Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2171958	08/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sentara Rmh Advanced Imaging Center	2509 Pleasant Run Drive, Harrisonburg, VA	

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	An announced CLIA Initial survey was conducted at the Sentara RMH Advanced Imaging Center on 08/02/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of testing personnel (TP) competency records, lack of documentation and interviews, the laboratory failed to enroll with an approved proficiency testing (PT) program for the creatinine analyte, categorized as a non-waived, regulated analyte, from 01/01/22 up to the date of survey on 08/02/22. Findings include: 1. An interview with the technical consultant on 08/02/22 at approximately 11:35 AM and review of the TP competency records for the calendar year 2021 revealed the lab utilized an internal blind sample method for verification of the creatinine analyte. The technical consultant provided hand-written results of the internal blind sample method on the competency assessments of each testing personnel in the year 2021. The inspector requested to review enrollment and participation with an approved PT

	program for the above-specified analyte. The documentation was not available for review at the date of survey on 08/02/22. 2. A phone exit interview with the technical consultant on 08/03/22 at approximately 1450 confirmed the findings.