

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2074480	(X3) Date Survey Completed 02/14/2019
Name of Provider or Supplier Franciscan Health - Michigan City	Street Address, City, State 3500 Franciscan Way, Michigan City, IN	
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
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to specify, in writing, the duties and responsibilities of three of three testing personnel reviewed (SP2, SP3, and SP4). Findings included: 1. Review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 2-14-2019, indicated SP2, SP3, and SP4 were testing personnel. 2. Review of personnel records indicted the laboratory director did not assign duties and responsibilities for the following testing personnel: SP2, SP3, and SP4. 3. Review of patient records indicated the following: a. Patient #6 had an Activated Clotting Time (ACT) test performed by SP2 on 3-3-2018. b. Patient #7 had an ACT test performed by SP3 on 1-2-2019 4. In interview on 2-14-2019 at 2:30 PM, SP1 acknowledged the above testing personal did not have duties and responsibilities assigned to them in writing by the laboratory director. 5. Tests included: a. Activated Clotting Time (ACT), annual volume of 503 b. Ionized Calcium, annual volume of 159 c. Glucose, annual volume of 159 d. Hematocrit, annual volume of 159 e. Hemaglobin, annual volume of 159 f. Lactate, annual volume of 976 g. Oxygen saturation, annual volume of 159 h. Partial</p>

pressure of carbon dioxide, annual volume of 159 i. Whole blood pH, annual volume of 159 j. Partial pressure of oxygen, annual volume 159 k. Potassium, annual volume of 159 l. Sodium, annual volume of 159 m. Troponin, annual volume of 4090