

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0647000	<b>(X3) Date Survey Completed</b>  05/03/2019
<b>Name of Provider or Supplier</b>  Immunotransplant Lab Springfield Memorial Hosp	<b>Street Address, City, State</b>  701 N 1st Street, Springfield, IL	
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>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory records and interviews with the general supervisor (GS) and the hospital's clinical lab director; the laboratory failed to have a qualified laboratory director (LD) to manage and maintain proper laboratory operation. The laboratory director must meet the qualification requirements of 493.1443 and the overall management and direction in accordance with 493.1445. Findings include: 1. The laboratory failed to fill the position of LD. See D6078.</p>
<b>D6078</b>	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (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 possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is</p>

located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory records and interviews with the laboratory general supervisor (GS) and hospital's clinical lab director; the laboratory failed to fill the position of high complexity laboratory director (LD). Findings Include: 1. Review of the CMS-209 laboratory personnel report, completed during an on-site complaint survey on 5-3-2019, found no LD was identified for the laboratory. 2. Interview on 5-3-2019, at 8:40 am, with the GS confirmed the laboratory did not currently have a LD. 3. Interview on 5-3-19, at 8:45 am, with the hospital's clinical lab director confirmed the previous laboratory director left on 2-28-2019 and no new LD had filled the position.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**  
 CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:  
 Based on review of the laboratory records and interviews with the general supervisor (GS) and the hospital's clinical lab director; the laboratory failed to have a technical supervisor (TS) who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. Findings include: 1. The laboratory failed to fill the position of TS for the specialty of histocompatibility. See D6109.

**D6109**

**TECHNICAL SUPERVISOR QUALIFICATIONS**  
 CFR(s): 493.1449

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the

specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interviews with the laboratory general supervisor (GS) and the hospital's clinical lab director; the laboratory failed to have a technical supervisor (TS) for histocompatibility testing. Findings Include: 1. Review of the CMS-209, laboratory personnel report, completed during an on-site complaint survey on 5-3-2019, found no TS for histocompatibility was listed for the laboratory. 2. Interview on 5-3-2019, at 8:40 am, with the GS confirmed the laboratory did not have a TS for histocompatibility testing. 3. Interview on 5-3-2019, at 8:45 am, with the hospital's clinical lab director confirmed the previous histocompatibility TS left on 2-28-2019 and no new TS had filled the position.

**D6134**

**CLINICAL CONSULTANT**

CFR(s): 493.1453

The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory records and interviews with the general supervisor (GS) and the hospital's clinical lab director; the laboratory failed to have a clinical consultant (CC) who meets the qualification requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. Findings include: 1. The laboratory failed to fill the position of CC. See D6109.

**D6135**

**CLINICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interviews with the laboratory general supervisor (GS) and the hospital's clinical lab director; the laboratory failed to have a clinical consultant (CC). Findings Include: 1. Review of the CMS-209, laboratory personnel report, completed during an on-site complaint survey on 5-3-2019, found no CC was listed for the laboratory. 2. Interview on 5-3-2019, at 8:40 am, with the GS confirmed the laboratory did not have a CC. 3. Interview on 5-3-2019, at 8:45 am, with the hospital's clinical lab director confirmed the previous CC left on 2-28-2019 and no new CC had filled the position.