

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0437372	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Esse Health	Street Address, City, State 637 Dunn Road, Ste 170/180, Hazelwood, MO	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory refrigerator and interview with the technical consultant (TC), the laboratory failed to ensure patient protection from biohazardous materials. Findings: 1. Observation of the laboratory refrigerator showed children's liquid oral Tylenol and children's liquid oral Benadryl stored with the laboratory's positive and negative streptococci microbiology quality control swabs. 2. Interview with the TC on August 30, 2023 at 10:30 AM confirmed the laboratory failed to ensure protection from from biohazardous materials.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the "BD BBL Taxo A Discs" reagent vial, review of the "BD BBL Taxo A Discs" package insert and interviews with the clinic staff and the technical consultant (TC), the laboratory failed to follow manufacturer's instructions for reagent storage. Findings: 1. Observation of "BD BBL Taxo A Discs" reagent vial,</p>

lot # 3058506 expiration date September 30, 2024 showed the reagent vial stored on the laboratory counter at room temperature. 2. Review of the "BD BBL Taxo A Discs" package insert states "After use, store vial or cartridge to protect product integrity at 2 to 8 degrees C" and "Vials and cartridges from which discs have been frequently removed during one week and disc left out overnight in the laboratory should be discarded or the discs should be tested for performance with control organisms prior to continued use." 3. Interview with the medical assistant on August 30, 2023 at 10:15 AM, the medical assistant stated that "those were left out overnight." 4. Interview with the TC on August 30, 2023 at 11:00 AM, confirmed the laboratory failed to follow manufacturer's instructions for reagent storage.