Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0931719	01/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Valley Hematology-Oncology Associates Rllp	159 Barnegat Road, Suite 101, Poughkeepsie, NY	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's standard procedure (SOP) manual, lack of a written Quality Assessment (QA) procedure and an interview with the laboratory testing person, the laboratory failed to establish a written QA procedure to monitor, evaluate all phases of the laboratory's pre analytic, analytic and post analytic test systems. FINDINGS 1. The laboratory's standard operating procedure manual did not contain a written QA procedure to monitor, evaluate all phases of the laboratory's pre analytic, analytic and post analytic systems. 2. The testing person confirmed on January 4, 2022 at approximately 2:30 PM, that the laboratory did not have a written QA procedure to monitor, evaluate all phases of laboratory testing.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the SOP manual, lack of a written QA procedure and confirmed in an interview with the laboratory testing person, the laboratory director failed to establish a written QA for all phases for the general laboratory system. Refer to D5291.