

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0684962	(X3) Date Survey Completed 03/12/2020
Name of Provider or Supplier Mercy Health-Tiffin Hospital	Street Address, City, State 45 St Lawrence Drive, Tiffin, OH	
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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC) #1, the Laboratory Director (LD) failed to delegate Proficiency Testing (PT) attestation to the routine integration of PT samples into the patient workload using the laboratory's routine methods to qualified personnel for 12 out of 12 proficiency testing events for 2018 and 2019. All patients tested under the speciality of general chemistry had the potential to be affected. Findings Include: 1. Review of "General Supervisor Competency Evaluation," which listed the duties delegated to the TC #1 by the LD, found no mention of PT attestation delegation from the LD to the TC #1. Excerpt from "General Supervisor Competency Evaluation:" "...Is accessible to testing personnel at all times testing is performed to provide on-site telephone or electronic support Provide day to day supervision of personnel. Monitors test analyses and specimen examination to sure that acceptable levels of analytic performance are maintained. Fulfills certain responsibilities as delegated by the Laboratory Director or Technical Supervisor These may include: Resolving technical problems and ensuring that corrective actions are taken whenever test systems deviate from the laboratory's performance specifications. Ensuring patient test results are not reported until all</p>

corrective actions have been taken and the test system is functioning properly. Providing orientation to all testing personnel. Evaluating and documenting the performance of all testing personnel as required..." 2. Review of Automated Blood Gas (ABG) and Blood Oximetry (BOx) PT attestation from 2018, 2019 and 2020 found that TC #1 attested to the routine integration of PT samples into the patient workload using the laboratory's routine methods for 12 out of 12 PT events. PT Event Attestation ABG #1 2018 TC #1 BOx #1 2018 TC #1 ABG #2 2018 TC #1 BOx #2 2018 TC #1 ABG #3 2018 TC #1 BOx #3 2018 TC #1 ABG #1 2019 TC #1 BOx #1 2019 TC #1 ABG #2 2019 TC #1 BOx #2 2019 TC #1 ABG #3 2019 TC #1 BOx #3 2019 TC #1 3. An interview with TC #1, on 3/12/20 at 12:11 pm, confirmed that they attested to the routine integration of PT samples into the patient workload using the laboratory's routine methods without delegation by the LD.