Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0025217	08/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hca Florida South Shore Hospital	4016 Sun City Center Blvd, Sun City Center, FL	

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 validation survey was conducted at HCA Florida South Shore Hospital on 08/06/2024-08/08/2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found out of compliance with the following conditions: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] 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 the test menu, proficiency testing (PT) records, and laboratory policy, and interview with the technical consultant for virology , the laboratory failed to enroll in an approved PT program for non-waived infectious mononucleosis analyte for two out of two years (2022 - 2024). Findings included: 1. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) revealed the laboratory performed non-waived infectious mononucleosis testing with the Poly Stat Mono Test. 2. Review of the College of American Pathologists (CAP) PT records showed no PT was performed on non-waived infectious mononucleosis. 3. Review of the laboratory's CAP Proficiency Testing Procedure, with an origination date of 6/2/2020 and most recent effective date of 1/26 /2024, revealed "The Laboratory Director, department supervisor, or designee, orders

	appropriate PT material for all available analytes that are currently being performed." On 08/07/2024 at 10:30 AM, the Technical Consultant for virology confirmed the laboratory was not enrolled in a PT program for non-waived infectious mononucleosis testing from 2022 through the time of the validation survey.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the test menu, proficiency testing (PT) records, and laboratory policy, and interview with the technical consultant for virology , the Laboratory Director failed to ensure the laboratory was enrolled in an approved PT program for non-waived infectious mononucleosis analyte for two out of two years (2022 - 2024). Findings included: 1. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) revealed the laboratory performed non-waived infectious mononucleosis testing with the Poly Stat Mono Test. 2. Review of the College of American Pathologists (CAP) PT records showed no PT was performed on non-waived infectious mononucleosis. 3. Review of the laboratory's CAP Proficiency Testing Procedure, with an origination date of 6/2/2020 and most recent effective date of 1/26/2024, revealed "The Laboratory Director, department supervisor, or designee, orders appropriate PT material for all available analytes that are currently being performed." On 08/07/2024 at 10:30 AM, the Technical Consultant for virology confirmed the laboratory was not enrolled in a PT program for non-waived infectious mononucleosis testing from 2022 through the time of the validation survey.