

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0996882	<b>(X3) Date Survey Completed</b>  08/02/2018
<b>Name of Provider or Supplier</b>  South Valley Health Center	<b>Street Address, City, State</b>  38350 40th St East, Ste 100, Palmdale, CA	
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>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the second quarter (Q2-2018) College of the American Pathologists (CAP) proficiency testing records, laboratory's proficiency testing evaluation results and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event. The findings included: a. Q2-2018, CAP reported an unsatisfactory proficiency testing score of 40% for Lymphocytes. b. For fourteen (14) out of nineteen (19) random patient test results reviewed covering period from 10/11/2016 to 2/15/2018, fourteen patients have Complete Blood Count (CBC) ordered, analyzed and reported during which there was a failure in the proficiency testing results for Lymphocytes. c. The technical consultant affirmed (8/2/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing result for Lymphocytes.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the third quarter (Q3-2017) College of the American Pathologists (CAP) proficiency testing records, laboratory's proficiency testing evaluation results</p>

and interview with the technical consultant, it was determined that the laboratory failed to at least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. Q3-2017, CAP reported an unsatisfactory proficiency testing score of 60% for Lipase analyte. b. Based on the laboratory's testing declaration volume submitted for 2017-2018, the laboratory analyzed and reported 30,994 Routine Chemistry tests which included Lipase analytes. c. The technical consultant affirmed (8/2/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing result for Lipase analyte.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of random patient sampling test results and the lack of documentation for Wright's stain reactivity, and interview with the technical consultant, it was determined that the laboratory failed to each day of use, test materials for intended reactivity to ensure predictable staining characteristics. The findings included: a. The laboratory uses Neat Stain Step Hematology stain reagents for manual differential stains. b. The laboratory has no documentation to show that the stain reactivity is being monitored or inspected to ensure predictable staining characteristics of the stain. The laboratory has a notation in its procedure stating: "Note2: Any variation of the procedure other than describe above may adversely affect results." c. For fourteen (14) out of nineteen (19) random patient test results reviewed covering period from 10/11/2016 to 2/15/2018, fourteen patients have Complete Blood Count (CBC) ordered, analyzed and reported which the manual differential results could not be assured of its stain reactivity staining characteristics. d. The technical consultant affirmed (8/2/2018, 1500), that the laboratory has no documentation to show for the staining characteristics for each day of use.

**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 request, review and the lack of documentation for White Blood Cell (WBC) count auto differential and manual differential counts comparison studies, and interview with the technical consultant, it was determine that the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the different methodologies. The findings included: a. The laboratory

uses UNICEL DXH 800 a Hematology analyzer. There was no documentation to show that the laboratory has a system to verify for the White Blood Count (WBC) auto differential against WBC manual differential counts. b. For fourteen (14) out of nineteen (19) random patient test results reviewed covering period from 10/11/2016 to 2/15/2018, fourteen patient have Complete Blood Count (CBC) ordered, analyzed and reported which either auto WBC differentials or WBC manual differentials. c. The technical consultant affirmed (8/2/2018, 1500) that the laboratory had no documentation to show comparing the WBC Auto differential against WBC manual differential counts.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of random patient sampling test results and the lack of documentation for Wright's stain reactivity, and interview with the technical consultant, See D 5473, and based on request, review and the lack of documentation for White Blood Cell (WBC) count auto differential and manual differential counts comparison studies, and interview with the technical consultant, it was determine that the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. See D5775.