Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1053381	12/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ohio Valley Health Center	423 South Street, Steubenville, OH	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection of blood specimens collected for complete blood count (CBC) testing, prostate specific antigen (PSA) testing, thyroid-stimulating hormone (TSH) testing, and Vitamin D testing. This deficient practice had the potential to affect 363 out of 363 patients tested under the specialties of Hematology and Chemistry, and the subspecialty of Endocrinology from 08/29/2023 through 12/29 /2024. Findings Include: 1. Review of the laboratory's "Ohio Valley Health Center" policies and procedures, unapproved by the Laboratory Director, and provided on the date of inspection, did not find any mention of policies or procedures for specimen acceptability and rejection of blood specimens collected for CBC, PSA, TSH and Vitamin D testing. 2. The inspector requested policies and procedures for specimen acceptability and rejection of blood specimens collected for CBC, PSA, TSH and Vitamin D testing from TP #1. TP #1 confirmed the laboratory did not include specimen acceptability and rejection in their policies and procedures and did not have any documentation to provide on the date of the inspection. The interview occurred on 12/29/2024 at 10:40 AM.
D5807	TEST REPORT

	CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to report the correct Alkaline Phosphatase (ALP), Glucose (GLU), and Potassium (K+) reference range values for two out of two patient test reports reviewed. This deficient practice had the potential to affect 45 out of 45 patients tested in the subspecialty of Routine Chemistry from 11/01/2024 through 12/30/2024. Findings include: 1. Review of the laboratory's "Comprehensive Metabolic Panel by Abaxis Piccolo Xpress" policy and procedure unapproved by the laboratory director via signature and date, and provided on the date of inspection found the following: Analyte Male Range ALP (U/L) 53 - 128 Analyte Range GLU (mg/dL) 73 - 118 K+ (mmol/L) 3.6 - 5.1 2. Review of two chemistry test reports found the following reference ranges listed: Date DOB Reference Range 11/7/2024 5/21/1980 GLU 73-100 mg/dL K+ 3.6-5.3 mmol/L ALP 3.6-5.3 mmol/L Date DOB Reference Range 12 /10/2024 7/27/1970 GLU 73-100 mg/dL K+ 3.6-5.3 mmol/L 3. An interview with TP #1, confirmed the ALP, GLU, and K+ reference ranges listed in the policy and procedure did not match the reference ranges listed on the patient reports. The interview occurred 12/29/2024 at 1215 PM. U/L = units per liter mg/dL = milligrams per deciliter mmol/L = millimoles per liter
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure that the Vitamin D test accuracy verification (TAV) activities were conducted as required under subpart H of this part. There were no patients tested for Vitamin D from 05/23/2024 through 09/03/2024. Findings Include: 1. Review of the "Quality Management Policy" unapproved by the Laboratory Director, did not find any mention of the frequency for testing proficiency samples. 2. Review of the laboratory's 2024 American Proficiency Institute (API) Chemistry 3rd event documentation, provided on the date of the inspection, revealed a score of 0%. Further review found the following statement: "No Vitamin D testing performed during the testing period. Will resume when testing resumes." 3. TP#1 stated the laboratory did not perform any patient Vitamin D tests from 05/23/2024 through 09/03/2024, did not complete the API Chemistry 3rd event, and disposed of the samples upon receipt. The interview occurred on 12/30/2024 at 10:30 AM.
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 record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of complete blood count (CBC) testing, prostate specific antigen (PSA) testing, thyroid-stimulating hormone (TSH) testing, and Vitamin D testing procedures performed in the specialties of Hematology and Chemistry, and the subspecialty of Endocrinology. This deficient practice had the potential to affect 45 out of 45 patients tested from 11/01/2024 through 12/29/2024. Findings Include: 1. Review of the laboratory's "Ohio Valley Health Center" policies and procedures, did not find the Laboratory Director's approval via signature and date. 2. The inspector requested approved policies and procedures for any aspect of CBC testing, PSA testing, TSH testing, and Vitamin D testing procedures from TP #1 . TP #1 stated the Laboratory Director did not approve the new policies and procedures via signature and date, and was unable to provide the requested information. The interview occurred on 12/29/2024 at 10:15 AM.