

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2116576	<b>(X3) Date Survey Completed</b>  06/30/2022
<b>Name of Provider or Supplier</b>  Children's Wisconsin Clinics Mequon	<b>Street Address, City, State</b>  1655 W Mequon Rd, Mequon, WI	
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>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not include an evaluation of precision in their validation of the Sure-Vue (Trademark) STAT Serum/Urine hCG Test Kit approved by the laboratory director on March 19, 2021. Findings include: 1. Review of validation documentation for the Sure-Vue (Trademark) STAT Serum/Urine hCG Test Kit signed by the laboratory director on March 19, 2021 showed no data supporting evaluation of precision of the test system. The validation documentation included a process checklist that showed personnel were to evaluate precision with five quality control runs for each level of quality control material used. The laboratory had marked N/A for the precision step. 2. Interview with the technical consultant on June 30, 2022 at 11:00 AM confirmed the laboratory had not evaluated precision as part of the validation of the Sure-Vue (Trademark) STAT Serum/Urine hCG Test Kit.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not test negative and positive external control materials on four of four days of patient testing performed in February 2022 with the Sekisui Diagnostics OSOM Mono Test. The laboratory had not developed an Individualized Quality Control Plan (IQCP) that provided equivalent quality testing for this test system. Findings include: 1. Review of laboratory records showed testing personnel performed patient testing using the Sekisui Diagnostics OSOM Mono Test on February 7, 15, 22, and 25, 2022. Logs showed personnel tested external quality control materials on January 19, 2022 with lot 211270 and showed no record of external quality control testing in February 2022. 2. Interview with the technical consultant on June 30, 2022 at 11:10 AM confirmed the laboratory did not test external control materials each day of patient testing and confirmed the laboratory had not developed an IQCP for the Sekisui Diagnostics OSOM Mono Test.