Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0296633	05/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Suncoast Urology Pa	11373 Cortez Blvd Ste 209, Brooksville, 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 recertification survey was conducted at Suncoast Urology PA on 05/10/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the Medical Assistant, the laboratory failed to have the new Frend procedure manual signed by the Laboratory Director. Findings included: Record review of the laboratory's Frend procedure manual revealed the manual had not been signed by the Laboratory Director. Record review of the laboratory's validation of testosterone and prostate specific antigen revealed the Frend validation had been performed on 12/05/2019. Interview on 05/10/21 at 11:20 AM with the Medical Assistant revealed she did not know the Laboratory Director needed to sign the Frend procedure manual before patient testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with the Medical Assistant, the laboratory failed to have the Laboratory Director sign and approve the performance verification performed on 12/05/2019 on the Frend instrument which performs testosterone and prostate specific antigen testing. Findings included: Review of the performance verification performed 12/05/2019 for the Frend instrument, which performs testosterone and prostate specific antigen testing, revealed that the Laboratory Director had not approved the performance verification. Record review of email form the Practice Manager revealed the laboratory had tested 925 patients. Interview on 05 /10/21 at 10:45 AM with the Medical Assistant revealed she did not know that the Laboratory Director needed to sign and approve the completed performance verification for the Frend instrument.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions manual, quality control records, and interview with the Medical Assistant, the laboratory failed to perform external quality control every day of testing and did not develop an Individualized Quality Control Plan (IQCP) that would allow them to perform quality control once a month per manufactures instructions. Findings included: Record review of the Frend manufacturers instructions revealed external controls should be tested monthly or with each new lot of reagents. Record review of testosterone and prostate specific antigen external quality control records revealed the laboratory had not performed an external quality control (L1 and L2) monthly or each day of testing. Record review revealed the laboratory did not complete an IQCP. Record review revealed the laboratory only performed Daily Quality Control cartridge testing each day of testing from 02/13 /2020 to 05/10/2021: Testosterone 02/13/2020 02/14/2020 02/17/2020 02/18/2020 02 /19/2020 02/20/2020 02/27/2020 02/28/2020 03/02/2020 03/03/2020 03/04/2020 03/05 /2020 03/06/2020 03/09/2020 03/10/2020 03/11/2020 03/12/2020 03/13/2020 03/16 /2020 03/17/2020 03/18/2020 03/19/2020 03/20/2020 03/23/2020 03/24/2020 03/25 /2020 03/26/2020 03/27/2020 03/30/2020 03/31/2020 04/01/2020 04/02/2020 05/01 /2020 05/04/2020 05/21/2020 05/22/2020 05/26/2020 05/27/2020 05/28/2020 05/29 /2020 06/01/2020 06/02/2020 06/03/2020 06/04/2020 06/05/2020 06/08/2020 06/09 /2020 06/10/2020 06/12/2020 06/14/2020 06/15/2020 06/16/2020 06/17/2020 06/18 /2020 06/19/2020 06/22/2020 06/23/2020 07/22/2020 07/23/2020 08/05/2020 09/04 /2020 10/05/2020 11/04/2020 12/07/2020 01/07/2021 03/01/2021 04/19/2021 05/05 /2021 Prostate Specific Antigen 02/13/2020 02/24/2020 02/17/2020 02/18/2020 02/20 /2020 02/21/2020 02/24/2020 02/25/2020 02/27/2020 02/28/2020 03/02/2020 03/04

	/2020 03/05/2020 03/06/2020 03/09/2020 03/10/2020 03/11/2020 03/12/2020 03/13 /2020 03/16/2020 03/17/2020 03/18/2020 03/19/2020 03/20/2020 03/23/2020 03/24 /2020 03/25/2020 03/26/2020 03/27/2020 03/30/2020 03/31/2020 04/01/2020 04/02 /2020 05/01/2020 05/21/2020 05/22/2020 05/26/2020 05/27/2020 05/28/2020 05/29 /2020 06/01/2020 06/02/2020 06/03/2020 06/04/2020 06/05/2020 06/08/2020 06/09 /2020 06/10/2020 06/11/2020 06/12/2020 06/15/2020 06/16/2020 06/17/2020 06/18 /2020 06/19/2020 06/22/2020 06/23/2020 07/22/2020 07/23/2020 08/05/2020 09/04 /2020 09/22/2020 10/05/2020 11/04/2020 12/07/2020 01/07/2021 03/01/2021 04/19 /2021 Record review showed the laboratory performed 189 testosterone and 736 prostate specific antigen patient tests. On 05/10/21 at 11:50 AM., the Medical Assistant confirmed that external quality control was not done each day of testing and that no IQCP was performed to allow monthly external quality control.