Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0908165	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Sinai Grace Hospital Asc Berry Surgery Center	**Street Address, City, State** 28500 Orchard Lake Road Suite 100, Farmington Hills, MI	

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	A recertification survey was performed on October 8, 2025, by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director _____ 493.51 Standard: Notification requirements for laboratories issued a certificate of compliance Based on record review and interview with the technical consultant (TC), the laboratory failed to ensure compliance with 493.51 Notification requirements for laboratories issued a certificate of compliance. Findings include: 1. Record review of the CMS-116 and CMS-209 forms completed for the survey revealed a different individual listed as laboratory director compared to the laboratory director listed in the CMS database. 2. On 10/08/2025 at 9:30 am, the surveyor requested documentation of the submission the laboratory made to the State Agency, to meet the following notification requirements listed at 493.51: a. "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance." 3. On 10/8/2025 at 9:30 am, an interview conducted with the TC confirmed that a LD listed on the CMS-209 was hired on 9/1 /2025 and a notification regarding the change in LD had not been sent.
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 record review and interview with the technical consultant (TC) the laboratory failed establish policies and procedures for assessing techincal consultant competency for 3 (2023, 2024, 2025) of 3 years reviewed. Findings include: 1. A review of staff personnel records revealed that an annual competency assessment was not performed for the TC from May 2023 to October 2025. 2. A request was made to the TC on 10/8/2025 at 11:50 am for the missing competency assessments and the competency assessement policy for technical consultants. The documentation was not provided prior to survey exit. 3. An interview conducted with the TC on 10/8/2025 at 11:50 am confirmed that the competency assessments had not been performed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: . Based on observation and interview with the technical consultant (TC), the laboratory failed to ensure calibration of one thermometer used to monitor room temperature in the laboratory for 15 (July 2024 to September 2025) of 29 months reviewed. Findings include: 1. During a tour of the laboratory on 10/08/2025 at 10:00 am, the surveyor observed a Traceable thermometer (serial # 221637665) used to monitor room temperature. The thermometer was labeled with a calibration due date of 7/7/2024. 2. On 10/08/2025 at 10:00 am, an interview with the TC confirmed that there was no system in place to ensure the accuracy of the thermometer and the thermometer calibration due date had expired. 3. On 10/08/2025 at 12:30 pm the surveyor requested a policy on thermometer calibration and documentation was not provided.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to ensure the laboratory director met the qualification requirements for moderate complexity testing. Refer to D6003.

D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493. 1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours

	of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant (TC), the laboratory failed to ensure the laboratory director met the qualification requirements for moderate complexity testing. Findings include: 1. A review of the personnel file for the individual listed as laboratory director on the CMS 209 was performed. The review revealed a lack of documentation demonstrating the individual met qualification requirements stated at 493.1405 for laboratory director of a moderate complexity laboratory. There was no documentation the individual had either: a. at least one year of experience directing or supervising nonwaived testing or; b. 20 Continuing Education (CE) credit hours in laboratory directory responsibilities. 2. During an interview conducted on 10/08/2025 at 9:30 am, the TC stated that the individual listed as laboratory director on the CMS 209 began serving in the role on 9 /01/2025. The surveyor requested additional laboratory director qualification documentation. 3. On 10/08/2025 at 9:35 am, an interview conducted with the TC confirmed the individual did not meet the requirements for laboratory director.