

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0951668	<b>(X3) Date Survey Completed</b>  09/07/2021
<b>Name of Provider or Supplier</b>  Sinai Grace Endoscopy Center - Lahser Complex	<b>Street Address, City, State</b>  27207 Lahser Road, Suite 100, Southfield, 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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview with the Director of Quality Improvement (DQI), the Point-of-Care representative, and Testing Personnel (TP) #4, the Laboratory Director (LD) and/or designee failed to attest to the routine integration of the chemistry proficiency testing samples into the patient workload for 2 (AQI-A and AQI-B) of 2 events reviewed. Findings include: 1. Record review of the College of American Pathologists (CAP) proficiency testing documents revealed the following:                      a. AQI-A - the attestation statement sheet was not signed by the LD and/or designee b. AQI-B - lack of documentation of an attestation statement sheet 2. An interview on 9 /07/2021 at 10:44 am, the DQI, Point-of-Care representative, and TP4 confirmed the LD and/or designee did not sign the attestation statement sheet and lack of documentation of the attestation statement sheet for event AQI-B.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Director of Quality Improvement (DQI) and the Point-of-Care (POC) representative, the Laboratory Director (LD) failed to ensure proficiency testing final reports were reviewed for 2 (AQI-A and AQI-B) of 2 events in 2021 by the LD and/or designee and the Testing Personnel (TP). Findings include: 1. A review of the laboratory's College of American Pathologists (CAP) proficiency testing documents for 2 (AQI-A and AQI-B) of 2 events in 2021 revealed a lack of review of results by the LD and/or designee and the TP listed on the attestation statement sheets. 2. An interview on 9/07/2021 at 10:44 am, the DQI and POC representative confirmed the proficiency testing reports were not reviewed.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
. Based on record review and interview with the Director of Quality Improvement (DQI), the laboratory failed to ensure Testing Personnel #4 on the CMS 209 form who was performing the duties of a Technical Consultant (TC), met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the TC duty of performing testing personnel competency assessments was qualified. Refer to D6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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 possess qualifications that are equivalent to those required for such certification; 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 at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii)

Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Director of Quality Improvement (DQI), the laboratory failed to ensure personnel performing the Technical Consultant (TC) duty of performing testing personnel (TP) competency assessments was qualified for 3 (TP #1, #2, and #3) of 4 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed TP #4 had performed competency assessments for TP #1 - #3 on the following dates: a. TP#1 - 8/05/2021 dates: b. TP#2 - 9/03/2021 c. TP#3 - 6/16/2021 and 8/05/2021 2. A review of the qualifications for TP #4 were disclosed after a 7 day extension to provide the qualification documents revealed they did not meet the qualification requirements to perform TC responsibilities. 3. A phone interview on 9 /16/2021 at 9:12 am, the Director of Quality Improvement (DQI) confirmed TP #4 did not meet the qualification requirements to be Technical Consultants.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
. Based on record review and interview with the Director of Quality Improvement (DQI) and the Point-of-Care representative, the laboratory failed to ensure the testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel was qualified. Refer to D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on a lack of documentation and record review, the laboratory failed to ensure testing personnel were qualified for 1 (Testing Personnel (TP) #2) of 4 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for TP #2 performing moderate complexity testing. 2. The surveyor requested qualification documentation for TP #2 showing they were qualified to perform moderate complexity testing on 9/7/2021 at 10:37 am and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available.