Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0887857	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Immunodiagnostic	512 S Verdugo Dr, Burbank, CA	

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
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, quality assessment records from 2021 and 2022, and interview with the laboratory director and technical supervisor on March 29, 2023, at 11:45 am, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems in the preanalytic systems quality assessment. The findings include: 1. The laboratory had established the preanalytic systems quality assessment program by identifying problems in the sample rejection, wrong test entry into the laboratory information system, sample collection in wrong tubes, sample clotting etc. It was tabulating a combined error rate, periodically. However, it was not evaluating and monitoring the continuous improvement in preventing the recurrence. The problem correction process involves investigation, identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken has prevented recurrence of the original problem. The laboratory did not have documentation of the laboratory's efforts to reduce the recurrence of the problems. Therefore, the patient may have harmed by the repeat of the same type of problems in the laboratory's preanalytical system. 2. The laboratory director and technical supervisor on March 29, 2023, at 11: 45 am, affirmed that the laboratory did not monitor the effectiveness of the corrective

	actions taken in the recurrence of the problems. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/28/2023, stated that the laboratory performs approximately 1,410,967 tests, annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, quality assessment records from 2021 and 2022, and interview with the laboratory director and technical supervisor on March 29, 2023, at 11:45 am, it was determined that the laboratory director failed to assure the quality assessment programs are established and maintained for the quality of laboratory services provided. The findings include: See D5393.