

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0884173	<b>(X3) Date Survey Completed</b>  05/17/2022
<b>Name of Provider or Supplier</b>  Northwoods Urology Of Texas, Pllc	<b>Street Address, City, State</b>  135 Vision Park Blvd, Shenandoah, TX	
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>	<p>The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400- 42 C.F.R. 493.1250 Condition: Analytic systems D6076- 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the submitted Laboratory Personnel Report (CLIA) Form 209, review of personnel competency assessment documents, review of laboratory's policies and staff interview it was determined the laboratory failed to establish protocols for frequency and evaluation of competency for 1 of 1 Clinical Consultant, 1 of 1 Technical Supervisor and 1 of 1 General Supervisor employed by the facility. Findings included: 1. Review of the laboratory's submitted Form 209 and personnel records revealed the laboratory employed one Clinical Consultant, one Technical Supervisor and one General Supervisor. 2. Review of the laboratory's personnel</p>

competency assessment documents revealed there was no documentation of competency assessment for the laboratory's Clinical Consultant. 3. Review of laboratory's policies and procedures revealed there was no policy in place delineating frequency and/or requirements for assessment of competency for laboratory's Clinical Consultant, Technical Supervisor and General Supervisor. 4. In an interview on 5/17 /2022 at 1600 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**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 review of the laboratory's policies and procedures, review of manufacturer's instructions, review of instrument quality control and calibration documents, review of laboratory's test establishment studies, review of patient records and staff interview it was determined the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to ensure policies/procedures were established and followed. Refer to D5401 A, B and C. 2. The laboratory failed to ensure policies and procedures were approved by current laboratory director. Refer to D5407. 3. The laboratory failed to ensure storage temperatures were monitored for blood collection systems. Refer to D5413. 4. The laboratory failed to ensure test establishment studies were complete. Refer to D5423. 5. The laboratory failed to ensure quality control was performed as required. Refer to D5455. 6. The laboratory failed to ensure corrective actions were documented. Refer to D5781. 7. The laboratory failed to ensure Quality Assurance assessments identified and corrected issues with staff following procedures, completeness of establishment studies, performance of quality control and documentation of corrective action. Refer to D5791.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
A. Based on review of a random sampling of 5 laboratory's patient reports for Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) testing, review of laboratory's patient test logs for 2021, review of laboratory's policies and procedures, and staff interview it was determined the laboratory failed to address rectal swab specimens, 1 of 2

specimen types received in the laboratory, in its policies/procedures for testing by molecular methods. Findings included: 1. Review of a random sampling of the laboratory's patient reports for UTI Pathogens by Real-Time QPCR revealed that 2 of 5 of the specimens' reports had specimen source designation of rectal swabs. 2. Review of laboratory's patient test logs for 2021 revealed the laboratory performed testing on 100 rectal swab samples within the year. Refer to master list. 3. Review of laboratory's Determination of Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) procedure revealed the procedure did not address rectal swabs. 4. In an interview on 5/17/2022 at 17:10 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings. B. Based on surveyors observations on 05/17/2022 at 1400 hours in the laboratory, review of laboratory's policies and procedures, review of laboratory's centrifuge and pipette calibration records, and staff interview it was determined the laboratory failed to follow its own protocols for calibration of 2 of 2 centrifuges and 3 of 3 pipettes used by the laboratory. Findings included: 1. Surveyors observations on 05/17/2022 at 1410 hours in the laboratory revealed the following instrumentation was used for sample processing during Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) testing: Centrifuges: Benchmark Scientific VWR High Speed Microcentrifuge; model C1603; serial number 110-16031-20060069; in use March 2021 Benchmark Scientific VWR Mini-Plate Centrifuge; model C2001; serial 123-18031-20100040; in use March 2021 Pipettes: Eppendorf 220uL Pipette; serial number J47174J; in use March 2021 Eppendorf 20uL Pipette; serial number J50707; in use March 2021 Eppendorf 10uL 8 channel Pipette; serial number Q36585J; in use March 2021 2. Review of the laboratory's procedure for UTI Pathogens by Real-Time RT-QPCR, placed into effect on 03/12/2021, Section 13.0 "Maintenance" revealed: "13.1 Pipettes All pipettes in use in the laboratory are calibrated prior to initial use (by the manufacturer) and every 6 months thereafter." And "13.2 Centrifuges All centrifuges (plate and microcentrifuge) in use in the laboratory are calibrated prior to initial use (by the manufacturer) and every year thereafter." 3. Review of laboratory's centrifuge and pipette calibration records revealed documentation of initial manufacturer's calibration only. The laboratory failed to document subsequent calibration of the above centrifuges or pipettes as per laboratory's protocols. 4. In an interview on 5/17/2022 at 1410 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings. C. Based on review of the laboratory's policies and procedures, review of the laboratory's twice annual accuracy verification records for 2021 and staff interview it was determined the laboratory failed to follow its own protocols for verifying test performance accuracy for Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR), 1 of 2 tests performed by the laboratory. Findings included: 1. Review of the "Laboratory Quality Assurance Plan" policy, signed into effect on 03/12/2021, section 10 "Proficiency Testing Policy" revealed: "10.7 The laboratory will enroll in a split sample agreement for all non-waved analytes or if available, enroll in a CLIA approved proficiency test. 10.7.1 If split samples are conducted, then no fewer than 10 samples may be tested per year." 2. Review of the laboratory's accuracy verification records for 2021 revealed the laboratory performed 3 split sample test accuracy verification studies for its UTI Pathogens by Real-Time RT-QPCR test, each consisting of 3 samples, failing to achieve the required minimum 10 samples per year as per protocol. 3. In an interview on 5/17/2022 at 1020 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**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, review of laboratory's personnel records and staff interview it was determined the current laboratory director failed to approve, sign and date all the laboratory policies and procedures upon assumption of the laboratory director's position. Findings included: 1. Review of the laboratory's Procedure Manual revealed all policies and procedures were last approved, signed and dated by the former laboratory director. There was no evidence of current laboratory director's approval of the policies and procedures used by the laboratory. 2. Review of the laboratory's personnel records revealed the current laboratory director assumed his position in March of 2021. 3. In an interview on 5/17/2022 at 1030 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**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 surveyor's observations throughout the facility on 05/17/2021 at 1430 hours, review of the manufacturer's instructions for storage and staff interview it was determined the laboratory failed to ensure the facility monitored storage temperatures for 3 of 3 blood collection tube types used by the facility to send patient blood samples to a reference laboratory for testing. Findings included: 1. Surveyor's observations throughout the facility on 05/17/2021 at 1430 hours revealed each patient exam room and a main storage area stored the following blood collection tubes: Vacurette Tube K2E K2EDTA - lavender top; used for hematology testing Lot B22023WV; Expiration date 2023-06-16 BD Vacutainer Serum Blood Collection Tubes - red top; used for serology testing Lot 1123114; Expiration date 2023-04-30 Lot 1020643; Expiration date 2021-01-31 Vacurette CAT Serum Separator Clot Activator - red top; used for serology testing Lot C211034X; Expiration date 2023-04-02 Lot A21083MV; Expiration date 2023-02-16 2. Review of the manufacturer's instructions for storage for the above blood collection tubes revealed storage requirements for temperature to be 4-25C. 3. The laboratory was asked to provide documentation of temperature monitoring for the rooms where blood collection tubes were stored and no such documentation was available for review. 4. In an interview

on 5/17/2022 at 1750 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor's observations on 05/17/2022 at 1400 in the laboratory, review of patient test logs for 2021, review of laboratory's policies and procedures, review of manufacturer package inserts for specimen transport systems, review of the laboratory's establishment studies for its laboratory developed Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) test and staff interview it was determined the laboratory failed to document verification of performance characteristics for specimen stability intervals for 2 of 2 specimen collection/transport systems and one of 2 specimen types accepted in the laboratory. Findings included: 1. Surveyor's observations on 05/17/2022 at 1400 in the laboratory revealed the laboratory used 2 specimen collection/transport systems: a. Andwin Scientific Boritex Urine Stabilization System (cups) b. Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System 2. Review of patient test logs for 2021 revealed the laboratory accepted 2 specimen types for testing: a. Urine (clean catch and catheterized) b. Rectal swabs 3. Review of laboratory's "Determination of Urinary Track Infection Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR)" procedure (signed into effect 03/12/2021), section 3.3 "Storage Conditions" revealed: "If the specimen will be processed (nuclear extraction) for analysis within 5 days after collection, keep it at room temperature (20-25C) or refrigerate at 4-8C. Samples must be tested within 5 days after collection." 4. Review of manufacturer package inserts for specimen transport systems revealed: a. For Andwin Scientific Boritex Urine Stabilization System: "Boritex stabilizes the specimens up to 72 hours for delayed microbiological culture and analysis and prevents the over growth of incidental organisms." b. For Copan ESwab: "To maintain optimum organism viability, transport specimen collected using ESwabs directly to the laboratory, preferably within 2 hours of collection... If immediate delivery or processing is delayed, then specimens should be refrigerated at 4-8C or stored at room temperature (20-25C) and processed within 48 hours except for Neisseria gonorrhoeae cultures, which should be processed within 24 hours." 5. Review of the laboratory's establishment studies for its laboratory developed UTI Pathogens by Real-Time RT-QPCR test revealed: a. Verification studies did not encompass the 5 day span of specimen stability described in the test procedure (exceeding manufacturer recommendations) for either of the collection/transport media (2 of 2). b. Verification studies did not address rectal swab (1 of 2

specimen types). 6. In an interview on 5/17/2022 at 1500 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**D5455**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(v)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records for 2021, review of the laboratory's policies and procedures, review of laboratory's patient logs and staff interview it was determined the laboratory failed to document QC at least once each day of specimen testing for its laboratory developed Urinary Tract Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) procedure, 1 of 2 tests performed by the laboratory. Findings included: 1. Review of the laboratory's QC records for 2021 for its laboratory developed UTI Pathogens by Real-Time RT-QPCR molecular test revealed the laboratory was documenting QC performance once each week of specimen testing, as per its individualized quality control plan (IQCP). 2. Review of the laboratory's established IQCP for UTI Pathogens by Real-Time RT-QPCR revealed the IQCP was not approved (signed and dated) by the laboratory director prior to implementation. 3. Review of the laboratory's patient logs revealed the laboratory performed UTI Pathogens by Real-Time RT-QPCR testing on 843 samples in 2021 (refer to master list). 4. In an interview on 5/17/2022 at 1120 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**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 review of the laboratory's temperature charts for February and March of 2022, review of laboratory's policies and staff interview it was determined the laboratory failed to document corrective action for 19 of 59 reviewed days the

temperature was out of laboratory defined range. Findings included: 1. Review of the laboratory's temperature charts revealed the acceptability range for the laboratory's room temperature was defined as 20-25C. 2. Further review of the laboratory's temperature charts for February to March of 2022 revealed the documented room temperature was out of laboratory's defined acceptability range on the following 19 of 59 days reviewed: Date: Temperature: 02/04/2022 18.3C 02/07/2022 19.9C 02/08/2022 19.1C 02/09/2022 19.2C 02/10/2022 19.4C 02/11/2022 19.8C 02/14/2022 18.4C 02/18/2022 19.4C 02/21/2022 19.5C 02/24/2022 19.9C 02/25/2022 19.0C 02/28/2022 19.1C 03/01/2022 19.6C 03/07/2022 19.5C 03/10/2022 19.5C 03/11/2022 18.2C 03/14/2022 19.2C 03/24/2022 19.5C 03/25/2022 19.9C 3. The laboratory was asked to provide documentation of corrective action for the out of range temperatures and no such documentation was available for review prior to survey exit. 4. In an interview on 5/17/2022 at 1750 hours in the conference room the laboratory's General Supervisor (as described on submitted Form 209, signed by laboratory director on 05/17/2022) confirmed the findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's quality control (QC) records, review of the laboratory's quality assessment (QA) reports and staff interview it was determined the laboratory's QA failed to identify and correct issues with laboratory's personnel not following facility's policies and procedures (refer to D5401 A, B and C), storage temperature monitoring (refer to D5413), verification of test system performance (refer to D5423), performance of quality control (refer to D5455) and out of range temperatures' corrective action documentation (refer to D5781).

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, review of manufacturer's instructions, review of instrument quality control and calibration documents, review of laboratory's test establishment studies, review of patient records and staff interview it was determined the laboratory director failed to provide the laboratory with overall management and direction. Findings included: 1. The laboratory director failed to ensure laboratory's compliance with applicable regulations. Refer to D6079. 2. The laboratory director failed to ensure test establishment studies were complete. Refer to D6086. 3. The laboratory director failed ensure the establishment of quality control for the in-house developed Urinary Tract Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR)

procedure was completed. Refer to D6093. 4. The laboratory director failed to ensure quality assessment identified failures in quality as they occurred. Refer to D6094. 5. The laboratory director failed to ensure the Procedure Manual was approved upon assumption of duties. Refer to D6106.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of manufacturer's instructions, review of instrument quality control and calibration documents, review of laboratory's test establishment studies, review of patient records and staff interview it was determined the laboratory director failed to ensure laboratory's compliance with applicable regulations. Refer to D5400.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's test establishment studies for its in-house developed Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) test, review of manufacturer package inserts for collection/transport systems, review of patient records and staff interview it was determined the laboratory director failed to ensure test establishment studies were complete. Refer to D5423.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 review of the laboratory's quality control records, review of its

	<p>Individualized Quality Control Plan and staff interview it was determined the laboratory director failed to complete the establishment of quality control for the in-house developed Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) procedure. Refer to D5455.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment records for 2021 and staff interview it was determined the laboratory director failed to ensure quality assessment identified failures in quality as they occurred. Refer to D5791.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and staff interview it was determined the laboratory director failed to approve the Procedure Manual upon assumption of duties. Refer to D5407.</p>
<b>D6115</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test establishment studies for its in-house developed Urinary Track Infection (UTI) Pathogens by Real-Time Reverse Transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) test, review of manufacturer package inserts for collection/transport systems, review of patient records and staff interview it was determined the laboratory's technical supervisor failed to ensure test establishment studies were complete. Refer to D5423.</p>
<b>D6118</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(5)</p> <p>The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's temperature charts for February and March of 2022, review of laboratory's policies and staff interview it was determined the laboratory's technical supervisor failed to ensure remedial actions are documented as required. Refer to D5781.