

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1021626	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Valley Physician Services, Inc	Street Address, City, State 400 Old Hook Road Suite 2-1, Westwood, NJ	
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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on one out of one testing personnel for the calendar years 2020 and 2021. The OM confirmed on 11/30/22 at 10:30 am that the CA was not performed as stated above.</p>
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of Electronic Medical Records (EMR), Accession Log (AL), Work Records (WR) and interview with the Office Manager (OM), the laboratory failed to ensure that WR were entered accurately into the EMR system for all tests from 11/14/19 to the date of the survey. The OM confirmed on 11/30/22 at 11:00 am that the laboratory did not ensure that WR were entered accurately into the EMR system.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

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 surveyor observation of the Quality Control (QC) reagents and interview with the Office Manager (OM), the laboratory failed to put a new expiration date on the ABX Micros QC reagents in use on the Horiba analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 16 days after opening." 2. The laboratory did not put new expiration dates on the ABX Micros QC reagents after opening. 3. The OM confirmed on 11/30/22 at 11:10 am the laboratory failed to put new expiration date on the QC reagents.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of Calibration (C) records, User Manual (UM) and interview with the Office Manager (OM), the laboratory failed to perform, document and meet acceptable limits for all Calibration results and procedures at least once every six months for Hematology Tests performed on the Horiba analyzer in the calendar year 2022. The findings include: 1. A review of C records revealed that the laboratory failed to correctly perform and document "repeatability" a) The UM states in the "Preparation for Calibration" procedure to "perform a repeatability study by running one normal patient sample ten times mixing well before each run. Ensure repeatability is acceptable" 2. Calibration material was run on 8/25/22 repeatability was performed on 9/29/2022. 3. The OM confirmed on 11/30/2022 at 11:32 am that the laboratory failed to correctly perform, document and meet acceptable limits for C once every six months.

D5803

TEST REPORT

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Electronic Medical Records (EMR), Test Results (TR) and interview with the Office Manager (OM), the laboratory failed to have all tests performed in the EMR on the date of survey. The finding includes: 1. One out of five EMR reviewed did not have a TR. 2. The OM confirmed on 11/30/22 at 11:40 am that all TR were not in the EMR.