Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2015652	**(X3) Date Survey Completed** 05/11/2021
Name of Provider or Supplier Kidmed Southside	**Street Address, City, State** 5021 Craig Rath Boulevard Building - Iv, Midlothian, 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 on-site survey was conducted at the Kidmed Southside on May 11, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on April 19, 2021 with off-site record review of documentation and a follow-up phone conference on May 10, 2021. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493-803 Condition: Successful Participation. The laboratory is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on the review of the proficiency testing (PT) scores for the third event in 2020 and the first event in 2021, the CASPER 0155D Individual Laboratory PT report, and an interview with the primary testing personnel and technical consultant, the laboratory failed to achieved satisfactory performance of at least 80% for two consecutive events for the Platelet Count (PLT) parameter, in which the laboratory received scores of 0% and 60% respectively, resulting in unsuccessful performance (Cross Reference D 2130).
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and an interview, the laboratory failed to participate in one (1) of 7 Complete Blood Count (CBC) events reviewed. Record review included all three events in 2019, 2020 and the first event in 2021. Findings include: 1. Review of the CASPER 0155D Individual Laboratory Profile Report and the American Proficiency Institute (API) PT records for the third event in 2020 revealed the laboratory received a score of 0%. 2020 Event C- 0%- for the CBC module (Notation by API-failure to participate). 2. An exit interview with the technical consultant on 05/11/21 at approximately 2 PM confirmed the findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review the proficiency testing (PT) scores for the third event in 2020 and the first event in 2021, the CASPER 0155D Individual Laboratory PT report and interview with the technical consultant, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the Platelet Count (PLT) parameter, resulting in unsuccessful performance. Findings include: 1. Review of the API hematology PT scores and the CASPER 0155D Individual Laboratory PT report revealed the following scores: 2020 3rd event PLT- 0% 2021 1st event PLT- 60% The laboratory received an unsuccessful API PT score for the above listed analyte. 2. An exit interview with the technical consultant on 05/11/21 at approximately 2 PM confirmed the findings.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policy and procedures (P&P), Horiba Micros 60 calibration records, and interviews, the laboratory failed to document Horiba Micros 60 calibration procedures for hematology Complete Blood Count (CBC) testing according to their written policy in the calendar year 2019. Findings include: 1. Review of the P&P revealed a calibration policy (signed by the lab director 1/11/17) that outlined to calibrate CBC testing on the Horiba Micros 60 at a frequency of every six (6) months. 2. Review of the laboratory's 2018 and 2019 calibration records revealed calibrations were performed on the Horiba Micros 60 on 10/17/2018 and 8/5/2019. The surveyor requested additional documentation for calendar year of 2019 demonstrating calibration for the Horiba Micros every 6 months. The laboratory provided one (1) additional calibration documentation performed on 10/19/19 but no additional documents between 10/17/2018 to 8/5/2019. 3. An exit interview with the technical consultant at approximately 3:30 PM on 5/11/21 confirmed the findings.