

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0898889	<b>(X3) Date Survey Completed</b> 08/25/2023
<b>Name of Provider or Supplier</b> South Lake Pediatrics-Plymouth	<b>Street Address, City, State</b> 15535 34th Ave N Suite 100, Plymouth, MN	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to ensure one of one technical consultants(TC) received a competency assessment which included the specific TC position responsibilities listed in Subpart M. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 08/23/23 2. One TC was listed on the Form CMS-209 Laboratory Personnel Report (CLIA) obtained on date of survey. The TC was placed in this role in April 2023. 3. A TC competency assessment was not found during review of 2023 laboratory personnel records. The laboratory was unable to provide the competency assessment upon request. 4. In an interview at 2:30 p.m. on 08/23/23, the TC confirmed the above finding. .</p>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must</p>

be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for two of two Min/Max digital thermometers in 2023. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 08/23/23. 2. Reagents, control materials, and specimens were observed in the single refrigerator /freezer located in the laboratory. Digital Min/Max thermometers were in use to monitor storage temperatures. 3. The following information was found on the Min /Max thermometers: Refrigerator Model 2020L1062948 Serial Number - not found, the identification sticker was torn Calibration due date hand written on the front of the device - 03/19/23 Freezer Model 2020K0996466 Serial Number 32188 Calibration due date as indicated on the identification sticker - 02/22/23 4. Thermometers were recalibrated or replaced at the calibration due date as established in the Digital Timers and Digital Thermometers Calibration and Accuracy Verification Policy found in the Procedure Book. 5. Min/Max thermometer calibration records were not found during review of 2023 laboratory documents. The laboratory was unable to provide current calibration records upon request. 6. In an interview at 10:20 a.m. on 08/23/23, the TC confirmed the above finding. .

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure documented initial training on a new chemistry analyzer was performed and documented in 2022 for two of four testing personnel (TP). Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 08/23/23. 2. An Advanced Instruments Bilirubin STAT analyzer was observed as present and available for use during the tour: The laboratory began testing patients using this analyzer in February 2022 as indicated by the TC and confirmed in laboratory records.. 3. Competency assessment of testing personnel was required before testing specimens independently as established in the Observed Competency Assessment procedure found in the Procedure Book. 4. Initial Bilirubin STAT training documentation for TP2, TP3, and the TC was not found during review of 2022 laboratory records. The laboratory was unable to provide the missing training documents upon request. 5. In an interview at 2:25 p.m. on 08/23/23, the TC confirmed the above finding. 6. The laboratory was given an opportunity to provide the missing training records by 08/25/23. 7. In an email received at 10:18 a.m. on 08 /25/23, the TC indicated he was unable to locate the Bilirubin STAT training records for TP2 and TP3. .

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure competency assessments were completed in their entirety for three of three testing personnel in 2021 and 2022. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the TC during a tour of the laboratory on 08/23/23 at 10:05 a.m. 2. The following non-waived analyzers and equipment were observed as present and available for use during the tour: Hematology -Medonic M-Series (CBC) Chemistry -Advanced Instruments Bilirubin STAT (Bili) Microbiology - Nikon Labophot microscope [Used for Urine Sediment (US), Vaginal Wet Preparation (VWP), KOH Preparation (KOH), and Pinworm Examination (PE) testing] 3. The following items were incomplete on the 2021 and 2022 Observed Competency Assessment documents: 2021 Direct observation of test performance TP1 - VWP, KOH, PE TP2 - VWP, KOH, PE TP3 - VWP, KOH, PE Review of testing records TP1 - US, VWP, KOH, PE Direct observation of maintenance TP1 - Microscope TP2 - Microscope Problem solving assessment TP1 - VWP, KOH, PE TP2 - VWP, KOH, PE TP3 - VWP, KOH, PE 2022 Direct observation of test performance TP1 - VWP, KOH, PE TP2 - VWP, KOH, PE TP3 - VWP, KOH, PE Review of testing records TP1 - VWP, KOH, PE TP2 - VWP, KOH, PE TP3 - VWP, KOH, PE Direct observation of maintenance TP1 - CBC, Bili, Microscope TP2 - CBC, Bili, Microscope Problem solving assessment TP1 - VWP, KOH, PE TP2 - VWP, KOH, PE TP3 - VWP, KOH, PE 4. In an interview at 12:00 p.m., the TC confirmed the above finding. .

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure competency assessments included a problem solving assessment for for each moderate complexity test. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing as confirmed by the TC during a tour of the laboratory on 08/23/23 at 10:05 a.m. 2. A Nikon Labophot microscope used for Vaginal Wet Preparation (VWP), KOH Preparation (KOH), and Pinworm Examination (PE) testing was observed as present and available for use during the tour: 3. 2021 and 2022 Observed Competency Assessment documents reviewed for three of three testing personnel (TP) did not include problem solving evaluations for VWP, KOH, and PE. 4. In an interview at 12:00 p.m. on 08/23/23, the TC confirmed the above finding. .