36557 no data Min/Max thermometer Storage room 181773286 12 /01/20 The refrigerator held Microbiology and Hematology testing supplies and patient specimens. The Boekel incubator was used for Throat Cultures. The storage room contained vacutainer tubes and Hematology diluent. 3. A thermometer function check protocol was not found during review the laboratory's Policy and Procedure Manual. 4. Thermometer function check documentation was not found during review of laboratory records. 5. The laboratory was unable to provide a thermometer maintenance protocol or documentation of thermometer function checks for the above equipment upon request. 6. The laboratory performed approximately 19,214 tests annually as indicated on documentation provided by the laboratory on date of survey. 7. In interviews at 10:20 a.m.,10:22 a.m., and 10:25 a.m. on 12/28/23, the TC confirmed the above findings. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow established quality assurance procedures in 2021 and 2022. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Microbiology -Olympus CH30 microscope (Vaginal Wet Preparation, KOH Preparation, Post-vasectomy Examination, and Fern test) -Boekel incubator (Throat Cultures) Chemistry -Olympus CH30 microscope (Urine Sediment) Hematology -Beckman Coulter AcT diff2 (Complete Blood Count) -Alcor miniiSED (Erythrocyte Sedimentation Rate) 3. Quality Assurance (QA) reviews were required at least annually as established in the Quality Assurance Plan procedure found in the Policy and Procedure Manual. Monthly QA review criteria was designated as follows: January - Procedure manual February - Draw log, Expired products, Coulter calibration March - Proficiency testing, Critical values log April - Personnel records May - Daily Draw log, Product inserts June - Critical values log, Proficiency testing July - Safety August - Coulter calibration, Draw log, Expired products September - Critical values log October - Proficiency testing November - Daily draw log, Review QA plan, LIS audit December - Critical values log, Competencies 4. QA review documentation from October 2021 through December 2022 was not found during review of laboratory records. The laboratory was unable to provide the missing documentation upon request. 5. The laboratory performed approximately 19,214 tests on patient specimens annually as indicated on documentation provided by the laboratory on date of survey. 6. In an interview at 2:35 p.m. on 12/28/23, the TC confirmed the above finding. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to provide adequate oversight of the laboratory. The laboratory performed approximately 19,214 tests on patient samples annually. Findings are as follows: 1. The laboratory director failed ensure testing personnel and the laboratory director attested to the routine integration of proficiency testing samples into the laboratory's testing workload. See D2009 2. The laboratory director failed to ensure proficiency testing results were reviewed and evaluated. See D5211 3. The laboratory director failed to ensure a written Microbiology procedure was followed. See D5401 4. The laboratory director failed to ensure a written Hematology procedure included all required elements. See D5403 5. The laboratory director failed to ensure written procedures were approved before use. See D5407 6. The laboratory director failed to ensure a thermometer maintenance protocol was established and thermometers were not used after calibration expiration. See D5433 7. The laboratory director failed to ensure Quality Assurance activities were performed as established in procedure. See D5791 8. The laboratory director failed to ensure an initial competency evaluation was completed in 2022. See D6045 9. The laboratory director failed to ensure comprehensive annual competency evaluations were completed in 2022. See D6046 10. The laboratory director failed to ensure competency evaluations included blind sample assessment in 2022. See D6051 11. The laboratory director failed to ensure the competency of new testing personnel was assessed at least twice annually during the first year of testing. See D6053
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive initial training for one of three new testing personnel (TP) was performed and documented in 2022. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Microbiology -Olympus CH30 microscope (Vaginal Wet Preparation, KOH Preparation, Post-vasectomy Examination, and Fern test) -Boekel incubator

	(Throat Cultures) Chemistry -Olympus CH30 microscope (Urine Sediment) Hematology -Beckman Coulter AcT diff2 (Complete Blood Count) -Alcor miniiSED (erythrocyte Sedimentation Rate) 3. Competency evaluation of new testing personnel was required before testing specimens independently as established in the Competency Evaluation for Personnel Performing Clinical Diagnostic Testing procedure found in the Policy and Procedure Manual. 4. TP6 was hired on 02/22/22 as indicated on competency evaluation documents. 5. Initial training documents for TP6 were not found in laboratory records. TP6's initial competency evaluation form included one item only; documentation of blind sample evaluation on the Beckman Coulter AcT diff2 analyzer. 6. The laboratory was unable to provide the missing training records and competency evaluation upon request. 7. In an interview at 12:00 p.m. on 12/28/23, the TC confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure three of seven testing personnel (TP) were assessed for automated hematology testing competency at least annually in 2022 Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. A Beckman Coulter AcT diff2 hematology analyzer was observed as present and available for use during the tour: 3. Annual competency evaluations were required as established in the Competency Evaluation for Personnel Performing Clinical Diagnostic Testing procedure found in the Policy and Procedure Manual. 4. Beckman Coulter AcT diff2 hematology analyzer competency evaluations were not documented as completed on annual competency evaluation forms for three of seven TP in 2022; TP1, TP2, TP3. 5. The laboratory was unable to provide the missing competency evaluation documentation upon request. 6. In an interview at 12:00 p.m. on 12/28/23, the TC confirmed the above finding. .
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure three of seven testing personnel (TP) were assessed at least annually in 2022 through testing previously analyzed specimens, blind samples, or proficiency testing samples. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of

	the laboratory at 10:15 a.m. on 12/28/23. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Microbiology -Olympus CH30 microscope (Vaginal Wet Preparation, KOH Preparation, Post-vasectomy Examination, and Fern test) -Boekel incubator (Throat Cultures) Chemistry -Olympus CH30 microscope (Urine Sediment) Hematology - Beckman Coulter AcT diff2 (Complete Blood Count) -Alcor miniiSED (Erythrocyte Sedimentation Rate) 3. Annual competency evaluations was required as established in the Competency Evaluation for Personnel Performing Clinical Diagnostic Testing procedure found in the Policy and Procedure Manual. The competency evaluation forms in use included the assessment of blind samples or proficiency testing samples. 4. Blind sample competency assessments were not documented as completed on annual competency evaluation forms for the above moderate complexity tests for three of seven TP in 2022; TP1, TP2, TP3. 5. The laboratory was unable to provide the missing blind sample evaluation documentation upon request. 6. In an interview at 12:00 p.m. on 12/28/23, the TC confirmed the above finding. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of three testing personnel hired in 2022. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 12/28/23. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Microbiology -Olympus CH30 microscope (Vaginal Wet Preparation, KOH Preparation, Post-vasectomy Examination, and Fern test) - Boekel incubator (Throat cultures) Chemistry -Olympus CH30 microscope (Urine Sediment) Hematology -Beckman Coulter AcT diff2 (Complete Blood Count) -Alcor miniiSED (Erythrocyte Sedimentation Rate) 3. Competency evaluation of new testing personnel was required semi-annually as established in the Competency Evaluation for Personnel Performing Clinical Diagnostic Testing procedure found in the Policy and Procedure Manual. 4. TP6 was hired on 02/22/22 as indicated on competency evaluation documents. Initial training documentation for TP6 was not found during review of laboratory records. See D6045 5. Semi-annual competency evaluation documentation for TP6 was not found during review of laboratory records. The laboratory was unable to provide the missing competency evaluation upon request. 6. In an interview at 12:00 p.m. on 12/28/23, the TC confirmed the above finding. .