Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403641	06/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cmh Raiter Family Clinic	417 Skyline Blvd, Cloquet, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, 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 failed ensure one of three testing personnel who routinely performed moderate complexity testing on patient samples participated in proficiency testing (PT) in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed Testing Personnel 1 during a tour of the laboratory at 9:00 a.m. on 06/08/23. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency provider. 3. Testing Personnel 3 did not participate in nine of nine API PT events completed by the laboratory in 2022 and four of four PT events completed by the laboratory in 2023 as indicated in laboratory records. 4. In an interview at 11:10 a.m. on 06/08/23, the Technical Consultant confirmed the above finding. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory

	failed to ensure one of one technical consultants(TC) received a competency assessment at this laboratory which included specific position responsibilities listed in Subpart M. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. One TC was listed on the Form CMS-209 Laboratory Personnel Report (CLIA) obtained on date of survey. 3. A competency assessment procedure was not found in laboratory procedure manuals on date of survey. See D6030. 4. A TC competency assessment was not found during review of 2021 and 2022 laboratory personnel records. The laboratory was unable to provide the competency assessment upon request. 5. In an interview at 10:45 a.m. on 06/08/23, 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 two of six testing procedures reviewed included all required elements. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. An Olympus CH30 microscope was observed as present and available for use during the tour. The laboratory performed Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examinations using this microscope. 3. The following procedures located in the Policy and Procedure Manual 1 and Manual 2 did not include specimen acceptability, stability, and storage requirements: Potassium Hydroxide (KOH) Wet Mounts Direct Wet Preparation for Trichomonas Vaginalis Direct Wet Preparation for Sarcoptes Scabiei (Scabies) 4. In an interview at 3:30 p.m. on 06/08/23, the Technical Consultant 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 failed to ensure one of two performance verifications completed in 2023 was approved, signed, and dated by the laboratory director prior to implementation. In addition, the laboratory director failed to approve each and every policy and procedure in use by the laboratory. Findings are as follows: The laboratory performed Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory at 9:00 a.m. on 06/08/23. A. Performance verification approval 1. An Alcor mini iSED analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing using this analyzer: 2. The performance verification (PV) for ESR on the mini iSED analyzer was completed in April 2022 as indicated in the PV records found in the Mini iSED Operator's Manual. The ESR implementation date was 04/03 /23 as indicated on the Alcor mini iSED Quality Control log. 3. The laboratory director's approval signature was dated 04/26/23. 4. In an interview at 12:50 p.m. on 06/08/23, the Technical Consultant confirmed the above finding. B. Policy and procedure approval 1. The following manuals were observed as present and available for use on date of survey: -Policy and Procedure Manual 1 -Policy and Procedure Manual 2 -Laboratory Safety Manual -Laboratory Quality Assurance manual 2. Laboratory Director approval of the above manuals and the policies and procedures contained therein was not found during review on date of survey. 3. In an interview at 12:55 p.m. on 06/08/23, the Technical Consultant confirmed the above finding. 4. The Laboratory Director assumed the role on 12/14/22 as indicated in Federal database records. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to ensure testing personnel competency was assessed annually in accordance with 493.1407 of this subpart. Findings are as follows: 1. The Laboratory Director failed to ensure a corrective action plan was followed for one 2021 non-graded proficiency testing (PT) result when the laboratory did not obtain a result in agreement with other participating laboratories. See D6019 2. The Laboratory Director failed to ensure established quality assurance procedures were followed for eight of twelve months in 2021 and 2022. See D6021 3. The Laboratory Director failed to ensure comprehensive initial training for one of one new testing personnel was performed and documented in 2021. See D6029 4. The Laboratory Director failed to ensure the procedure manual included specific procedures for personnel training and competency assessments. See D6030 5. The Laboratory Director failed to ensure the procedure manual included procedures for each laboratory activity and test. See D6031 .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure a corrective action plan was followed for one 2021 non-graded proficiency testing (PT) result when the laboratory did not obtain a result in agreement with other participating laboratories. Findings are as follows: 1. The laboratory performed Vaginal Wet Preparation (VWP) testing as confirmed by Testing Personnel 1 during a tour of the laboratory at 9:00 a.m. on 06/08/23. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. A proficiency testing procedure was not found in laboratory procedure manuals on date of survey. See D6031. 4. The VWP result for sample VKP-03 from the third 2021 Hematology/Coagulation PT event was not graded by API due to lack of consensus. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. 5. The API data summary for VKP indicated the laboratory's VKP-03 result was not in concordance with the other participating laboratories. See below. Laboratory result VKP-03 No yeast seen API data summary VKP-03 Number of laboratories No yeast seen 233 Yeast seen 3847 6. An evaluation of the non-graded result and corrective action documentation was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 7. In an interview at 11:10 a.m. on 06/08/23, the Technical Consultant confirmed the above finding.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on document review, and interview with laboratory personnel, the Laboratory Director failed to ensure established quality assurance procedures were followed for eight of twelve months in 2021 and 2022. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The Laboratory Quality Assurance manual included an annual calendar which established monthly review criteria. 3. Required monthly quality assurance review documentation was not found in the Laboratory Quality Assurance manual for 2021 and 2022 as listed below. January - Personnel and Quality Assurance Plan February - Communication breakdown and complaints March - Safety April - Calibration July -

	Test menu and methods August - Vendor/reference laboratory relationships September - Proficiency testing October - Policy and procedure manuals 4. In an interview at 3:40 p.m., the Technical Consultant confirmed the above finding. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Laboratory Director failed to ensure initial training for one of one new testing personnel was performed and documented in 2021. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Sysmex XP-300 -Alcor mini iSED Chemistry -Beckman Coulter Access 2 -Ortho Clinical Diagnoatics Vitros 3400 -Triage Meter Pro Microbiology -Olympus CH30 microscope (Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examination) 3. A competency assessment procedure was not found in laboratory procedure manuals on date of survey. The laboratory was unable to provide this procedure upon request. See D6030. 4. One new testing personnel (TP3) was hired in 2021. The TC indicated TP3's dates of testing were as follows: 11/22/21 - 09/30/22 1/23/23 - present 5. Initial training documents for TP3 were not found in laboratory records. The laboratory was unable to provide the missing training records upon request. 6. In an interview at 10:20 a.m. on 06/08/23, the TC confirmed the above finding. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	. Based on observation, document review, and interview with laboratory personnel, the Laboratory Director failed to ensure the procedure manual included specific procedures for personnel training and competency assessments. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Sysmex XP-300 -Alcor mini iSED Chemistry -Beckman Coulter Access 2 -Ortho Clinical Diagnostics Vitros 3400 -Triage Meter Pro Microbiology -Olympus CH30 microscope (Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examination) 3. The following procedures were not found during review of laboratory manuals: -Personnel training -Personnel Competency Assessment 4. In an interview at 3:35 p.m. on 06/08/23, the Technical Consultant confirmed the above finding. .
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Laboratory Director failed to ensure the procedure manual included procedures for each laboratory activity and test. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Sysmex XP-300 -Alcor mini iSED Chemistry -Beckman Coulter Access 2 -Ortho Vitros 3400 -Triage Meter Pro Microbiology -Olympus CH30 microscope (Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examination) 3. The following procedures were not found during review of laboratory manuals: -Proficiency testing -Amended reports -Specimen referral -Complete Blood Count using the Sysmex XP-300 4. In an interview at 3:35 p.m. on 06/08/23, the Technical Consultant 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 (TC) failed to ensure competency assessments were

	completed by qualified personnel in 2021 and 2022. In addition, the TC failed to ensure three of four microscopic examinations were included on the competency assessment forms used to assess two of two testing personnel in 2021. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Sysmex XP-300 -Alcor mini iSED Chemistry -Beckman Coulter Access 2 -Ortho Vitros 3400 -Triage Meter Pro Microbiology -Olympus CH30 microscope (Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examination) 3. A competency assessment procedure was not found in laboratory procedure manuals on date of survey. See D6030. A. Competency assessment performance by testing personnel 1. 2021 and 2022 competency assessment documents reviewed for TP1 and TP2 were performed by TP2 and TP1, respectively. TP1 and TP2 hold Associate of Applied Science degrees as indicated in personnel records. 2. In an interview at 9:55 a.m., the TC confirmed the above finding. B. Competency assessment not performed for microscopic examinations in 2021 1. The following microscopic examinations were not included on the 2021 Individual Competency Assessment forms for TP1 and TP2 : -KOH Preparation -Vaginal Wet Preparation -Post-vasectomy Examination 2. In an interview at 9:55 a.m., 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 one testing personnel hired in 2021. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/08/23 at 9:00 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Sysmex XP-300 -Alcor mini iSED Chemistry -Beckman Coulter Access 2 -Ortho Vitros 3400 -Triage Meter Pro Microbiology -Olympus CH30 microscope (Urine Sediment, Vaginal Wet Preparation, KOH Preparation, and Post-vasectomy Examination) 3. A competency assessment procedure was not found in laboratory procedure manuals on date of survey. See D6030. 4. Testing Personnel 3 (TP3) was hired on 11/22/21 as indicated by the TC. Initial training documentation for TP3 was not found during review of personnel records. See D6029 5. Semi-annual competency assessment documents for TP3 were not found during review of laboratory records. The laboratory was unable to provide the missing competency assessment upon request. 6. In an interview at 10:20 a.m. on 06/08/23, the TC confirmed the above finding. .