

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0922251	(X3) Date Survey Completed 04/12/2018
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 5414 South 900 East, Salt Lake City, UT	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of qualifying documentation and email interview and request for qualifying documentation with the facility manager, the laboratory failed to have a qualified technical consultant to provide technical oversight for one moderate complexity test performed, Total protein testing. See D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(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</p>

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 lack of documentation of training or experience in routine chemistry non waived testing and email interview with the laboratory facility manager, the laboratory failed to ensure the new director had documentation of training of experience to qualify as the total protein technical consultant. The laboratory performed approximately 30,000 tests per year. Findings include: 1. The laboratory had a change in director less than one year prior to the survey on 04/12/2018. The previous director provided service as the technical consultant. 2. The new director lacked documentation of moderate complexity testing experience in routine chemistry testing or board certification from a qualifying board to meet the qualification requirements. 3. In an email with the laboratory manager on 04/25/2018, the request for documentation of moderate complexity experience was made. The email reply included documentation previously sent to qualify as the laboratory director. The reply did not include experience or training in moderate complexity routine chemistry testing.