

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1053381	<b>(X3) Date Survey Completed</b>  08/29/2023
<b>Name of Provider or Supplier</b>  Ohio Valley Health Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to enroll in a proficiency testing (PT) program for the specialty of Hematology and the subspecialty of Endocrinology. This deficient practice had the potential to affect 53 patients tested under the specialty of Hematology and 15 patients tested under the subspecialty of Endocrinology from 03/13/2023 through 08/29/2023. Findings Include: 1. The laboratory failed to enroll in a PT program for the specialty of Hematology and the subspecialty of Endocrinology. (Refer to D2001)</p>
<b>D2001</b>	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p>

This STANDARD is not met as evidenced by:  
 Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to enroll in a proficiency testing (PT) program for the specialty of Hematology and the subspecialty of Endocrinology. This deficient practice had the potential to affect 53 patients tested under the specialty of Hematology and 15 patients tested under the subspecialty of Endocrinology from 03/13/2023 through 08/29/2023. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policies" policy and procedure, approved via signature and date by the Laboratory Director on 02/21 /2023, found the following statement: "QA Manual FastPack IP System Quality Assurance Manual ...This laboratory enrolls annually in PT for all non-waived tests, such as the FastPack IP System tests." 2. The inspector asked for the 2023 PT records for Hematology and Endocrinology from TP #1. 4. TP #1 confirmed the laboratory was not enrolled with an HHS approved PT provider for the specialty of Hematology and the subspecialty of Endocrinology and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 08/29/2023 at 11:00 AM.

**D3011**

**FACILITIES**  
 CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:  
 Based on direct observation and an interview with Testing Personal (TP) #1, the laboratory failed to establish safety procedures which ensured protection from chemical and biological hazards. This deficient practice had the potential to affect all personnel in or near the laboratory. Findings Include: 1. Document review did not find any chemical and biological spill procedures, or disposition of chemical and biological waste procedures available to facility personnel. 2. Direct observation in the laboratory revealed a Sysmex XP-300 analyzer with a CellPack reagent container connected and next to the instrument. Review of the material safety data sheet (MSDS) found the following statements: "6 Accidental release measures Ensure adequate ventilation. For large spills, wear protective clothing. For large spills, use respiratory protective device against the effects of fumes/dust/aerosol. Environmental precautions Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Methods and material for containment and cleaning up Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Send for recovery or disposal in suitable receptacles." 3. Further observation revealed a red sharps biohazard disposal container on the counter next to a patient blood draw chair. 4. TP #1 stated patient blood draws and urine testing were performed in the same laboratory as the Sysmex instrument testing. The inspector requested safety policies and procedures, chemical and biological spill kits, and an eye wash station from TP #1. TP #1 confirmed the laboratory did not have safety policies and procedures, chemical and biological spill kits, or an eye wash station. The interview occurred on 08/29/2023 at 1:30 PM.

**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 and thyroid-stimulating hormone (TSH) testing. This deficient practice had the potential to affect 53 patients tested under the specialty of Hematology and 15 patients tested under the subspecialty of Endocrinology from 03/13/2023 through 08/29/2023. Findings Include: 1. Review of the laboratory's "QA Manual FastPack IP System" quality assurance manual provided to the laboratory by the manufacturer, approved via signature and date by the Laboratory Director on 02/21/2023, did not find any mention of policies or procedures for specimen acceptability and rejection of blood specimens collected for CBC testing and TSH testing. 2. The inspector requested policies and procedures for specimen acceptability and rejection of blood specimens collected for CBC testing and TSH testing from TP #1. TP #1 confirmed there was no policy or procedure, or documentation for specimen acceptability and rejection. The interview occurred on 08/29/2023 at 11:30 AM.

**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 record review, direct observation and an interview with Testing Personnel (TP) #1, the laboratory failed to have a written procedure manual for complete blood count (CBC) testing. This deficient practice had the potential to affect 53 patients tested under the specialty of Hematology from 03/13/2023 through 08/29/2023. Findings include: 1. Review of the form CMS-116 section VIII found the speciality of Hematology marked as being performed.. 2. Direct observation found a Sysmex XP-300 blood analyzer in the laboratory. 3. The inspector requested a written procedure manual for the complete blood count testing from TP #1. TP #1 confirmed there was no written procedure manual for the Sysmex XP-300 procedures and was unable to provide the requested documentation. The interview occurred on 08/29/2023 at 1:15 PM.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with Testing Personal (TP) #1, the laboratory failed to document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 53 patients tested under the specialty of Hematology and 15 patients tested under the subspecialty of Endocrinology from 03/13/2023 through 08/29/2023. Findings Include: 1. Review of the "Quality Assurance Assessment Program" signed and dated by the Laboratory Director on 02/21/2023 found no mention of documenting assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 2. Further document review did not find any written assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 3. The inspector requested post analytic quality assurance documentation from TP #1. TP #1 stated the post analytic assessment activities were completed but not documented and was unable to provide the requested information. The interview occurred on 08/29/2023 at 1:45 PM.

**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 record review and an interview with Testing Personnel (TP) #1, the Technical Consultant (TC) failed to evaluate and document the competency of one out of one Testing Personnel (TP) in 2023 assuring their competency was maintained in order to perform moderately complex complete blood count (CBC) and automated differential (Adiff) testing in the specialty of Hematology, and report the test results promptly, accurately, and proficiently. This deficient practice had the potential to affect 53 out of 53 patient CBC and Adiff tests conducted from 03/13/2023 through 08/29/2023. Findings Include: 1. Review of the laboratory's form CMS-209 found one out of one individual listed, credentialed and approved by the Laboratory Director via signature and date on 08/10/2023 to function in the role of TP for moderate complexity testing. 2. Review of the laboratory's 2023 competency assessment documentation, provided on the date of inspection, did not find any competency assessments completed for CBC testing. 3. The inspector requested the competency assessment policies and procedures, and the 2023 CBC competency assessment records for TP #1 from TP #1. 4. TP #1 confirmed there was no CBC competency policy or procedure, competency assessments were not conducted for CBC testing, and could not provide the requested documents. The interview occurred on 08/29/2023 at 10:35 AM.