Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2281361	09/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oak Park Laboratory, Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the Technical Consultant (TC); the laboratory failed to ensure attestation statements were completed for eight of eight PT events for testing in the specialties of chemistry and hematology in 2025 and 2026. Findings include: 1. Review of API PT records for 2025 and 2026 revealed a lack of attestation statements for eight of eight events in the specialties of chemistry and hematology in 2025 and 2026. Specialty: Year: Hem** 2025 - Event 2 Hem** 2025 - Event 3 Chem* 2025 - Event 3 Hem** 2026 - Event 1 Hem** 2026 - Event 2 Chem* 2026 - Event 1 Chem* 2026 - Event 2 Chem* 2026 - Event 3 *Routine Chemistry, Endocrinology; **Hematology; Urinalysis 2. Interview with the TC on 09/08/2026, at 10:47 am, confirmed the laboratory failed to ensure attestation statements were completed for eight of eight PT events testing in the specialties of chemistry and hematology in 2025 and 2026.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) Proficiency testing (PT) records, lack of documentation and interviews with Technical Consultant (TC); the laboratory failed to evaluate non-graded PT scores in three of eight PT Events reviewed from 2025 to the date of survey, 09/08/2026. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled " Quality Control " which stated on page ten under " Proficiency Testing Assessment " , " Where applicable. Samples (unacceptable, Unsatisfactory, or unsuccessful proficiency testing result(s) will be re-evaluated by the laboratory staff. ... A PT Deviancy report will be filled with all supporting documentation." 2. Review of API PT comparative evaluation summaries identified not graded performances for the following five analytes: Specialty: Hematology PT Event: Analyte: Sample: 2025 E3 Monocyte ABT-11 2025 E3 Monocyte ABT-15 Specialty: Chemistry PT Event: Analyte: Sample: 2025 E3 Total Bilirubin CH-11 2025 E3 Total Bilirubin CH-15 2026 E1 Total Bilirubin CH-05 *E = Event 3. Review of laboratory records revealed lack of documented review or self-grade of the five not graded PT samples in hematology 2025 Event 3, chemistry 2025 Event 3 and 2026 Event 1. 4. Interview with TC on 09/08/2026, at 11:30 AM, confirmed the laboratory failed to evaluate non-graded PT scores in three of eight PT Events reviewed from 2025 to the date of survey, 09/08/2026.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of policies and procedures, laboratory records, lack of documentation, and interview with the Technical Consultant (TC); the laboratory failed to outline 1 of 14 required components of the test procedure including imminently life-threatening test results, panic, or alert values for testing in the specialties of Chemistry and Hematology. Findings Include: 1. Review of laboratory policies and procedures for chemistry analytes performed on the TOSOH AIA 900 (serial number 11066208R), the Medica Easy RA (serial number: 21118013717) and the Diatron Abacus 5 analyzer (serial number: 510941) revealed the procedures

	lacked panic values. 2. Interview with TC, on 09/08/2026, at 12:50 pm, confirmed the laboratory failed to outline 1 of 14 required components of the test procedure including imminently life-threatening test results, panic, or alert values for testing in the specialty of Chemistry.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting identified problems in the specialties of Hematology and Chemistry for 20 of 20 months reviewed from 2025 through the date of survey, 09/08/2026. Findings include: 1. Review of laboratory policies and procedures revealed a policy titled "Quality Control" which stated on page 15 under "Quality Assurance [QA] Records", "Items which may be included in the QA records are QA documentation related to ...Patient test records, ... linearity studies /reportable range, ... etc and other records deemed necessary by the laboratory director and his/her representative. These records will be reviewed and reflect the overall operation of the laboratory. ... All work is documented and where necessary corrective action taken." 2. Review of laboratory records revealed a lack of documentation of quality assurance checks performed to identify and correct reference range discrepancies between patient test records, instrument printouts and operator's manual from 2026 through the date of survey 09/08 /2026. 3. Interview with the LD on 09/08/2026, at 4:10 pm, confirmed the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting identified problems in the specialties of Hematology and Chemistry for 20 of 20 months reviewed from 2025 through the date of survey, 09/08/2026.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory test reports and interview with the laboratory Director (LD); the laboratory failed to have a reliable system to ensure pertinent reference ranges for complete blood count (CBC) testing on the Diatron Abacus 5 analyzer (serial number: 510941) were available to testing personnel and ordering provider affecting six of six patients reviewed. Findings include: 1. Review of laboratory policies and procedures revealed a policy titled "Quality Control" which stated on page 40 under "Reference Ranges", "The laboratory will evaluate samples, where applicable, to evaluate reference range for patients and substantiate the manufacturer's recommendations." 2. Review of six of six finalized patient testing reports for CBC revealed a lack of correlation between

	reference ranges on the patient reports, the laboratory's copy of the Abacus Analyzer operator's manual version 2 (v2.0) and the Abacus 5 patient testing result printouts. Analyte: WBC (White Blood Cell Count) RR Report*** 3.4 - 10.8 K/uL^ RR Manual**** 5.0 - 10.0 K/uL^ RR Analyzer* 4.0 - 11.0 K/uL^ Analyte: RBC (Red Blood Cell Count) RR Report*** 3.80 - 5.00 M/uL (million per microliter) RR Manual** 4.0 - 5.50 K/uL^ RR Analyzer* 4.0 - 6.00 K/uL^ Analyte: Hemoglobin RR Report*** 11.7 - 14.9 g/dL^^ RR Manual** 12.0 - 17.4 g/dL^^ RR Analyzer* 9.0 - 17.4 g/dL^^ Analyte: Hematocrit RR Report*** 34.9 -44.3 % RR Manual** 36.0 - 52.0 % RR Analyzer* 36.0 - 52.0 % Analyte: MCV (Mean Corpuscular Volume) RR Report*** 81 - 99 fL^^^ RR Manual** 76.0 - 96.0 fL^^^ RR Analyzer* 76.0 - 96.0 fL^^^ Analyte: MCH (Mean Corpuscular Hemoglobin) RR Report*** 25.7 - 33.2 pg*^ RR Manual** 27.0 - 32.0 pg*^ RR Analyzer* 27.0 - 32.0 pg*^ Analyte: MCHC (Mean Corpuscular Hemoglobin Concentration) RR Report*** 32.8 - 35.4 g/dL^^ RR Manual** 30.0 - 35.0 g/dL^^ RR Analyzer* 30.0 - 35.0 g/dL^^ Analyte: MPV (Mean Platelet Volume) RR Report*** 8.0 - 11.0 fL^^^ RR Manual** 8.0 - 15.0 fL^^^ RR Analyzer* 8.0 - 15.0 fL^^^ Analyte: RDW% (Red Cell Distribution Width) RR Report*** 12.3 - 15.6 % RR Manual** 0.0 - 16.0 % RR Analyzer* 1.5 - 16.0 % Analyte: RDW-SD (Red Cell Distribution Width -Standard Deviation) RR Report*** 37.0 - 54.0 fL^^^ RR Manual** 20.0 - 42.0 fL^^^ RR Analyzer* 46.0 - 59.0 fL^^^ Analyte: Platelets RR Report*** 140 - 450 K/uL^ RR Manual** 150 - 400 K/uL^ RR Analyzer* 150 - 400 K/uL^ Analyte: Neutrophils RR Report*** 1.40 - 7.0 K/uL^ RR Manual** 2.0 - 7.5 K/uL^ RR Analyzer* 2.0 - 6.9 K/uL^ Analyte: Lymphocytes RR Report*** 0.7 - 3.1 K/uL^ RR Manual** 1.3 - 4.0 K/uL^ RR Analyzer* 0.7 - 3.1 K /uL^ Analyte: Monocytes RR Report*** 0.0 - 0.9 K/uL^ RR Manual** 0.15 - 0.7 K /uL^ RR Analyzer* 0.0 - 0.9 K/uL^ Analyte: Eosinophils RR Report*** 0.0 - 0.2 K /uL^ RR Manual** 0.0 - 0.5 K/uL^ RR Analyzer* 0.0 - 0.2 K/uL^ Analyte: Basophils RR Report*** 0.0 - 0.2 K/uL^ RR Manual** 0.0 - 0.15 K/uL^ RR Analyzer* 0.0 - 0.2 K/uL^ Analyte: Neutrophils RR Report*** 40.0 - 74.0% RR Manual** 40.0 - 75.0% RR Analyzer* 40.0 - 75.0% Analyte: Lymphocytes RR Report*** 14.0 - 46.0% RR Manual** 21.0 - 40. % RR Analyzer* 20.0 - 40.0% Analyte: Monocytes RR Report*** 4.0 - 12.0% RR Manual** 3.0 - 7.0% RR Analyzer* 3.0 - 7.0% Analyte: Eosinophils RR Report*** 0.0 - 5.0% RR Manual** 0.0 - 5.0% RR Analyzer* 0.0 - 5.0% Analyte: Basophils RR Report*** 0.0 - 3.0% RR Manual** 0.0 - 1.5% RR Analyzer* 0.0 - 1.5% *** Reference ranges on the finalized patient reports ** Reference ranges on A5US-1 Abacus Analyzer operator's manual v2.0 * Reference ranges on Diatron Abacus 5 analyzer (Abacus 5) serial number: 510941 ^ thousands per microliter ^^ grams per deciliter ^^^ femtoliters *^ picograms 3. Interview with the LD via email on 09/08/2026, at 4:10 pm, confirmed the laboratory failed to have a reliable system to ensure pertinent reference ranges for CBC testing on the Diatron Abacus 5 analyzer were available to testing personnel and ordering provider affecting six of six patients reviewed.