

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0703873	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier Valley Medical Group	Street Address, City, State 238 Northampton Street, Easthampton, MA	
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
D0000	A CLIA recertification survey was conducted for the Valley Medical Group laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date as evidenced by the following: a) During a tour of the laboratory on 6/25/24 at 2:37 PM, the surveyor observed the following expired item in the laboratory area where Physician Performed Microscopy Procedures (PPMP) are performed: * One (1) bottle of Potassium Hydroxide (KOH), lot number 6124, expiration date 1/27/24. b) There were no other in-date reagents available in the laboratory. Based on this evidence the accuracy and reliability of microscopic examinations, utilizing this reagent, could not be assured. Three (3) patient samples for KOH had been tested since the reagent expired (1/29/24, 5/1/24, and 6/20/24). c) The laboratory performs approximately 82 KOH preparations annually.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems</p>

identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the postanalytic phases of testing as evidenced by the following: a) A review of post analytical quality assessment procedures for calendar years 2023 and 2024 revealed that the laboratory routinely reviewed five (5) patient reports for all aspects of the testing process. b) A review of the procedure manual revealed no post analytic policies and procedures to be followed.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to fulfill the responsibility for verification of the laboratory's test performance characteristics as evidenced by the following: a) Documentation was not available to verify that the technical consultant reviewed and approved validation studies of the C Reactive Protein (CRP) analyte for accuracy, linearity (reportable range), as well as day to day and within run precision prior to implementing the analyzer for patient testing and reporting. b) General Supervisor #2 confirmed in an interview on 6/25/24 at 4:40 PM that the designated technical consultant had not documented an approval for the CRP procedure. c) The laboratory performs approximately 2,799 CRP tests annually. .