

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2194728	<b>(X3) Date Survey Completed</b>  05/19/2022
<b>Name of Provider or Supplier</b>  Ocatpharma Plasma, Inc	<b>Street Address, City, State</b>  1030 W University Dr, Denton, TX	
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>D0000</b>	<p>An entrance conference was held with laboratory representatives. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 05/19/2022, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1421 Testing Personnel (moderate complexity) An exit conference was held with laboratory representatives. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. The process for submitting the corrections was explained. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed</p>

to have documentation that 2 of 13 testing persons (TP-1 and TP-11 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official 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); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have documentation that 2 of 13 testing persons (TP-1 and TP-11 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Findings: 1. Review of the CMS-209 form included TP-1 through TP-13 listed to perform moderate complexity testing. 2. Review of the laboratory's policy titled "Job Description- Medical Screener" revealed: "JOB SPECIFICATIONS: A high school diploma, or equivalent (GED) is required." 3. A random review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: TP-1; No education documents provided TP-11; No education documents provided 4. During an interview on 05/19/2022 at 10:56 am, the Ops Admin QAS confirmed there was no educational documentation for TP-1 and TP-11.