

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 99D2283230	<b>(X3) Date Survey Completed</b> 06/07/2023
<b>Name of Provider or Supplier</b> Eve Technologies Corporation	<b>Street Address, City, State</b> 3415a 3 Ave Nw, Not Available, FN	
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>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) Boston CLIA Branch Location federal surveyor conducted an announced remote CLIA initial survey on May 30, 2023 through June 1, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5413</b>	Based on record review, manufacturer's instructions, and interview with the Technical Supervisor (TS), the laboratory failed to ensure the room temperature and humidity were maintained as required by the manufacturer for the Luminex 100/200 instrument. Findings include: 1. Record review conducted on 05/31/2023 revealed that the laboratory failed to document the room temperature and humidity where the Luminex 100/200 instrument was used during the establishment and verification of performance specifications for the following panels: a. Human Cytokine 71-Plex Discovery Assay (HD71) b. Human Cytokine Proinflammatory Focused 15-Plex Discovery Assay (HDF15) c. Soluble Cytokine Receptor 14-Plex (HDSCR14) d. Serum Amyloid A (SAA) & ADAMTS 13 2-Plex 2. Review of the Operator's Manual on 05/31/2023 stated under "System Specifications" a. "Operating Temperature: 15 C to 30 C (59 F to 86 F)" b. "Operating Humidity: 20% to 80%, non-condensing" 3. Interview with TS on 05/31/2023 at 04:06 PM confirmed the laboratory failed to ensure the room temperature and humidity were maintained as required by the manufacturer as indicated above
<b>D5423</b>	Based on review of establishment and verification of performance specifications and interview with the Technical Supervisor (TS), the laboratory failed to establish normal reference intervals for one of one procedure Findings include: 1. Interview with the TS on 05/30/2023 at 11:30 AM confirmed the laboratory used the Luminex 100/200 instrument to perform establishment and verification of performance specifications for the following panel and specimen type: a. Serum Amyloid A (SAA) - Cerebrospinal Fluid (CSF) 2. Record review on 05/31/2023 of the laboratory's establishment and

verification of performance specification revealed the normal reference interval for CSF was not established. 3. Interview with TS on 06/01/2023 at 01:06 PM confirmed the findings as indicated above.