Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1003570	04/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Specialty Care, Inc, Mercy Hospital	4050 Coon Rapids Blvd, Coon Rapids, MN	

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
D0000	The Specialty Care, Inc. Mercy Hospital laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on April 23, 2024. The following standard-level deficiencies were cited: 493.1235 Personnel competency assessment policies 493.1236 Evaluation of proficiency testing performance
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure two of two Technical Consultants (TC) received a competency assessment which included the specific TC position responsibilities listed in Subpart M in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing as confirmed by Technical Consultant 2 (TC2) during a tour of the laboratory at 10:20 a.m. on 04/23/24. 2. Abbott i-STAT analyzers and Medtronic HMS Plus analyzers were observed as present and available for use during the tour. The laboratory performed the following tests during Cardiovascular perfusion: i-STAT - CG8+ cartridge (Sodium, Potassium, ionized Calcium, Glucose, Hematocrit, Hemoglobin, pH, PCO2, PO2) HMS Plus - Red and Blue cartridges (Activated clotting time. Heparin dose response, and Heparin /protamine titration) 3. Two TC's were listed on the Form CMS-209 Laboratory Personnel Report (CLIA) obtained on date of survey. TC1 and TC2 were in this role in 2022 and 2023 as confirmed by TC2. 4. TC1 and TC2 competency assessments were not found during review of 2022 and 2023 laboratory personnel records. The

	laboratory was unable to provide the missing competency assessments upon request. 5. A TC competency assessment procedure was not found during review of the Policy & Procedure manual. 6. In an interview at 1:50 p.m. on 04/23/24, TC2 confirmed the above finding. TC2 stated 2023 TC competencies had not been performed and she was unable to locate 2022 TC competency assessments during survey. 7. The laboratory was given an opportunity to provide the 2022 TC competency assessments within five days of the survey. 8. In an email received at 4:09 p.m. on 04/26/24, TC2 indicated the 2022 TC competency assessments could not be found. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of two of three non-regulated Hematology tests at least twice annually in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Technical Consultant 2 (TC2) during a tour of the laboratory at 10:20 a.m. on 04/23/24. 2. Medtronic HMS Plus analyzers were observed as present and available for use during the tour. The laboratory performed the following tests using the HMS Plus analyzer during Cardiovascular perfusion: HMS Plus - Red and Blue cartridges (Activated clotting time, Heparin dose response, Heparin/protamine titration) 3. HMS Plus accuracy verification was required twice annually as established in the HMS+ Biannual Comparison procedure located in the Policy & Procedure Manual. Activated clotting time was verified with proficiency testing via the American Proficiency Institute provider. 4. Accuracy of Heparin testing performed using the HMS Plus Red and Blue cartridges was verified in December 2022. No other verification documentation was found for these cartridges from 2022. Verification of accuracy documentation was not found for Heparin testing performed using the Red cartridge in 2023. 5. The laboratory was unable to provide the missing verification of accuracy documentation upon request. 6. The laboratory performed approximately 5,950 Hematology tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 7. In interviews at 12:00 p.m. and 12:35 p.m. on 04/23 /24, TC2 confirmed the above finding. .