Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0722304	01/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of South Florida & Treasure	2300 N Florida Mango Rd, West Palm Beach, 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	A recertification survey was conducted on December 4, 2024- January 30, 2025. PLANNED PARENTHOOD OF SOUTH FLORIDA AND TREASURE DBA PLANNED PARENTHOOD OF SOUTH,EAST, NORTH FLORIDA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Conditions were not met: D5400 Analytic Systems
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records, and interview, the Laboratory Director failed to sign the attestation forms for one (2023 2nd) of five (2023 1st, 2nd, 3rd, 2024 1st, 2nd) from the Kendall Laboratory in the specialty of Immunohematology and three (2024 1st, 2nd, 3rd) of six (2023 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) events for the West Palm Beach laboratory in the specialty of Endocrinology, and the Testing Personnel failed to sign the attestation forms for two (2024 1st, 3rd) of six (2023 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) events for the West Palm Beach laboratory in the specialty of Endocrinology. Findings Included: 1. Review of the American Proficiency Institute (API) PT instructions noted, "Signature Required - For all PT results, an attestation must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 2. Review of the API PT attestation forms showed, the Laboratory Director had not signed the attestation for the 2023 2nd event for the Kendall laboratory in the specialty of Immunohematology, and 2024 1st, 2nd, and 3rd events for the West Palm Beach laboratory in the specialty of Endocrinology. 3. Review of the API PT attestation forms showed Testing Personnel had not signed the attestation for the 2024 1st and 3rd events for the West

	Palm Beach laboratory in the specialty of Endocrinology. 4. On 12/05/2024 at 2:32 PM, the Health Center Manager acknowledge the attestations were not signed.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to run proficiency testing samples the same number of times as it routinely tested patient samples for one (2024 2nd) of six (2023 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) events for the West Palm Beach laboratory in the specialty of Endocrinology and for one (2024 2nd) of five (2023 1st, 2nd, 3rd, 2024 1st, 2nd) from the West Palm Beach Laboratory in the specialty of Immunohematology. Findings Included: 1. The API PT company sends five samples to be tested per event. Review of the PT attestation form for the 2024 2nd event to Endocrinology listed nine names of the persons who performed the test. Review of the instrument printout showed each sample had two sets of results for each sample dated 05/21/2024 and 05/22/2024. Review of the API 2024 catalog noted the PT Results Due Date was 06/05/2024. 2. Review of the PT attestation form for the 2024 2nd event to Immunohematology listed eight names of the persons who performed the test. Review of the attestation showed for sample #6, #7, #8,and #9 each had the names of two Testing Personnel listed as the person performing the test and were all dated 08/09 /2024. Review of the API 2024 catalog noted the PT Results Due Date was 08/14 /2024. 3. On 12/05/2024 at 3:30 PM, the Health Center Manager acknowledge the proficiency testing samples were run more that once.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview, the laboratory failed to submit PT results for Human Chorionic Gonadotropin (hCG) within the time frame specified by API for one (2023 2nd) of six (2023 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) events for the Kendall laboratory, and failed to submit one (2023 2nd) of six (2023 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) events for the Port St Lucie laboratory. Findings Included: 1. Review of API Performance Summary for hCG at the Kendall laboratory noted, "Test results were not received by American Proficiency Institute." 2. Review of API Performance Summary for hCG at the Port St Lucie laboratory noted, "Test results were not received by American Proficiency Institute." 3. On 12/05/2024 at 2:00 PM, the Health Center Manager stated the laboratory failed to submit the PT results before the deadline.
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)

	Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) records and interview, the laboratory failed to submit PT results for Rh (Rhesus) test within the time frame specified by API for one (2023 2nd) of five (2023 1st, 2nd, 3rd, 2024 1st, 2nd) events for the West Palm Beach laboratory, and failed to submit one (2023 2nd) of five (2023 1st, 2nd, 3rd, 2024 1st, 2nd) events for the Port St Lucie laboratory. Findings Included: 1. Review of API Performance Summary for West Palm Beach revealed the laboratory received a score of 0% for the 2023 2nd event for Rh. 2. Review of API Performance Summary for Port St Lucie revealed the laboratory received a score of 0% for the 2023 2nd event for Rh. 3. On 12/05/2024 at 2:00 PM, the Health Center Manager stated the laboratory failed to submit the PT results before the deadline. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to complete their performance verification on the i-stat system for beta-human chorionic gonadotropin (b-hCG) for all 5 laboratory locations before patient testing (D5421) and failed to follow their unreviewed TOTAL BETA-HUMAN CHORIONIC GONADOTROPIN (b-hCG)(Moderate Complexity Test) Individualized Quality Control Plan for performing Liquid Controls, levels 1 and 3, on the first day of patient care every month for all their testing locations(D5445).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the i-Stat 1 System Manual and quality control records, and

	interview, the laboratory failed to record the temperature and humidity of the laboratories at each location (West Palm Beach, Golden Glades, Kendall, Pembroke Pines, Treasure Coast) from 10/01/2022 to 12/05/2024. Findings Included: 1. Review of the i-Stat system manual revealed, the operating temperature for the i-Stat was 16-30 degrees Celsius and the relative humidity was 10-90%. 2. Review of quality control records revealed the laboratory had not recorded the room temperature or the humidity of the laboratory in each location. 3. On 12/04/2024 at 12:10 AM, the Health Center Manager stated they did not know they had to record the room temperature and humidity, and they had not recorded them.
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, the laboratory failed to complete their performance verification on the i-stat system for beta-human chorionic gonadotropin (b-hCG) for all 5 laboratory locations before patient testing. Finding Included: 1. Review of Mango Health Center i-STAT SYSTEM VERIFICATION revealed it was not signed by a testing personnel and the laboratory director. There was no instrument documentation on calibration runs and quality control runs for the verification of b-hCG tested on the i-stat instrument. 2. Review of Pembroke Pines Health Center i-STAT SYSTEM VERIFICATION revealed it was not signed by a testing personnel and laboratory director. There was no instrument documentation on calibration runs and quality control runs for the verification of b-hCG tested on the i-stat instrument with i-stat serial numbers. 3. Review of Golden Glades Health Center i-STAT SYSTEM VERIFICATION revealed it was not signed by a testing personnel and laboratory director. There was no instrument documentation on calibration runs and quality control runs for the verification of b-hCG tested on the i-stat instrument with i-stat serial numbers. 4. Review of Kendall Health Center i-STAT SYSTEM VERIFICATION revealed it was not signed by a testing personnel and laboratory director. There was no instrument documentation on calibration runs and quality control runs for the verification of b-hCG tested on the i-stat instrument with i-stat serial numbers. 5. Review of Treasure Coast Health Center i-STAT SYSTEM VERIFICATION revealed it was not signed by a testing personnel and laboratory director. There was no instrument documentation on calibration runs and quality control runs for the verification of b-hCG tested on the i-stat instrument with i-stat serial numbers. 6. Review of patients' test log revealed the following: A. 249 patients were tested for b-hCG from September 1, 2023 to present at location Mango. B. 125 patients were tested for b-hCG from September 1, 2023 to present at location Golden Glades. C. 47 patients were tested for b-hCG from September 1, 2023 to present at location Kendall. D. 15 patients were tested for b-hCG from September 1,2023 to present at Pembroke Pines location. E. 26 patients were tested for b-hCG from September 1, 2023 to present at location Treasure Coast. 7. On 12/5/2024 at 6:25 PM, the Quality Risk Manger confirmed the i-stat verifications were incomplete.

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 record review and interview, the laboratory failed to follow their unreviewed TOTAL BETA-HUMAN CHORIONIC GONADOTROPIN (b-hCG) (Moderate Complexity Test) Individualized Quality Control Plan for performing Liquid Controls, levels 1 and 3, on the first day of patient care every month for all their testing locations. Findings Included: 1. Review of the testing log revealed b-hCG testing was performed on the i-stat at 5(Mango, Golden Glades, Kendall, Pembroke Pines and Treasure Coast) out of 5 locations. 2. Review of TOTAL BETA-HUMAN CHORIONIC GONADOTROPIN (b-hCG) (Moderate Complexity Test) Individualized Quality Control Plan (IQCP) read, "Liquid Controls, levels 1 and 3, on the first day of patient care every month. Liquid Controls, levels 1 and 3, with each new shipment of cartridges." The plan was not signed by the Laboratory Director. There was no individualized quality control plan for the 5 (Mango, Golden Glades, Kendall, Pembroke Pines and Treasure Coast) out of 5 locations that performed b-hCG on the i-stat. 3A. Review of Mango patient testing log revealed the following: a. 13 patients were tested for b-hCG in August 2024 b. 9 patients were tested for b-hCG in June 2024 c. 2 patients were tested for b-hCG in September 2024 3B. Review of Treasure Coast patient testing log revealed the following: a. 2 patients were tested for b-hCG in November 2023 b. 2 patients were tested for b-hCG in December 2023 c. 2 patients were tested for b-hCG in January 2024 d. 1 patient was tested for b-hCG in February 2024 e. 6 patients were tested for b-hCG in April 2024 3C. Review of Pembroke Pines patient testing log revealed the following: a. 1 patient was tested for b-hCG in November 2023 b. 4 patients were tested for b-hCG in March 2024 c. 1 patient was tested for b-hCG in April 2024 3D. Review of Kendall patient testing log revealed the following: a. 2 patients were tested for b-hCG in November 2023 b. 1 patient was tested for b-hCG in December 2023 c. 5 patients were tested for b-hCG in March 2024 d. 20 patients were tested for b-hCG in May 2024 3E. Review of Golden Glades patient testing log revealed the following: a. 1 patient was tested for b-hCG in January 2024 b. 8 patients were tested for b-hCG in February 2024 c. 20 patients were tested for b-hCG in March 2024 d. 67 patients were tested for b-hCG in May 2024 4a. Review of Mango i-stat Quality Control revealed level 1 and 3 controls were not performed for the months of September 2023, June 2024 and August 2024. 4b. Review of Treasure Coast i-stat Quality Control revealed level 1 and 3 controls were not performed for the months of November 2023, December 2023, January 2024, February 2024 and April 2024. 4c. Review of Pembroke Pines i-stat Quality Control revealed level 1 and 3 controls were not performed for the months of November 2023, March 2024 and April 2024. 4d. Review of Kendall i-stat Quality Control revealed level 1 and 3 controls were not performed for the months of November 2023, December 2023, March 2024 and May 2024. 4e. Review of Golden Glades i-stat Quality Control revealed level 1 and 3 controls were not performed for the months of

	January 2024, February 2024, March 2024 and May 2024. 5. On 12/5/2024 at 6:25 PM, the Quality Risk Manger confirmed the IQCP was not followed and quality controls were not performed at 5 out of 5 locations that performed b-hCG.
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, review of temperature logs, and interview, the laboratory failed to document corrective action for the refrigerator temperatures that were out of range for the i-Stat Beta-human chorionic gonadotropin (B-hCG) controls and the Rhesus (Rh) negative control in the refrigerators at the laboratories at each location (West Palm Beach, Golden Glades, Kendall, Pembroke Pines, Treasure Coast) for four months (December 2022, September 2023, May 2024, August 2024) reviewed. Findings Included: 1. Observation on 12/04/2024 at 12:10 PM, revealed the temperature range listed on the boxes for the B-hCG Level 1 and 2 controls was 2-8 degrees Celsius (C) (35.6 - 46.4 degrees Fahrenheit (F)). Review of temperature storage requirements for the Rh-negative control provided by the manufacturer listed 2-8 degrees C. 2a. Review of the temperature logs for West Palm Beach laboratory showed the refrigerator temperatures where the B-hCG controls and Rh-negative control were stored were out of range for the following dates: 12/12/2022 recorded 34 degrees F 12/17/2022 recorded 35 degrees F 09/01/2023 recorded 20 degrees F 09/12 /2023 recorded 35 degrees F 08/26/2024 recorded 34 degrees F 2b. Review of the temperature logs for the Golden Glades laboratory showed the temperature for the refrigerator where the B-hCG was stored was recorded in the AM and PM. Review of the temperature logs showed the refrigerator temperatures where the B-hCG controls were stored were out of range for the following dates: 12/08/2022 recorded 34 degrees F at 8:44 AM 12/08/2022 recorded 35 degrees F at 3:05 AM 12/09/2022 recorded 32 degrees F at 3:09 PM 12/13/2022 recorded 34 degrees F at 6:00 PM 12/14/2022 recorded 34 degrees F at 8:44 AM 12/14/2022 recorded 34 degrees F at 5:40 PM 12/22 /2022 recorded 35 degrees F at 8:11 AM 12/22/2022 recorded 32 degrees F at 2:51 PM 12/23/2022 recorded 35 degrees F at 7:30 AM 12/31/2022 recorded 34 degrees F at 2:15 PM 09/07/2023 recorded 34 degrees F at 3:42 PM 09/07/2023 recorded 34 degrees F at 3:44 PM 09/11/2023 recorded 34 degrees F at 9:08 AM 09/12/2023 recorded 35 degrees F at 6:07 PM 09/14/2023 recorded 33 degrees F at 8:08 AM 09/14 /2023 recorded 34 degrees F at 3:32 PM 09/16/2023 recorded 33 degrees F at 8:20 AM 09/16/2023 recorded 33 degrees F at 2:59 PM 09/21/2023 recorded 35 degrees F at 8:21 AM 09/21/2023 recorded 34 degrees F at 2:56 PM 09/25/2023 recorded 34 degrees F at 9:12 AM 09/25/2023 recorded 32 degrees F at 5:20 PM 09/26/2023 recorded 32 degrees F at 6:16 PM 05/08/2024 recorded 34 degrees F at 5823 AM 05 /08/2024 recorded 3 degrees F at 4:40 PM 05/09/2024 recorded 34 degrees F at 8:23 PM 05/25/2024 recorded 34 degrees F at 8:23 PM 05/25/2024 recorded 34 degrees F

at 8:23 PM 05/28/2024 recorded 34 degrees F at 8:23 PM 08/12/2024 recorded 35 degrees F at 4:56 PM 08/14/2024 recorded 35 degrees F at 8:40 AM 08/14/2024 recorded 34 degrees F at 8:23 PM 08/22/2024 recorded 34 degrees F at 7:41 AM 08/22/2024 recorded 35 degrees F at 3:47 PM 08/23/2024 recorded 34 degrees F at 3:10 PM 08/29/2024 recorded 34 degrees F at 3:53 PM 2c. Review of the temperature logs for Golden Glades laboratory showed the refrigerator temperatures where the Rh-negative control was out of range for the following dates: Golden Glades (Rh neg - specimen) 12/06/2022 recorded 34 degrees F 12/14/2022 recorded 34 degrees F 12/15/2022 recorded 34 degrees F 12/17/2022 recorded 34 degrees F 12/19/2022 recorded 34 degrees F 12/21/2022 recorded 34 degrees F 12/23/2022 recorded 34 degrees F 12/27/2022 recorded 16 degrees F 12/28/2022 recorded 34 degrees F 12/31/2022 recorded 32 degrees F 09/05/2023 recorded 34 degrees F 09/08/2023 recorded 25 degrees F 09/13/2023 recorded 32 degrees F 09/16/2023 recorded 26 degrees F 09/18/2023 recorded 29 degrees F 09/19/2023 recorded 31 degrees F 09/20/2023 recorded 30 degrees F 09/21/2023 recorded 32 degrees F 09/22/2023 recorded 31 degrees F 09/23/2023 recorded 32 degrees F 05/01/2024 recorded 34 degrees F 05/18/2024 recorded 24 degrees F 05/21/2024 recorded 34 degrees F 05/28/2024 recorded 34 degrees F 05/30/2024 recorded 34 degrees F 05/31/2024 recorded 34 degrees F 08/01/2024 recorded 32 degrees F 08/02/2024 recorded 32 degrees F 08/03/2024 recorded 30 degrees F 08/05/2024 recorded 34 degrees F 08/06/2024 recorded 34 degrees F 08/07/2024 recorded 30 degrees F 08/08/2024 recorded 32 degrees F 08/09/2024 recorded 32 degrees F 08/10/2024 recorded 34 degrees F 08/14/2024 recorded 30 degrees F 08/15/2024 recorded 28 degrees F 08/16/2024 recorded 30 degrees F 08/23/2024 recorded 32 degrees F 08/26/2024 recorded 27 degrees F 08/27/2024 recorded 28 degrees F 08/28/2024 recorded 32 degrees F 08/29/2024 recorded 32 degrees F 08/30/2024 recorded 32 degrees F 08/31/2024 recorded 34 degrees F 2d. Review of the temperature logs for Kendall laboratory showed the refrigerator temperatures where the B-hCG controls and Rh-negative control were stored were out of range for the following dates: 12/02/2022 recorded 50 degrees F 12/08/2022 recorded 32 degrees F 12/09/2022 recorded 32 degrees F 12/10/2022 no temperature recorded 12/12/2022 recorded 32 degrees F 12/13/2022 recorded 33 degrees F 12/15/2022 recorded 35 degrees F 12/19/2022 recorded 32 degrees F 12/20/2022 recorded 32 degrees F 12/21/2022 recorded 32 degrees F 12/22/2022 recorded 30 degrees F 12/23/2022 recorded 33 degrees F 12/27/2022 recorded 32 degrees F 12/28/2022 recorded 30 degrees F 12/29/2022 recorded 30 degrees F 12/30/2022 recorded 30 degrees F 12/31/2022 recorded 32 degrees F 09/01/2023 recorded 32 degrees F 09/02/2023 recorded 32 degrees F 09/07/2023 recorded 34 degrees F 09/12/2023 recorded 33 degrees F 09/14/2023 recorded 34 degrees F 09/16/2023 recorded 34 degrees F 09/19/2023 recorded 32 degrees F 09/20/2023 recorded 32 degrees F 09/21/2023 recorded 32 degrees F 09/22/2023 recorded 32 degrees F 09/23/2023 recorded 34 degrees F 09/25/2023 recorded 34 degrees F 09/26/2023 recorded 32 degrees F 09/27/2023 recorded 34 degrees F 09/28/2023 recorded 33 degrees F 09/29/2023 recorded 31 degrees F 09/30/2023 recorded 32 degrees F 05/01/2024 recorded 32 degrees F 05/02/2024 recorded 31 degrees F 05/03/2024 recorded 35 degrees F 05/04/2024 recorded 30 degrees F 05/06/2024 recorded 32 degrees F 05/07/2024 recorded 28 degrees F 05/08/2024 recorded 28 degrees F 05/14/2024 recorded 35 degrees F 05/15/2024 recorded 32 degrees F 05/16/2024 recorded 30 degrees F 05/17/2024 recorded 32 degrees F 05/20/2024 recorded 34 degrees F 05/22/2024 recorded 35 degrees F 05/25/2024 recorded 34 degrees F 05/28/2024 recorded 34 degrees F 05/29/2024 recorded 33 degrees F 08/20/2024 recorded 34 degrees F 08/30/2024 recorded 35 degrees F 2e. Review of the temperature logs for Pembroke Pines laboratory showed the refrigerator temperatures where the B-hCG controls and Rh-negative control were stored were out of range for the following dates: 12/02/2022 no temperature recorded 12/09/2022 no temperature

	recorded 09/08/2023 recorded 34 degrees F 09/09/2023 recorded 32 degrees F 09/11 /2023 recorded 32 degrees F 09/12/2023 recorded 32 degrees F 09/13/2023 recorded 34 degrees F 05/23/2024 recorded 33 degrees F 08/19/2024 recorded 30 degrees F 08 /27/2024 recorded 34 degrees F 2f. Review of the temperature logs for Treasure Coast laboratory showed the refrigerator temperatures where the B-hCG controls and Rh-negative control were stored were out of range for the following dates: 12/01/2022 recorded 32 degrees F 12/08/2022 recorded 32 degrees F 12/15/2022 recorded 35 degrees F 12/16/2022 recorded 35 degrees F 12/21/2022 recorded 32 degrees F 12/22 /2022 recorded 34 degrees F 09/05/2023 recorded 35 degrees F 09/08/2023 recorded 30 degrees F 09/11/2024 recorded 34 degrees F 09/12/2023 recorded 35 degrees F 09 /14/2023 recorded 32 degrees F 09/15/2023 recorded 32 degrees F 09/26/2023 recorded 32 degrees F 09/28/2023 recorded 34 degrees F 09/29/2023 recorded 34 degrees F 05/01/2024 recorded 30 degrees F 05/02/2024 recorded 27 degrees F 05/03 /2024 recorded 30 degrees F 05/06/2024 recorded 29 degrees F 05/07/2024 recorded 30 degrees F 05/08/2024 recorded 30 degrees F 05/09/2024 recorded 30 degrees F 05 /10/2024 recorded 30 degrees F 05/13/2024 recorded 35 degrees F 05/14/2024 recorded 35 degrees F 05/15/2024 recorded 30 degrees F 05/16/2024 recorded 35 degrees F 05/17/2024 recorded 30 degrees F 05/20/2024 recorded 30 degrees F 05/21 /2024 recorded 28 degrees F 05/22/2024 recorded 35 degrees F 05/24/2024 recorded 30 degrees F 05/28/2024 recorded 30 degrees F 05/29/2024 recorded 28 degrees F 05 /30/2024 recorded 29 degrees F 05/31/2024 recorded 28 degrees F 08/01/2024 recorded 35 degrees F 08/02/2024 recorded 31 degrees F 08/06/2024 recorded 29 degrees F 08/07/2024 recorded 30 degrees F 08/09/2024 recorded 31 degrees F 08/12 /2024 recorded 30 degrees F 08/13/2024 recorded 35 degrees F 08/14/2024 recorded 31 degrees F 08/15/2024 recorded 29 degrees F 08/19/2024 recorded 30 degrees F 08 /21/2024 recorded 29 degrees F 08/22/2024 recorded 32 degrees F 08/23/2024 recorded 31 degrees F 08/26/2024 recorded 31 degrees F 08/27/2024 recorded 28 degrees F 08/28/2024 recorded 30 degrees F 08/29/2024 recorded 30 degrees F 08/30 /2024 recorded 30 degrees F 3. On 12/04/2024 at 2:15 PM, the Health Center Manager acknowledged corrective action for refrigerator temperature that were out of range was not always documented.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Director's personnel records, the Testing Personnel's competency evaluation, and interview, the laboratory failed to have the competency evaluations signed by a qualified Technical Consultant for 2 (O, P) of 28 i-Stat Testing Personnel (B - D, G - J, O, P, Q, U - HH, JJ, KK), 1 (A) of 28 RhD (Rhesus D antigen) Testing Personnel (A - T, V, W, Y - DD, GG, UU), and six of six Wet Preparation Testing Personnel (MM, OO-SS) in 2023; and 28 of 28 i-Stat Testing Personnel (A, B, D, G, H, J, O - Q, S, U - KK), 21 (A, C - N, P, AA - CC, FF - HH) of 32 RhD Testing Personnel (A, C - T, W, X, AA - CC, EE - KK, UU), and nine of nine Wet Preparation Testing Personnel (LL-TT) in 2024. Findings Included: 1. Review of the Laboratory Director's personnel records showed she received Commission on Laboratory Accreditation Director Continuing Medical Education Certificate on 08/10 /2024, and her curriculum vitae did not have any clinical laboratory experience

	required to qualify to be the Technical Consultant. 2. Review of the 2023 competency evaluations showed the competencies were signed by the Laboratory Director for Testing Personnel O and P for i-Stat testing, Testing Personnel A for RhD testing, and Testing Personnel MM and OO-SS for Wet Preparation testing 3. Review of the 2024 competency evaluations showed the competencies were signed by the Laboratory Director for Testing Personnel A, B, D, G, H, J, O - Q, S, and U - KK for i-Stat testing, Testing Personnel A for RhD testing, Testing Personnel A, C - N, P, AA - CC, and FF - HH, and Testing Personnel LL-TT for Wet Preparation testing, 4. On 12/04 /2024 at 1:15 PM, the Laboratory Director stated her laboratory experience was in research and she did not have any clinical laboratory patient testing experience. 5. On 12/04/2025 at 3:50 PM, the Health Center Manager acknowledged some of the competency evaluations were signed by the current Laboratory Director.