

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657391	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Lghp/Penmed A&R Harrisburg Pike	Street Address, City, State 2108 Harrisburg Pike Ste 200, Lancaster, PA	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based a review of Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed the accuracy of the results obtained on proficiency testing for 2 of 3 MLE events for General Immunology in 2021 and 2022. Findings: 1. On the day of survey, 04/12 /2023 at 09:17 am., review of the laboratory's MLE PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the proficiency testing agency - MLE 2021 M2: Anti-SSB AE-6 - MLE 2021 M3: Anti-RNP/SM AE-12 - MLE 2022 M1: Anti-RNP/SM AE-1 - MLE 2022 M3: Anti-SSA AE-13 and Anti-SM AE12 2. The TS confirmed the findings above on 04/12 /2023 around 11:40 am.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on review of the Beckman DXH 520 analyzer validation records and interview with the Technical Supervisor (TS), the laboratory failed to establish criteria for acceptable performance specifications for 13 of 13 analytes performed on the Beckman DXH 520 analyzer from 08/12/2021 to 04/12/2023. Findings Include: 1. On the day of survey, 04/12/2023 at 09:54 am, review of the Beckman DXH 520 analyzer validation records revealed, the validation performed on 08/12/2021 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy and Reportable ranges for the following analytes: - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) - Neutrophils (NEU) - Lymphocytes (LYM) - Monocytes (MON) - Eosinophyls (EOS) - Basophyls (BAS) 2. The laboratory could not provide documentation for the following validation studies on the Beckman DXH 520 analyzer for accuracy, and precision: -Automated differentials (NEU, LYM, MON, EOS, BAS) 3. The laboratory's annual volumen for hematology is 6040 (CMS 116). 4. The TS confirmed the findings above on 04/12/2023 around 11:40 am.