Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0418588	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oak Crest Laboratory Services	1452 Merchant Dr - Unit B, Algonquin, 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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. 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 representative; the laboratory failed to retain test requisitions for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Manual", which stated, under "11.5. Record Retention", "The Quality Manager is responsible for the proper archiving of documents and records. "All policies, procedures, processes, and related formed are kept for 2 years from their retirement date. Any retention time not defined by regulation or accreditation standards is set by laboratory policy. "A copy of an obsolete document is kept proving a means for review if the situation arises." 2. Surveyors requested test requisitions for patients tested in the specialties of microbiology, diagnostic immunology, chemistry, hematology. The laboratory representative was unable to provide any test requisitions prior to 06/10/2024. 3. Interview with the laboratory representative on 06/10/2025, at 1:25 pm, confirmed the laboratory failed to retain test requisitions for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: 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 representative; the laboratory failed to retain instrument printouts for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Manual", which stated, under "11.5. Record Retention", "The Quality Manager is responsible for the proper archiving of documents and records. "All policies, procedures, processes, and related formed are kept for 2 years from their retirement date. Any retention time not defined by regulation or accreditation standards is set by laboratory policy. "A copy of an obsolete document is kept proving a means for review if the situation arises." 2. Surveyors requested instrument printouts for patients tested in the specialties of microbiology, diagnostic immunology, chemistry, hematology. The laboratory representative was unable to provide any instrument printouts prior to 06/10/2024. 3. Interview with the laboratory representative on 06/10/2025, at 1:25 pm, confirmed the laboratory failed to retain instrument printouts for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting 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 representative; the laboratory failed to retain patient test reports for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Manual", which stated, under "11.5. Record Retention", "The Quality Manager is responsible for the proper archiving of documents and records. "All policies, procedures, processes, and related formed are kept for 2 years from their retirement date. Any retention time not defined by regulation or accreditation standards is set by laboratory policy. "A copy of an obsolete document is kept proving a means for review if the situation arises." 2. Surveyors requested patient test reports for patients tested in the specialties of microbiology, diagnostic immunology, chemistry, hematology. The laboratory representative was unable to provide any patient test reports prior to 06/10/2024. 3. Interview with the laboratory representative on 06/10/2025, at 1:25 pm, confirmed the laboratory failed to retain patient test reports for the specialties of microbiology, diagnostic immunology, chemistry, hematology from 06/10/2023 through 06/09/2024.

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 laboratory personnel records, the CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with the laboratory representative; the laboratory failed to have qualifying documentation for one of one delegated clinical consultant for the subspecialty of virology (see D6135).
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) for the subspecialty of oral pathology, 493.1443(b)(5); 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 personnel records, the CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with the laboratory representative; the laboratory failed to have qualifying documentation for one of one delegated clinical consultant (CC) for the subspecialty of virology. Findings include: 1. Review of laboratory personnel records revealed one of one CC, identified on the CMS-209, failed to have qualifying documentation for the role of CC. 2. Interview with the laboratory representative on 06/10/2025, at 2:25 pm, confirmed the laboratory failed to have qualifying documentation for one of one delegated CC for the subspecialty of virology.