

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0350731	<b>(X3) Date Survey Completed</b> 11/22/2022
<b>Name of Provider or Supplier</b> Valley Diagnostic Labs	<b>Street Address, City, State</b> 1504 Jackson Pike/Po Box 33, Gallipolis, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor (TS), General Supervisor (GS) and Testing Personnel (TP) based on the responsibilities of the position, as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect 228,000 patients tested under the specialties of microbiology, diagnostic immunology, chemistry and hematology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the LD on 11/09/2022, showed one individual qualified by the Laboratory Director to function in the assigned position of TS, the same individual qualified by the Laboratory Director to function in the assigned position of GS, and two individuals qualified by the Laboratory Director to function in the assigned position of TP. 2. Review of the laboratory's policies and procedures titled "QA Log", provided for the inspection, did not find any policy or procedure for personnel competency assessment. 3. The Inspector requested the laboratory's competency assessment policy and procedure for the TS, GS and TP based on the responsibilities of the position from the TS. The TS confirmed the laboratory did not establish a policies and procedures for the assessment of the TS, GS and TP, did not assess the competency of the TS and GS based on the responsibilities of the assigned positions, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 11/22/2022 at 11:00 AM.</p>
<b>D5805</b>	<b>TEST REPORT</b>

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 record reviews and an interview with the Technical Supervisor (TS), the laboratory failed to include the gender specific reference ranges for hemoglobin and hematocrit on the final test report. This deficient practice had the potential to affect 73,877 patients tested under the specialty of hematology. Findings Include: 1. Review of policies and procedures titled "QA Log" did not find any mention of gender specific reference ranges for hemoglobin and hematocrit tests. 2. Review of six out of six of the laboratory's final hematology patient test reports revealed all six test reports did not indicate gender specific reference ranges for hemoglobin and hematocrit. 3. The inspector requested gender specific reference ranges for hemoglobin and hematocrit tests from the TS. The TS confirmed the laboratory did not have gender specific ranges for hemoglobin and hematocrit and was unable to provide the requested information. The interview occurred 11/22/2022 at 12:45 PM.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 reviews and an interview with the Technical Supervisor (TS), the Technical Supervisor (TS) failed to evaluate the competency of Testing Personnel (TP) #1 and TP #2 to ensure they maintained their competency to perform high complexity test procedures and report test results promptly, accurately, and proficiently in 2021 and 2022. All patient testing under the specialties of microbiology, diagnostic immunology, chemistry and hematology, performed by TP #1 and TP #2, had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the LD on 11/09/2022, showed two individuals qualified by the Laboratory Director to function in the assigned position of TP. 2. Review of the laboratory's policies and procedures titled "QA Log" did not find any mention of competency assessment. 3. Review of 2021 and 2022 competency assessment records for TP #1 and TP #2 revealed incomplete documents. 4. The inspector requested competency assessment policies and procedures, and 2021 and 2022 completed competency assessment documentation for TP #1 and TP #2 from the TS. The TS verified there were no

policies and procedures for competency assessment, and competency assessment records were not fully completed for TP #1 and TP #2 in 2021 and 2022, and was unable to provide the requested information. The interview occurred 11/22/2022 at 10:30 AM.