

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2281361	<b>(X3) Date Survey Completed</b>  06/23/2025
<b>Name of Provider or Supplier</b>  Oak Park Laboratory, Llc	<b>Street Address, City, State</b>  6525 North Ave - Ste 107, Oak Park, 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>D5201</b>	<p>CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) records, direct observation, and interview with the laboratory director (LD); the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process on 5 of 14 API proficiency testing (PT) self-assessments in the specialty of hematology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "General Policy", which stated, under "Test Report", "Patient confidentiality, including restricted computer access codes and other information which is accessed only on a need-to-know basis, will be maintained throughout the testing process." 2. Upon review of the API PT records on 06/23/2025, at 11:22 am, surveyors observed 5 of 14 API PT self-assessment hematology result forms printed on paper which included past patients' names, ages, sex, specimen numbers, names of the test ordered, and test result. 3. Interview with the LD on 06/23 /2025, at 2:37 pm, the LD confirmed the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process that were under the laboratory's control.</p>
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL 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>

This CONDITION is not met as evidenced by:  
Based on review of personnel records, lack of documentation, the CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP) #3; the laboratory failed to have qualifying academic documentation/records for one of three TP to meet the qualification requirement for moderate complexity testing in the specialties of chemistry and hematology (see 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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of personnel records, lack of documentation, the CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP) #3; the laboratory failed to have qualifying academic documentation/records for one of three TP to meet the qualification requirement for moderate complexity testing in the specialties of chemistry and hematology. Findings include: 1. Review of personnel records found no foreign equivalency documentation were available to qualify moderate complexity TP #3 listed on the CMS-209 form dated 06/20/2025. 2. Interview with TP #3 on 06/23/2025, at 12:40 pm, confirmed the laboratory failed to have qualifying academic documentation/records for one of three TP to meet the qualification requirement for moderate complexity testing in the specialties of chemistry and hematology.