Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0622849	11/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
West Hills Health Care Clinic	2163 Nw 2nd St, Mcminnville, OR	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of written policies and procedures for this laboratory and interview with the lead testing personnel (TP 1), the laboratory failed to ensure an approved and current Quality Assessment (QA) plan was in place and QA activities were being conducted and documented. Findings include: 1. Upon request for evidence of written QA activities for this laboratory for 2022 and 2023, none could be produced. 2. Interview with TP 1 at 12:30 pm confirmed that no formal QA activities were in place and being performed for 2022 and 2023. 3. See D6021
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 review of written laboratory documents, interview with the lead testing

	personnel (TP 1) and MD owner of the facility, the laboratory director (LD) failed to fulfill the duties of the LD. Findings include: Please see D6019, D6021, D6030, D6031, D6033, D6046
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 review of proficiency testing (PT) records for 2022 and 2023 and interview with the lead testing personnel (TP 1), the laboratory director (LD) failed to ensure a current and approved corrective action (CA) plan for PT failures was available for the laboratory and testing personnel (TP) when PT results are unacceptable. Findings include: 1. Upon review of the laboratory's policy and procedure manual, no current approved written corrective action plan for addressing unacceptable PT results could be produced. 2. Six (6) missed PT results were reviewed for 2022 and 2023. 3. Interview with TP 1 at 12:00 pm during survey confirmed that no current LD approved procedure for CA for unacceptable PT results existed. 4. The laboratory reports performing 56,068 tests per year.
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 review of the laboratory's written procedure manual and interview with the lead testing personnel (TP 1), the laboratory director (LD) failed to ensure an approved Quality Assessment (QA) plan was in place and that QA monitoring events were being conducted at least twice a year. Findings include: 1. Review of the laboratory's written policy and procedure manual failed to provide a current and approved QA plan. 2. Request for written evidence of QA monitors and monitoring events for 2022 and 2023 failed to yield any evidence of QA monitors or monitoring events. 3. Interview with TP 1 at 12:30 pm during survey confirmed that no current and approved QA monitors and QA monitoring events were in place and being monitored for 2022 and 2023. 4. The laboratory reports performing 56,068 test per year.
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 review of written policies and procedures provided for review during survey and interview with the lead testing personnel (TP 1), the laboratory director (LD) failed to ensure an approved policy/procedure for assessing testing personnel (TP) competency was in place and being followed. Findings include: 1. Upon review of the laboratory's procedure manual, no written policy/procedure for competency assessment of TP could be produced. 2. Review of competency records for TP 1 revealed that TP 1 had performed her own competency assessment for years 2022 and 2023 for moderate complexity Hematology assays and CLIA waived testing. 3. Further investigation of the competency assessments self performed by TP 1 and on record for 2022 and 2023, failed to yield any competency assessment by self or any other qualified person for moderate complexity Chemistry and Endocrinology assays performed in this laboratory. 4. Interview with TP 1 at 12:30 pm during survey confirmed that no current approved policy/procedure for competency assessment existed and that she had done her own competency assessments for all current assays except Chemistry and Endocrinology assays. 5. The laboratory reports performing 56,068 tests per year.
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 review of the laboratory's written Policy and Procedures (PP) manual and interview with the lead testing personnel (TP 1), the laboratory director (LD) failed to ensure a current approved, signed and dated PP manual was available to all testing personnel. Findings include: 1. Upon review of the PP manual, there was no evidence of review or approval by the current LD. 2. A randomly selected 15 page procedure for COVID testing revealed no LD signature or date of approval, no effective date, no author or review date 3. Interview with TP 1 at 1130 during survey confirmed that none of the signatures within the PP manual belonged to the current LD. 4. The laboratory reports performing 56,068 tests per year.

D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of written competency records reviewed during survey for 2022 and 2023 and interview with the lead testing personnel (TP 1), the technical consultant (TC) failed to fulfill the duties of the TC. Findings include: Please see D6046
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 review of written competency assessments for testing personnel (TP), the technical consultant (TC) failed to conduct competency assessments for all TP performing moderate complexity testing in this laboratory. Findings include: 1. Upon review of written competency assessments during survey, the TC failed to perform competency assessments with the required six (6) elements of competency for TP performing moderate complexity testing in Hematology, Chemistry and Endocrinology in this laboratory in 2022 and 2023. 2. Further investigation of the written competency assessments revealed that no qualified evaluator (the TC) signature or date was present for 2022 and 2023 on the competency assessment for the lead testing personnel (TP 1) for moderate complexity Hematology testing. 3. No evidence of competency assessment for moderate complexity testing in Chemistry or Endocrinology for 2022 or 2023 could be produced during survey. 4. Interview with the lead testing personnel (TP 1) confirmed that the TC had not performed any competency assessment for moderate complexity Hematology, Chemistry or Endocrinology on herself or other TP for 2022 and 2023. 5. The laboratory reports performing 56,068 tests per year.