Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2054677	01/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Physician Services, Pc - Oncology	1 Valley Health Plaza, Paramus, 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
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to submit the College of American Pathologists (CAP) Hematology with Auto Differential PT results for event FH13-B 2018 on time. The TP # 1 listed on the CMS form 209 confirmed on 1/8/19 at 1:30 pm that the above results were not returned to the provider in required time frame .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow the instructions on the CA form to correctly assess CA on three of three testing personnel in 2017. The findings include: 1. The laboratory failed to use the Competency Evaluation Tools listed on the CA form. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 12:30 pm that CA form was not followed. b. Based on surveyor review of the CA records and interview with the TP, the laboratory failed to

	establish and follow an accurate CA form in the calendar year 2018. The findings include: 1. The CA form did not include: a. Monitoring the reporting and recording results. b. Assessment of test performance. c. Assessment of problem solving skills. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 12:35 pm that an accurate CA form was not established.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the College of American Pathologists (CAP) for Hematology with Auto Differential events performed in 2018. The findings include: 1. There was no evaluation documented when the laboratory received an exception code of 26 (Educational Challenge) for Blood Cell Identification in FH13-A and C. 2. There was no evaluation documented when the laboratory received an exception code of 26 (Educational Challenge) for nucleated Red Blood Cell (percent and absolute) in FH13-A and C. 3. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 1:45 pm that the laboratory did not review and evaluate all PT results.
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: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a written procedure for verification of new controls used in Hematology tests from 2/3/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 1:50 pm a written procedure was not established. b) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the procedure for Critical Values (CV) in August 2018. The finding includes: 1. The CV procedure stated "Notify the attending physician and document notification by writing CBC verified by repeat" but there was not documented evidence the PM was followed for four of four patients reviewed with CV. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 2:10 pm the PM was not followed. c. Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the procedure for reviewing results with flags obtained on the Unicel DXH 600 analyzer used for Hematology testing in August 2018. The findings include: 1. A review of 11 patient results with flags revealed: a. "R" PM stated: Review result and parameter derived from from R flag cannot be recalculated until flag is edited. b. "c" PM stated: critical limit exceeded c. "a" PM stated: action

	limit exceeded 2. There was no documented evidence of review of flags. 3. The TP # 1 listed on the CMS form 209 confirmed on 1/8/19 at 2:35 pm that the laboratory did not follow the procedure for result review.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for correlating the open and closed mode on the Unicell DXH 600 from 2/3/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 2:10 pm that the laboratory did not establish the above procedure.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the laboratory failed to perform and document comparison studies for the open and closed mode Complete Blood Count (CBC) test performed on the Unicell DXH 600 twice per year in 2017 and 2018. The TP # 1 listed on the CMS Form 209 confirmed on 1/8/19 at 11:20 am that the laboratory did not have studies for the comparison of the open and closed mode.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL) and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when the Refrigerator Temperature (RT) was out of range from May to December 2018. The findings include: 1. A review of the TL revealed that RT was outside the established range: a. 5 out of 22 days in May b. 4 out of 21 days in July c. 2 out of 23 days in October d. 4 out of 21 days in November e. 3 out of 20 days in December 2. There was no documented evidence of corrective action taken. 3. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 1:45 pm the laboratory did not document corrective action.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Levy Jennings Charts (LJ) and interview with the Testing Personnel (TP) the laboratory failed to take and document Corrective Action (CA) when LJ charts for Hematology Quality Controls (QC) failed to meet established criteria for acceptability from November 2017 to December 2018. The findings include: 1. There was no documented CA taken when LJ charts showed the Coefficient of Variant (CV) to be outside established values as follows: a. Platelets: Low QC - 11/3/17 - 7/20/18 and 10/18/18 to 12/5/18. b. Platelets: High QC - 6/8/18 to 12/5/18. c. Mean Corpuscular Volume (MCV): Low and Normal QC- 11/3/17 - 1/14 /18. d. MCV: High QC - 6/11/18 - 7/20/18. 2. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 2:30 pm that CA was not taken.
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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to verify manually entered results into Electronic Medical Records (EMR) from 2/3/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 2:15 pm that the laboratory did not have the procedure mentioned above.
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 surveyor review of the Personnel Files, Competency Assessment records and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to perform CA from 2/3/17 to the date of survey. The findings include: 1. The CA was not performed by the TC. 2. The TP #1 performed CA on two of three TP, TP #3 performed CA on one of three TP but neither TP was qualified to perform CA. 3. The TP #1 listed on CMS form 209 confirmed on 1/8/19 at 1:15 pm that the CA was not performed by TC.