Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2168465	02/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Orion Laboratories, Llc	6300 Corporate Boulevard, Baton Rouge, LA	

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
D0000	A Complaint survey (LA00069894) was performed at Orion Laboratories, LLC, CLIA ID 19D2168465, on February 2, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, complaint form, and interview with personnel, the laboratory failed to document complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's "Complaint Investigation Policy" revealed for customer complaints the Chief Operating Officer is to be notified immediately. "If the Chief Operations Officer is not immediately available, document complainant name, facility and call back number. Notify complainant that issue will be investigated and resolved. Personnel taking phone call will complete a 'Complaint Documentation Form,' (found in Orion Laboratories Dropbox), upon receiving complaint. the form includes documentation for the problem, investigation, corrective action, follow up and patient impact, as applicable. Completed forms will be sent to Laboratory Medical Director for review. Any/all staff as appropriate will be notified /counseled of complaint." For staff complaints "All complaints should be brought to Chief Operating Officer. If complaint is not resolved by end of normal work week, then Laboratory Medical Director should then be notified of issue. Supervisor /manager will complete a 'Corrective Action Form' upon receipt of complaint. The form includes documentation for the problem, investigation, corrective action, follow up and patient impact, as applicable. Any/all staff as appropriate will be notified

	/counseled of complaint." 2. Review of the laboratory's "Documentation of Customer, Patient, or Staff Complaint" form revealed the following information would be documented: Complainant, Date of complaint, details of complaint, investigation, corrective action, patient impact (if applicable), follow-up, documented by signature and date, and Medical Director signature and date. 3. Interview with complainant on January 30, 2024 at 4pm revealed the complainant contacted the laboratory with concerns on January 26, 2024. The complainant was told a manager of the laboratory would contact by phone to resolve the patient concern. The complainant received no further communication by the laboratory. 4. Review of the laboratory records revealed the laboratory had not documented a complaint or investigation from customer, patient or staff in the last two years. 5. In interview on February 2, 2024 at 12:03 pm, the President stated the accessioners said they had not received any calls lately and no complaints within the last two weeks. The laboratory did not have any documentation of complaints/problems reported to the laboratory.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of policies, complaint form, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was followed. Refer to D5205.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of policies, complaint form, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was followed. Refer to D5205.