

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0697954	<b>(X3) Date Survey Completed</b>  04/03/2025
<b>Name of Provider or Supplier</b>  Total Health Partners	<b>Street Address, City, State</b>  4400 N Grant Blvd, Yukon, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The validation survey was performed on 04/02,03/2025. The laboratory was found out of compliance with the following CLIA Conditions: 493.1207; D5012: Syphilis Serology 493.1212; D5020: Endocrinology 493.1403; D6000: Laboratory Director The findings were reviewed with the technical consultant at the conclusion of the survey.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for Coag-Sense expiration dates. Findings include: (1) On 04/02/2025 at 10:45 am observation of the laboratory revealed the following expired materials which appeared to be available for use: (a) One Coag-Sense Prothrombin Time (PT)/INR Test Strip Kit, lot #230018, with a manufacturer's expiration date of 01/31/2025. (2) A review of the Coag-Sense professional user manual stated, "PT test strips, Control Strips, and Control Activation Solution are perishable goods with a limited shelf life. Do not use items if the expiration date has passed"; (3) The findings were reviewed with the technical consultant, who stated on 04/02/2025 at 10:45 am the test kit had expired and was available for use.</p>
<b>D5012</b>	<p>SYPHILIS SEROLOGY CFR(s): 493.1207</p> <p>If the laboratory provides services in the subspecialty of Syphilis serology, the</p>

	<p>laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, written procedure, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Syphilis serology for four of four months reviewed. Findings include: (1) The laboratory failed to have documentation to substantiate that reactive, weak reactive, and non-reactive control materials were performed each day of patient qualitative RPR (Rapid Plasma Reagin) testing. Refer to D5449.</p>
<p><b>D5020</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Endocrinology for nine of nine months reviewed. Findings include: (1) The laboratory failed to perform a negative and positive control material each day of Serum Qualitative Pregnancy testing. Refer to D5449.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 04/02/2025 at 11:00 am, identified the following expired supplies available for use: (a) Four Copan UTM-RT transport media collection kits, lot #33002214, expired 01/21/2024. (2) Interview with the technical consultant on 04/02/205 at 11:00 am confirmed the expired kits were available for use.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for the Roche c6000 analyzer between September 2024 and February 2025. Findings include: (1) On 04/02/2025 at 3:30 pm, the technical consultant stated chemistry and immunoassay testing were performed using the Roche c6000 analyzer; (2) On 04/02/2025, a review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly (i) Clean cell overs, rinse stations, IS bath; (b) Biweekly (i) Liquid flow path cleaning; (c) Quarterly (i) Replace reaction cells, ISE pinch valve, sipper tubing, clean incubation bath, KCl filter, detergent filters, air filters, ultrasonic mixers, and ISE measuring cartridges. (d) Six month (i) Replace reference cartridge; (ii) Clean inlet water and cooling fans; (3) A review of maintenance logs from September 2024 through February 2025 identified no documentation maintenance had been performed as follows: (a) Weekly (i) Between 11/11/2024 and 11/28/2024; (ii) Between 12/02/2024 and 12/19/2024; (iii) Between 12/19/2024 and 01/02/2025. (b) Biweekly (i) Between 10/09/2024 and 10/31/2024; (ii) Between 02/03/2025 and 02/24/2025. (c) Quarterly (i) Between 09/01/2024 and 02/28/2025. (d) Six month (i) Between 09/01/2024 and 04/02/2025. (4) The records were reviewed with the technical consultant who stated on 04/03/2025 at 10:00 am, the analyzer maintenance had not been documented as performed as stated above.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
 CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
 Based on a review of records, policies and procedures, and interview with the technical consultant, the laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly during the review period of January 2024 through the current date. Findings include: (1) On 04/02/2025 at 11:00 am, the technical consultant stated the following: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Premiere XC-2000 centrifuge. (2) A review of the laboratory policy and procedure manual identified no evidence of a function check protocol that defined the frequency of the urine centrifuge speed and timer checks and the acceptable limits for the checks; (3) Interview with the technical consultant on 04/02/2025 at 11:30 am confirmed the laboratory did not have a written function check protocol and speed and timer checks had not been performed during the review period.

**D5441**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of records, QC (quality control) package inserts, and interview with the technical consultant, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for Calcium, Chloride, Glucose Potassium, and Sodium testing for three of three months reviewed from December 2024 through February 2025. Findings include: (1) On 04/02/2025 at 2:30 pm, the technical consultant stated the following: (a) The laboratory performed Calcium, Chloride, Glucose Potassium, and Sodium using the Roche Cobas 6000 analyzer; (b) Three levels of Bio-Rad Liquid Assayed Multiquel Control materials were performed each day of patient testing. (c) When new lot numbers of control materials were put into use, the laboratory established means and two SD (Standard Deviation) ranges for each analyte. (2) A review of the manufacturer's instructions (package insert) for the control materials stated, "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (3) A review of QC records for three lot numbers of control materials used during the review period of 12/01/2024 through 02/28/2025 identified the following: (a) Level one lot #46021, level two lot#46022 and level three lot #46023 were in use - The laboratory was using ranges wider than the package insert guideline ranges as follows: (i) Level one package insert guideline range were as follows; (aa) Calcium 5.51 - 6.34 mg/dL (bb) Chloride 67.3 - 76.0 mEq/L (cc) Glucose 57.4 - 66.8 mg/dL (dd) Potassium 2.21 - 2.88 mEq/L (ee) Sodium 106 - 117 mEq/L (ii) Level two package insert guideline range were as follows; (aa) Calcium 9.36 - 10.6 mg/dL (bb) Chloride 90.4 - 110 mEq/L (cc) Glucose 107 - 123 mg/dL (dd) Potassium 3.65 - 4.32 mEq/L (ee) Sodium 131 - 144 mEq/L (iii) Level three package insert guideline range were as follows; (aa) Calcium 12.5 - 14.0 mg/dL (bb) Chloride 114 - 126 mEq/L (cc) Glucose 346 - 397 mg/dL (dd) Potassium 6.98 - 7.69 mEq/L (ee) Sodium 148 - 165 mEq/L (b) The laboratory ranges in use were as follows; (i) Level one; (aa) Calcium 4.85 - 6.85 mg/dL (bb) Chloride 58.6 - 86.6 mEq/L (cc) Glucose 50.5 - 74.5 mg/dL (dd) Potassium 2.22 - 3.02 mEq/L (ee) Sodium 93.8 - 133.8 mEq/L (ii) Level two; (aa) Calcium 7.97 - 11.97 mg/dL (bb) Chloride 76.0 - 114.0 mEq/L (cc) Glucose 90.7 - 138.7 mg/dL (dd) Potassium 3.32 - 4.92 mEq/L (ee) Sodium 76.0 - 114.0 mEq/L (iii) Level Three (aa) Calcium 10.58 - 16.18 mg/dL (bb) Chloride 97.2 - 145.2 mEq/L (cc) Glucose 298.6 - 446.6 mg/dL (dd) Potassium 6.04 - 8.84 mEq/L (ee) Sodium 127.4 - 191.4 mEq/L (4) The records were reviewed with the technical consultant who stated on 04/02/2025 at 02:00 pm, the laboratory had used ranges wider than the package insert 3 SD (standard deviation) guideline ranges as shown above.

D5449

CONTROL PROCEDURES  
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on a review of records, written procedure, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to perform a negative and positive control material 40 of 40 days of patient qualitative serum pregnancy testing reviewed from July 2024 through March 2025; and failed to have documentation to substantiate that reactive, weak reactive, and non-reactive control materials were performed 11 of 27 days of patient qualitative RPR (Rapid Plasma Reagin) testing reviewed in July 2024, December 2024, January 2025, and February 2025. Findings include: I. QUALITATIVE SERUM PREGNANCY TESTING (1) On 04/02/2025 at 10:05 am, the technical consultant stated Qualitative Serum Pregnancy testing was performed using the Beckman Coulter ICON 25 hCG test kit and serum samples; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 65 qualitative serum pregnancy tests annually; (3) A review of QC (Quality Control) and patient testing records for testing performed from July 2024 through March 2025 identified no evidence negative and positive QC materials had been performed each day of patient testing for 40 of 40 days reviewed from July 2024 through March 2025; (4) The records were reviewed with the technical consultant who stated on 04/02/2025 at 11:50 am that, although the internal negative and positive controls were observed and documented each day of patient testing, negative and positive QC materials had not been performed; (5) The following were patient Serum Qualitative Pregnancy tests performed when negative and positive QC materials had not been performed: (a) Patient #240708059 - Testing performed on 07/08/2024 (b) Patient #240710004 - Testing performed on 07/10/2024 (c) Patient #240711068 - Testing performed on 07/11/2024 (d) Patient #240712094 - Testing performed on 07/12/2024 (e) Patient #240717050 - Testing performed on 07/17/2024 (f) Patient #240719081 - Testing performed on 07/19/2024 (g) Patient #240723129 - Testing performed on 07/23/2024 (h) Patient #240812125 - Testing performed on 08/12/2024 (i) Patient #240823080 - Testing performed on 08/23/2024 (j) Patient #240904136 - Testing performed on 09/04/2024 (k) Patient #240919124 - Testing performed on 09/19/2024 (l) Patient #240923183 - Testing performed on 09/23/2024 (m) Patient #240926065 - Testing performed on 09/26/2024 (n) Patient #241003069 - Testing performed on 10/03/2024 (o) Patient #241015089 - Testing performed on 10/15/2024 (p) Patient #241016009 - Testing performed on 10/16/2024 (q) Patient #241022035 - Testing performed on 10/22/2024 (r) Patient #241024021 - Testing performed on 10/24/2024 (s) Patient #241029128 - Testing performed on 10/29/2024 (t) Patient #241030075 - Testing performed on 10/30/2024 (u) Patient #241104073 - Testing performed on 11/04/2024 (v) Patient #241108091 - Testing performed on 11/08/2024 (w) Patient #241111020 - Testing performed on 11/11/2024 (x) Patient #241121124 - Testing performed on 11/21/2024 (y) Patient #241122052 - Testing performed on 11/22/2024 (z) Patient #241211188 - Testing performed on 12/11/2024 (aa) Patient #241212082 - Testing performed on 12/12/2024 (bb) Patient #250108227 - Testing performed on 01/08/2025 (cc) Patient #250113146 - Testing performed on 01/13/2025 (dd) Patient #250114148 - Testing performed on 01/14/2025 (ee) Patient #250115100 - Testing performed on 01/15/2025 (ff) Patient #250120084 - Testing performed on 01/20/2025 (gg) Patient #250128191 - Testing performed on 01/28/2025 (hh) Patient #250210112 - Testing performed on 02/10/2025 (ii) Patient #250213019 - Testing performed on 02/13/2025 (jj) Patient #250303112 - Testing performed on 03/03/2025 (kk) Patient #250305151 - Testing performed on 03/05/2025 (ll) Patient #250307059 - Testing performed on 03/07/2025 (mm) Patient

#250326172 - Testing performed on 03/26/2025 (nn) Patient #250331030 - Testing performed on 03/31/2025 II. QUALITATIVE RPR TESTING (1) On 04/02/2025 at 10:55 am, the technical consultant stated RPR testing was performed using the ASI (Arlington Scientific Inc.) RPR Card Test for Syphilis until 04/01/2025, when it was discontinued and the Stanbio RPR Quicktest was put into use on 04/02/2025, however a patient test had not yet been performed (note that the findings are based on the testing performed using the ASI RPR Card Test); (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 270 qualitative RPR tests annually; (3) A review of the manufacturer's package insert under the heading, "Assay Protocol-Qualitative" stated, "Using a stirrer pipette, dispense one free-falling drop (0.05 ml) of each serum or plasma sample onto a separate circle on the test card" and "Repeat by adding one free-falling drop of REACTIVE, WEAK REACTIVE, or NONREACTIVE CONTROL from the dropper vials supplied"; (4) A review of the written procedure titled, "RPR Screen" under "Quality Control" stated, "Run External QC (3 levels) with each batch and document on RPR worksheet along with patient results"; (5) A review of QC and patient testing records for testing performed during July 2024, December 2024, January 2025, and February 2025, identified that three levels of QC had not been documented as performed or the specific reactions for each level of QC had not been documented for 11 of 27 days of patient testing reviewed as follows: (a) 07/11/2024 - Three levels of QC had not been documented as performed (b) 07/18/2024 - The documentation stated, "QC-all OK" (c) 07/30/2024 - Three levels of QC had not been documented as performed (d) 12/05/2024 - The documentation stated, "QC-OK" (e) 12/31/2024 - The documentation stated, "QC-OK" (f) 01/15/2025 - The documentation stated, "QC-all OK" (g) 01/16/2025 - The documentation stated, "QC-OK" (h) 01/17/2025 - Three levels of QC had not been documented as performed (i) 02/17/2025 - Three levels of QC had not been documented as performed (j) 02/20/2025 - The documentation stated, "QC OK" (k) 02/27/2025 - The documentation stated, "QC-all OK" (6) The records were reviewed with the technical consultant who stated on 04/02/2025 at 02:40 pm, QC had not been documented as performed as required; (7) The following were patient Qualitative RPR tests performed when the reactions for the three levels of QC had not been documented as performed: (a) Patient #240710042S - Testing performed on 07/11/2024 (b) Patient #240718041S - Testing performed on 07/18/2024 (c) Patient #240750059S - Testing performed on 07/30/2024 (d) Patient #241204007S - Testing performed on 12/05/2024 (e) Patient #24130066S - Testing performed on 12/31/2024 (f) Patient #250113064S - Testing performed on 01/15/2025 (g) Patient #250114278S - Testing performed on 01/16/2025 (h) Patient #250117036S - Testing performed on 01/17/2025 (i) Patient #250214104S - Testing performed on 02/17/2025 (j) Patient #250217242S - Testing performed on 02/20/2025 (k) Patient #250225217S - Testing performed on 02/27/2025

**D6000**

MODERATE COMPLEXITY LABORATORY DIRECTOR  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on a review of records, written procedure, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to provide overall management and direction during the review period of July 2024 through

March 2025. Findings include: (1) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on a review of records, written procedure, manufacturer's instructions, and interview with the technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of July 2024 through March 2025. Findings include: (1) The laboratory director failed to ensure a negative and positive control material was performed each day of patient Qualitative Serum Pregnancy testing. Refer to D5449; (2) The laboratory director failed to ensure there was documentation to substantiate that reactive, weak reactive, and non-reactive control materials were performed each day of patient qualitative RPR (Rapid Plasma Reagin) testing. Refer to D5449.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 04/02/2025 at 1130 am, a review of personnel records for one person hired to perform moderate complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #2 - The initial training was complete on 10/11/2023. There was no evidence a competency evaluation had been performed between 04/11/2024 and 03/05/2025. (2) The records were reviewed with the technical consultant who stated on 04/02/2025 at 11:30 am, a competency evaluation had not been performed semiannually during the first year of testing.