

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D2074747 | (X3) Date Survey Completed 03/07/2022 |
| Name of Provider or Supplier Kidmed Mechanicsville | Street Address, City, State 8356 Bell Creek Road, Mechanicsville, VA | |
| 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 | An announced CLIA Recertification survey was conducted at the Kidmed Mechanicsville on 03/07/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. |
| D2127 | <p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the CASPER Report 0096D CLIA Application and Survey Summary, proficiency testing (PT) documents and interview, the laboratory failed to submit one of six PT events within the PT program's established timeframe in the calendar year 2020. PT events reviewed include all three events in 2020 and 2021. Findings include: 1. Review of the CASPER Report 0096D CLIA Application and Survey Summary revealed the lab received a score of 0% for the third event in 2020 (Hematology module). 2. Review of the American Proficiency Institute (API) records for 2020 Event 3 Hematology revealed the lab received a score of 0% "Failure to Participate". 3. An exit interview with the technical consultant and site manager on 03 /07/22 at approximately 1515 confirmed the site failed to submit PT results within API's established timeframe and the score of 0%.</p> |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</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.

This STANDARD is not met as evidenced by:

Based on review of the performance verification records, lack of documentation, and interview, the laboratory failed to verify the reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the hematology analyzer prior to reporting patient results from 06/09/21 and up to the date of survey on 03/07/22. Findings include: 1. Review of the Horiba ABX 60 (serial number 103CS99468, installed 06/09/21) hematology analyzer's performance verification documentation revealed lack of documentation of verification of the reference (normal) ranges for CBCs during or after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges for the above-specified instrument prior to patient testing. The laboratory provided no documentation for review. 2. An exit interview with technical consultant on 03/07/22 at approximately 1515 PM confirmed the findings.