

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2123321	<b>(X3) Date Survey Completed</b>  10/26/2021
<b>Name of Provider or Supplier</b>  Serenity Pediatrics	<b>Street Address, City, State</b>  71 E Long Lake Road, Bloomfield Hills, MI	
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>D3011</b>	<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:</p> <p>. Based on observation and interview with the Technical Consultant (TC), the laboratory failed to store laboratory products in a designated refrigerator for 1 day (October 26, 2021) of 1 day of storing laboratory reagents, proficiency testing specimens, and quality control material. Findings include: 1. During a tour of the laboratory on 10/26/2021 at 11:51 am, the TC showed the surveyor an overflow refrigerator in the employee break room that housed the following laboratory products in their own drawer with their own VWR thermometer: a. BxH500 Series controls - level low, normal, and high (lot 352112911, 36211292, and 372112913) expiration date of 12/05/2021 b. College of American Pathologist (CAP) proficiency testing specimens FH16 specimens #11-#15 c. McKesson True Metrix Levels 1 (1BC1A50), Level 2 (13C2A54), and Level 3 13C3A46) expiration dates of 5/31/2023 d. Beckman Coulter DxH500 series Calibrators lot 492114400 expiration date 11/05/2021 e. Consult liquid Urine Controls lot UCD0100002 expiration date 9/26/2022 f. Abbott Cholesterol LDX multianalyte control lot 902941212 expiration date 8/18/2022 g. Consult hCG Urine Control lot KN00259 expiration date 7/31/2023 and lot KN00272 expiration date 10/31/2023 2. When queried on 10/26/21 at 11:51 the TC stated the AccuVux was just restocked with vaccines so they had to move the laboratory products to another refrigerator. 3. An interview on 10/26/2021 at 11:51 am, the TC confirmed the laboratory products had been moved over to the break room refrigerator for one day due to lack of storage space.</p>
<b>D5801</b>	TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure test results were accurately entered into the laboratory information system (LIS) from the patients printed report from the Beckman Coulter DxH500 hematology analyzer for 2 (11040 and 16519) of 13 patient test reports reviewed. Findings include: 1. A record review of the manually transcribed results into the LIS revealed for 2 (11040 and 16519) of 13 patient test reports reviewed, the following test parameters were manually entered into the LIS system incorrectly: a. 11040 test date 12/09/2020 - Mean Corpuscular Volume (MCV) result was transcribed into the LIS system as 97 and the actual result from the Beckman Coulter DxH500 hematology analyzer print out was 92.0 b. 16519 test date 02/24/2021 - Red Blood Cell Distribution Width (RDW-SD) result was transcribed into the LIS system as 35.2 and the actual result from the Beckman Coulter DxH500 hematology analyzer print out was 35.8 2. An interview on 10/26/2021 at 1:14 pm, the TC confirmed the transcribed results in the LIS system were entered incorrectly.