

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2293615	(X3) Date Survey Completed 07/29/2026
Name of Provider or Supplier Stuart Oncology Associates Pa	Street Address, City, State 11250 Sw Village Parkway, Ste C, Port Saint Lucie, 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 Stuart Oncology Associates PA on July 29, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited is as follows:
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to document corrective action when freezer temperatures were not recorded from 4/23/25 to 06/03/2025, and failed to document corrective action when temperatures were out of range for the chemistry controls for 34 of 145 days from 06/03/2025 to 12/31/2025. Findings: 1. Observations on 07/29/2026 at 1:30 PM, revealed the Technopath Multichem IA Plus (controls 1, 2 and 3), and the Technopath Multichem S Plus (controls 1, 2, and 3) indicated a storage temperature of -20 to -80 degrees Celsius (C). 2. Review of the Temp-Chex Temperature Record revealed, no temperatures were recorded from 04/23/2025 to 06/03/2025 and no corrective action was documented. 3. Review of the Temp-Chex Temperature Record revealed no corrective action was documented when temperatures were above the temperature requirements for the

following days: 06/06/2025 recorded -13 degrees C 06/09/2025 recorded -19.2 degrees C 06/10/2025 recorded -19.6 degrees C 06/11/2025 recorded -19.2 degrees C 08/21/2025 recorded -19.4 degrees C 08/22/2025 recorded -19.4 degrees C 08/25/2025 recorded -19.2 degrees C 08/26/2025 recorded -19.2 degrees C 08/27/2025 recorded -19.2 degrees C 09/15/2025 recorded -11.6 degrees C 09/16/2025 recorded -17 degrees C 09/17/2025 recorded -17 degrees C 09/18/2025 recorded -17 degrees C 09/19/2025 recorded -11 degrees C 09/22/2025 recorded -18 degrees C 09/23/2025 recorded -18 degrees C 09/24/2025 recorded -18 degrees C 09/25/2025 recorded -19 degrees C 09/26/2025 recorded -19 degrees C 09/29/2025 recorded -17.8 degrees C 09/30/2025 recorded -17.8 degrees C 10/01/2025 recorded -17.6 degrees C 10/02/2025 recorded -17.6 degrees C 10/03/2025 recorded -17.6 degrees C 10/27/2025 recorded -19.9 degrees C 10/28/2025 recorded -19.9 degrees C 10/29/2025 recorded -19.9 degrees C 12/15/2025 recorded -18.4 degrees C 12/16/2025 recorded -18.4 degrees C 12/18/2025 recorded -18.4 degrees C 12/26/2025 recorded -18.6 degrees C 12/29/2025 recorded -18.6 degrees C 12/30/2025 recorded -18.6 degrees C 12/31/2025 recorded -18.6 degrees C 4. During an interview on 07/29/2026 at 1:45 PM, Technical Consultant C acknowledged there were missing temperatures and temperatures were out of range, and no corrective action was documented.