

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D0668495	<b>(X3) Date Survey Completed</b> 11/28/2022
<b>Name of Provider or Supplier</b> Trinity Healthbrighton Laboratory	<b>Street Address, City, State</b> 7575 W Grand River, Suite 104, Brighton, 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>D5463</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Point of Care Coordinator, the laboratory failed to ensure control material testing was rotated among operators performing testing using the iSTAT analyzer for 2 (November 2020 to November 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's quality control documentation for the iSTAT analyzers revealed the Point of Care Coordinator performed controls almost exclusively from November 2020 to November 2022. 2. An interview with the Point of Care Coordinator on 11/28/22 at 2: 21 pm revealed only the Point of Care Coordinator or staff in the main laboratory perform quality control testing for the iSTAT and staff using the meters in Radiology and the Pre-Operation areas had not.</p>
<b>D6141</b>	<p><b>GENERAL SUPERVISOR</b> CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the General Supervisor did not meet the</p>

qualification requirements of 493.1463. Findings include: 1. The General Supervisor failed to provide experience documentation to qualify as a General Supervisor. Refer to D6143.

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. 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). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual

who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, Lab Manager, Point-of-Care Coordinator, and the Group Lead, the testing personnel performing competency assessments failed to have the proper educational credentials to qualify as a General Supervisor for 2 (Testing personnel [TP] #3 and TP#7) of 10 testing personnel in the main laboratory. Findings include: 1. Record review revealed for 2 of 10 testing personnel, the personnel signing off on the competency assessments do not have the educational credentials to evaluate competency for moderate and/or highly complex testing. 2. An interview on 11/2/2022 at 2:47 pm, the Lab Manager, Point-of-Care Coordinator, and the Group Lead confirmed the personnel signing off on the competency assessments do not have the educational credentials to evaluate testing personnel.