| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D0677408 | 05/11/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kedplasma Llc D/B/A Somerset Labs | 15 Limestone Drive, Williamsville, NY | |

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 |
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| **D0000** | An announced CLIA exempt-state validation survey was conducted at KEDPlasma LLC D/B/A Somerset Labs on May 12, 2023 by CMS Boston CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found not to be in compliance with standard-level CLIA requirements. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Alfa Wasserman ACE AXCEL and Sebia CAPILLARYS 2 Flex System for 12 of 12 months reviewed. Findings include: 1. On 05/11/2023 at 09: 30 am, the laboratory supervisor confirmed Total Protein testing was performed using the Alfa Wasserman ACE AXCEL analyzer. 2. A review of the Alfa Wasserman ACE AXCEL analyzer manual titled, " Operator's Manual" in Section 4.2.1 "Site Specifications" stated "Relative humidity is 20% to 80%, non-condensing. 3. A review of laboratory temperature records from January 2022 through December 2022 revealed for 12 of 12 months, humidity was not documented. 4. Interview with the laboratory supervisor on 05/11/2023 at 02:34 pm, confirmed the laboratory humidity was not maintained as required by the manufacturer as indicated above. |
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| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the laboratory supervisor, the technical supervisor failed to ensure competency evaluations for high complexity testing was performed semiannually during the first year of testing for one of one testing person. Findings include: 1. On 05/11/2023 a review of personnel records for one person hired to perform high complexity testing revealed the following for one of one testing person: a. Testing Person #1 - The initial training was completed on 09/09/2020. There was no evidence a competency evaluation had been performed between 09/09 /2020 and 01/16/2023. 2. Interview with the laboratory supervisor on 05/11/2023 at 02:00 pm, confirmed a semiannual competency evaluation was not performed. |