Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1056275	02/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Evans Medical Clinic, Pllc	3493 Veteran'S Drive North Suite C, Huntingdon, TN	

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
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 observation of the laboratory, review of the laboratory procedure manual, testing personnel competency assessments, and staff interview, the laboratory failed to follow its' own policy for testing personnel competency assessment when it did not specify the test system(s) evaluated for the annual competencies performed for testing persons one and two in 2023 and 2024; and failed to include evaluation of problem solving for the annual competencies performed in 2022 and 2023 for testing person three (six of six competency evaluations reviewed). The findings include: 1. Observation of the laboratory on 02/05/24 at 8:15 am revealed the following non-waived test systems used for patient testing: Sysmex XN 330 used for patient testing for Complete Blood Count with automated White Blood Cell Differential (CBC w /diff). Ortho Vitros 250 Chemistry instrument used for patient testing for chemistry analytes. Microscope used for patient testing for urine microscopic analysis and wet prep. 2. Review of the laboratory's testing personnel policy revealed competency assessments for testing personnel would be performed using the six criteria required by CLIA. 3. Review of the testing personnel competency assessments revealed the following: The 2023 and 2024 competency assessments did not include the test system (s) evaluated for testing persons one and two. The 2022 and 2023 annual testing personnel competency assessments for wet prep did not include problem solving for testing person three. 4. Interview with the laboratory director on 02/05/24 at 9:30 am

	confirmed the laboratory failed to follow its' own policy for testing personnel competency assessment in 2022, 2023, and 2024. Word Key: CLIA=Clinical Laboratory Improvement Amendments
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, and staff interview, the laboratory failed to label the Ortho Performance Verifier I and II controls with corrected expiration date on the date of the survey (02/05/24). The findings include: 1. Observation of the laboratory on 02/05/24 at 8:15 am revealed reconstituted Ortho Performance Verifier I and II used for performing quality control on the Ortho Vitros 250 chemistry instrument. The controls were not labeled with a corrected expiration date. 2. Review of the Ortho Vitros Performance Verifier I and II control package inserts revealed the following control stability statements: Reconstituted Stability: "When stored at 2-8C (36-46 F): Stable for seven days." "Stable for 3 days:" "ALKP", "BuBc", "Ca", "TBIL". 3. Interview with the laboratory director on 02/05/24 at 4:00 pm confirmed the laboratory failed to label the Performance Verifier I and II controls with corrected expiration date after reconstitution.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory' log for recording urine microscopic findings, final patient test reports and staff interview, the laboratory failed to ensure the final patient test report for urine microscopic was accurately reported for one of two patient urine microscopic reports reviewed. The findings include: 1. Review of the log used for recording patient urine microscopic results revealed results which included a recorded observation of 1+ amorphous crystals for patient ID #29416, performed on 01/12/24. 2. Review of the final patient test report for patient ID #29416 revealed the report did not include the laboratory finding of 1+ amorphous crystals. 3. Interview with the laboratory director on 02/05/24 at 4 pm confirmed the laboratory failed to ensure the urine microscopic results for patient ID #29416 were accurately reported when the

	amorphous crystal results were omitted from the final patient test report. Word Key: ID=Identification #=number
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a final patient test report and staff interview, the final patient test report for wet prep failed to include the specimen source (one of one reports reviewed). The findings include: 1. Review of the final patient test report for patient ID #33285 revealed patient testing for wet prep reported on 01/12/24. The patient test report did not include the specimen source. 2. Interview with the lab director on 02/05 /24 at 4 pm confirmed the final patient test report for wet prep did not include the specimen source. Word Key: ID=identification #=number