

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0659062	<b>(X3) Date Survey Completed</b>  09/18/2025
<b>Name of Provider or Supplier</b>  Tennessee Department Of Health	<b>Street Address, City, State</b>  630 Hart Lane, Nashville, TN	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on direct observation, review of laboratory freezer temperature records, laboratory's policies and procedures, test volumes, and interview with the Technical Supervisor (TS)-16, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to follow its own policy for the storage of Syphilis Serology specimens after testing for 2 of 2 freezers. Findings Included: 1) During a tour of the laboratory on 9/16/2025 at 11:08 AM, the following two freezers were observed with the storage of Syphilis Serology specimens inside: a. Freezer - Thermo Scientific #1 (Thermo Serial Number: M77487, Serial Number: 11464320501240322) b. Freezer - Thermo Scientific #2 (Thermo Serial Number: S29944, Serial Number: 1146922201240919) 2) Review of the laboratory's freezer temperature record charts from July through September 2025 revealed the following acceptable temperature ranges set for the two freezers: a. Freezer - Thermo Scientific #1 (-85 degrees Celsius to -65 degrees Celsius) b. Freezer - Thermo Scientific #2 (-85 degrees Celsius to -65 degrees Celsius) 3) Review of the laboratory's policy titled 'TN Department of Health Division of Laboratory Services Procedure for Fujirebio Serodia-TPPA' stated the following: "B. Specimen Handling, Transport &amp; Storage: 3. Following testing, all non-reactive specimens are stored at 1 to 8 degrees Celsius for seven (7) days. Specimens with initially detected reactive results are aliquoted and stored at less than or equal to -70 degrees Celsius." 4. Review of the laboratory's test volumes revealed an annual test volume of 2,081 for the Serodia TP-PA. 5. In an interview on 9/16/2025 at 11:10 AM in the Serology section of the laboratory, TS-16</p>

confirmed the accepted temperature ranges set for the freezers did not follow the laboratory's policy for storing syphilis serology serum samples. II. Based on direct observation, review of laboratory freezer temperature records, laboratory's policies and procedures, test volumes, and interview with the Technical Supervisor (TS)-16, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to follow its own policy for freezer storage temperatures of norovirus extracts for 9 of 55 days (random review from July 1 to September 17, 2025). Findings Included: 1. During a tour of the laboratory on 9/17/2025 at 1:49 PM, one ThermoScientific TSX freezer (Serial Number: 1146521701240521) was observed, with an acceptable temperature range set to -90 degrees Celsius to -70 degrees Celsius, and seven boxes of Norovirus extracts stored within. 2. Review of the laboratory's freezer temperature records revealed the following dates where temperature were recorded warmer than -80 degrees Celsius: 7/22, 7/23, 7/25, 7/29, 8/7, 8/19, 8/27, 9/10, 9/12 3. Review of the laboratory's policy titled 'TN Department of Health Norovirus' stated the following under 'specimen criteria': "Samples tested for norovirus GI and GII will have an extract stored at -80 degrees Celsius, a stool aliquot spun and stored at -80 degrees Celsius and an original stool sample stored for 6 months at 4 degrees Celsius ..." 4. Review of the laboratory's test volume revealed an annual test volume of 246 Norovirus PCR tests performed 5. In an interview on 9/16/2025 at 11:10 AM in the Virology section of the laboratory, TS-16 confirmed the accepted temperature ranges set for the freezers did not follow the laboratory's policy for storing Norovirus extracts and stool aliquots. 47272 III. Based on written laboratory procedure, observation, and staff interview, the laboratory failed to follow its own procedure for specimen storage for one of one box of dried blood spot filter cards. Findings included: 1. On 09/17/25 at 09:45 am, Technical Supervisor #15 (TS#15) verified the laboratory performed newborn screening to measure amnio acids, succinylacetone, free carnitine, acylcarnitines, nucleosides, and lysophospholipids testing from dried blood spots using the Revvity NeoBase 2 kit. 2. Review of the laboratory's procedure titled, "NBS NeoBase 2 Procedure Manual" section, "III. SPECIMEN REQUIREMENTS" stated, "A 1/8-inch disc is punched from a dried blood spot (DBS) collected properly on Whatman paper grade #903 or equivalent. DBS filter cards are stored in large plastic boxes containing desiccants in the specimen refrigerator at 2-8C." 3. Observation on 09/17/25 at 10:10 am of one plastic storage box for DBS specimens revealed no evidence of a desiccant. a. Examples of patient DBS filter cards Patient# - 20252481101 Patient# - 20252481102 Patient# - 20252481103 Patient# - 20252481104 Patient# - 20252481105 4. Interview on 09/17/25 at 10:15 am with TS #15, confirmed the findings above 5. Laboratory performs 121,396 tests annually using the NeoBase 2 kit. Word Key NBS - Newborn Screening IV. Based on written laboratory procedure, record review and staff interview, the laboratory failed to follow its own procedure for calibration verification for one of one year. Findings included: 1. On 09/17/25 at 02:10 pm, Technical Supervisor #15 (TS #15) verified the laboratory performed X-Linked Adrenoleukodystrophy (X-ALD) Screening by LC/MS/MS (Liquid Chromatography-Tandem Mass Spectrometry). 2. Review of the written laboratory procedure titled, "X-Linked Adrenoleukodystrophy Screening by LC/MS/MS" section, "D. Calibration Verification:" stated the following: a. "Frequency: After lot change, after major maintenance, or twice a year." b. "Purposed: To verify the reportable range." c. "To meet requirements, run CBC controls for X-ALDs like patient specimens on each system and compare values to CDC stated values. Values must be within 2 s.d." 3. Review of 2024 records revealed no evidence the laboratory performed calibration verification. 4. Interview on 09/17/25 at 02:40 pm with TS #15, confirmed the findings above. 5. Laboratory performs 11,653 screening tests annually. Word Key s. d. - standard deviation V. Based on laboratory written procedure, record review, and

laboratory staff interview, the laboratory failed to follow its own laboratory procedure for Blind Study/Tech Checks for six of six months for five of five testing persons. Findings included: 1. On 09/17/25 at 03:20 pm, Technical Supervisor #15 (TS #15) verified the laboratory performed G6PD (Glucose-6-phosphate dehydrogenase) testing from dried blood spots specimens. 2. A review of the laboratory's written procedure titled, "Glucose-6-phosphate Dehydrogenase (G6PD) Procedure Manual" section, "F. Blind Study/Tech Checks" stated, "A blind study is performed monthly to assess the method, reagents, and to verify the technique and proficiency of each tech." 3. Record review of "Tech Check" from March 2025 through August 2025 revealed no evidence of monthly Blind Study/Tech Checks for six of six months for the five of five Testing Persons (TP): a. TP# 6 b. TP# 38 c. TP# 58 d. TP# 63 e. TP# 70 4. Interview on 09/17/25 at 03:40 pm with TS #15, confirmed the findings above. 5. The laboratory performs 3,787 G6PD tests annually.

**D5407**

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

(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 general supervisor interview and bacteriology media quality control record review on September 18, 2025 at 09:15 am, the laboratory failed to have a written STEC CHROMagar media quality control procedure that had been approved, signed, and dated by the laboratory director before use. Findings included: a. In the bacteriology section, the laboratory performed patient bacteriology testing using STEC CHROMagar media. To ensure the quality of each lot of STEC CHROMagar media used, the laboratory performed media quality control procedures pursuant to 42 CFR 493.1256(e)(4). b. The laboratory maintained no documentation to indicate that the written STEC CHROMagar media quality control procedure had been approved, signed, and dated by the laboratory director before use. c. On September 18, 2025 at 09:15 am, the general supervisor confirmed these findings and indicated that the laboratory used STEC CHROMagar media to culture approximately 300 patient bacteriology specimens annually.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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:  
I. Based on direct observation, manufacturer's instructions, laboratory temperature records, test volumes, and interview with the Technical Supervisor (TS)-16, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory

failed to define freezer temperature ranges consistent with the manufacturer's instructions for 4 of 4 boxes of Centers for Disease Control and Prevention (CDC) reagents. Findings Included: 1. During a tour of the laboratory on 9/17/2025 at 1:49 PM, one Kenmore Upright freezer (Serial Number: WBB5025067) was observed in the Virology section Area E (Mid) - 3rd Floor, with an acceptable temperature range set to -25 degrees Celsius to -18 degrees Celsius, and the following stored within: a. Two boxes of CDC Influenza A/B Sars-Cov-2 Multiplex Positive Controls, Panel Lot: 230914, Manufacturer storage instructions -20 degrees Celsius and/or colder. b. Two boxes of CDC Human Influenza Virus RT-PCR Diagnostic Panels Influenza A Subtyping, Panel Lot: 220808, Manufacturer storage instructions -20 degrees Celsius and/or colder. 2. Review of the laboratory's freezer temperature records from July 1 to September 17, 2025, indicated an acceptable temperature range between -25 degrees Celsius and -18 degrees Celsius. 3. Review of the laboratory's test volume revealed an annual test volume of 1,679 Influenza CDC Multiplex tests performed. 4. In an interview on 9/17/2025 at 1:50 PM in the Virology section of the laboratory, TS-16 confirmed the temperature ranges of the freezer were not defined in accordance with the manufacturer's storage instructions. 47272 II. Based on manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to monitor room temperatures as required by the manufacturer for two of two months. Findings included: 1. On 09/16/25 at 10:35 am, Technical Supervisor #15 (TS #15) verified the laboratory performed Newborn Screening (Neonatal immunoreactive trypsinogen, Neonatal Biotinidase, Neonatal Galactose-1-phosphate uridylyltransferase enzyme, Neonatal Galactose, Neonatal 17a-OH-Progesterone, and Neonatal Human Thyroid Stimulating Hormone) testing on the Revvity GSPs (Genetic Screening Processors). 2. Review of the Revvity GSP manufacturer's specifications section, "Environmental conditions" stated, "Temperature 18-27C". 3. Review of the laboratory's environmental records for July 2025 and August 2025 revealed no evidence of room temperature monitoring for two of two months. 4. Interview on 09/16/25 at 10:55 am with TS #15, confirmed the findings above. 5. The laboratory performs the following tests annually: Neonatal immunoreactive trypsinogen - 121,396 Neonatal Biotinidase - 121,396 Neonatal Galactose-1-phosphate uridylyltransferase enzyme - 121,396 Neonatal Galactose - 121,396 Neonatal 17a-OH-Progesterone - 121,396 Neonatal Human Thyroid Stimulating Hormone - 121,396 III. Based on direct observation, manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to monitor room temperatures as required by the manufacturer for two of two months Findings included: 1. On 09/17/25 at 11:20 am, Technical Supervisor #15 (TS #15) verified the laboratory performed a qualitative screen for the presence of hemoglobins F, A, S, D, C, and E in eluates of neonatal dried blood spots. 2. A review of the "Bio-Rad Variant nbs Sickle Cell Program" manufacturer's instructions for "PREPARATION AND STORAGE OF REAGENTS" revealed the following for the "Elution Buffers and Wash Solution": a. "The Elution Buffers and Wash Solution will be stable until the expiration date when stored unopened at 15-30C. After opening the bottles, these reagents are stable for 30 days when stored at 15-30C.". 3. Direct observation on 09/17/25 at 11:25 am revealed the following: a. Elution Buffer 1 Lot#64649186 b. Elution Buffer 2 Lot#64649188 c. Wash Solution Lot#64631972 4. Review of the laboratory's environmental records for July 2025 and August 2025 revealed no evidence of room temperature monitoring for two of two months. 5. Interview on 09/17/25 at 11:30 am with TS #15, confirmed the findings above. 6. The laboratory performs 121,396 Variant nbs Sickle Cell tests annually. Word Key nbs - newborn screening IV. Based on manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to monitor room temperatures as required by the manufacturer for two of two months. Findings included: 1. On 09/17/25 at 03:00 pm, Technical

Supervisor #15 (TS #15) verified the laboratory used PerkinElmer Panthera-Punchers dried blood spot punching devices for newborn screening testing four (serial numbers 2081017, 20810181, 20810179, and 20810331). 2. Review of the PerkinElmer Panthera-Puncher manufacturer's "Environmental conditions" stated, "Operating temperature: 15-30C". 3. Review of the laboratory's environmental records for July 2025 and August 2025 revealed no evidence of room temperature monitoring for two of two months. 4. Interview on 09/17/25 at 03:25 pm with TS #15, confirmed the findings above. 5. The laboratory performs 1,218,857 newborn screening tests annually. V. Based on manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to ensure the laboratory's humidity was maintained according to the manufacturer's requirements for 10 of 30 days

Findings included: 1. On 09/17/25 at 03:00 pm, Technical Supervisor #15 (TS #15) verified the laboratory used PerkinElmer Panthera-Punchers dried blood spot punching devices for newborn screening testing four (serial numbers 2081017, 20810181, 20810179, and 20810331). 2. Review of the PerkinElmer Panthera-Puncher manufacturer's "Environmental conditions" stated, "Relative humidity: 20-80% ". 3. Review of the laboratory's environmental records for March 2025 revealed documented humidity readings below the manufacturer's requirements for 10 of 30 days. a. Serial number 20810178 03/01/25 documented humidity reading 16% 03/02/25 documented humidity reading 12.7% 03/03/25 documented humidity reading 10% 03/06/25 documented humidity reading 16% 03/07/25 documented humidity reading 19% 03/09/25 documented humidity reading 15% 03/10/25 documented humidity reading 15% 03/17/25 documented humidity reading 18% 03/21/25 documented humidity reading 16% 03/22/25 documented humidity reading 18% b. Serial number 20810181 03/02/25 documented humidity reading 15% 03/06/25 documented humidity reading 16% 03/07/25 documented humidity reading 17% 03/09/25 documented humidity reading 15% 03/21/25 documented humidity reading 17% c. Serial number 20810179 03/01/25 documented humidity reading 17% 03/03/25 documented humidity reading 11% 03/05/25 documented humidity reading 16% 03/06/25 documented humidity reading 14% 03/10/25 documented humidity reading 15% d. Serial number 20810331 03/02/25 documented humidity reading 15% 03/03/25 documented humidity reading 15% 03/09/25 documented humidity reading 18% 03/10/25 documented humidity reading 18% 4. Interview on 09/17/25 at 03:30 pm with TS #15, confirmed the findings above. 5. The laboratory performs 1,218,857 newborn screening tests annually. VI. Based on direct observation, manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to ensure freezer temperatures met the manufacturer's requirement for seven of 31 days.

Findings included: 1. On 09/16/25 at 01:00 pm, Technical Supervisor #15 (TS #15) verified the laboratory performed GALT (Neonatal Galactose-1-phosphate uridyltransferase enzyme) and Neonatal Galactose testing on the Revvity GSPs (Genetic Screening Processors). 2. Direct observation on 09/16/25 at 01:10 pm of Kenmore Freezer #5 (serial number BA44414570) revealed the following: a. Revvity GSP Neonatal total Galatose kit (Lot#760764) with a manufacturer's storage requirement of -16C to -30C. b. Revvity GSP Neonatal GALT kit (Lot#760893) with a manufacturer's storage requirement of -16C to -30C. 3. A review of the Kenmore Freezer #5 July 2025 records revealed freezer temperatures warmer than manufacturer requirements for seven of 31 days as follows: a. 07/10/25 documented freezer temperature -15.5C b. 07/13/25 documented freezer temperature - 15.5C c. 07/18/25 documented freezer temperature - 15.0C d. 07/19/25 documented freezer temperature - 14.8C e. 07/24/25 documented freezer temperature - 15.7C f. 07/27/25 documented freezer temperature - 15.9C g. 07/29/25 documented freezer temperature - 15.8C 4. Interview on 09/16/25 at 01:15 pm with TS #15, confirmed the findings above. 5. The laboratory performs the following tests annually: Neonatal Galactose-1-phosphate

uridyltransferase enzyme - 121,396 Neonatal Galactose - 121,396 VII. Based on direct observation, manufacturer's instructions, environmental records, and laboratory staff interview, the laboratory failed to ensure freezer temperatures met the manufacturer's requirement for 4 of 31 days. Findings included: 1. On 09/16/25 at 01:20 pm, Technical Supervisor #15 (TS #15) verified the laboratory performed Biotinidase testing on the Revvity GSPs (Genetic Screening Processors). 2. Direct observation on 09/16/25 at 01:30 pm of Hotpoint Freezer #18 (serial number CTX18CAZARWW) revealed the Revvity GSP Neonatal Biotinidase kit (Lot#760895) with a manufacturer's storage requirement of -16C to -30C. 3. A review of the Hotpoint Freezer #18 July 2025 records revealed freezer temperatures warmer than manufacturer requirements for four of 31 days as follows: a. 07/08/25 documented freezer temperature -15.4C b. 07/11/25 documented freezer temperature - 15.7C c. 07/18/25 documented freezer temperature - 15.3C d. 07/27/25 documented freezer temperature - 13.6C 4. Interview on 09/16/25 at 03:30 pm with TS #15, confirmed the findings above. 5. The laboratory performs 121,396 Neonatal Biotinidase tests annually. VIII. Based on laboratory written procedure, direct observation, environmental records, and laboratory staff interview, the laboratory failed to ensure freezer temperatures met laboratory requirements for 16 of 16 days. Findings included: 1. On 09/17/25 at 03:20 pm, Technical Supervisor #15 (TS #15) verified the laboratory performed G6PD (Glucose-6-phosphate dehydrogenase) testing from dried blood spots specimens. 2. A review of the laboratory's written procedure titled, "Glucose-6-phosphate Dehydrogenase (G6PD) Procedure Manual" section, "VII. Quality Control" stated, " .... 8. Label a foil pouch with the level of control, the lot number, reconstitution date and expiration date. Expiration date is 6 months from the reconstitution date. Freeze at -20C in the foil pouch with desiccant and a humidity indicator card ....". 3. Direct observation on 09/17/25 at 03:25 pm of Hotpoint Freezer #18 (serial number CTX18CAZARWW) revealed the following G6D control material: a. Normal - Lot#01-96-25 b. Intermediate - Lot# 01-97-25 c. Deficient - Lot# 01-95-25 4. A review of the Hotpoint Freezer #18 (serial number CTX18CAZARWW) records from 09/02/25 through 09/17/25 revealed freezer temperatures warmer than the laboratory's written procedure for 16 of 16 days as follows: a. 07/02/25 documented freezer temperature -15.2C b. 07/03/25 documented freezer temperature -16.3C c. 07/04/25 documented freezer temperature -16.2C d. 07/05/25 documented freezer temperature -15.0C e. 07/06/25 documented freezer temperature -17.6C f. 07/07/25 documented freezer temperature -18.0C g. 07/08/25 documented freezer temperature -18.0C h. 07/09/25 documented freezer temperature -14.6C i. 07/10/25 documented freezer temperature -17.1C j. 07/11/25 documented freezer temperature -18.0C k. 07/12/25 documented freezer temperature -15.2C l. 07/13/25 documented freezer temperature -17.6C m. 07/14/25 documented freezer temperature -15.4C n. 07/15/25 documented freezer temperature -17.4C o. 07/16/25 documented freezer temperature -16.6C p. 07/17/25 documented freezer temperature -13.2C 4. Interview on 09/17/25 at 03:35 pm with TS #15, confirmed the findings above. 5. The laboratory performs 3,787 G6PD tests annually.

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 quality control package insert, electronic quality control records, and laboratory staff interview, the laboratory failed to ensure control procedures that would detect immediate errors and test system failures for one of three levels of quality control for 18 of 18 days. Findings included: 1. On 09/16/25 at 10:35 am, Technical Supervisor #15 (TS #15) verified the laboratory performed Neonatal immunoreactive trypsinogen (IRT) testing on three Revvity GSPs (Genetic Screening Processors) as follows: a. Instrument "Sonny" - serial number 2020157 b. Instrument "Cher" - serial number 20210158 c. Instrument "Prince" - serial number 20210180 2. On 09/17/25 at 09:20 am, General Supervisor #10 (GS #10) confirmed the following: a. Three levels of QC (quality control) material (Kit Control 1, Kit Control 2, and Kit Control 3) were performed each day of IRT patient testing. b. New lots of QC materials included 30 runs of QC to calculate the mean, 1 SD (standard deviation), 2 SD, 3 SD, and CV% (Coefficient of Variation Percent) to ensure the calculated QC ranges fell within the manufacturer's stated ranges. c. The laboratory used Kit Control 1, Kit Control 2, and Kit Control 3 manufacturer's QC ranges for limits of acceptability for patient testing. 3. Review of the laboratory's electronic QC records from 06/12/25 to 06/30/25 revealed the following: a. Lot# 760138 was put into use 06/12/25. b. No evidence of QC ranges for one of three levels of QC (Kit Control 3) for 18 of 18 days. 4. On 09/17/25 at 10:15 am, TS #15 confirmed the findings above. 5. The laboratory performs 121,396 IRT tests annually.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on general supervisor and testing personnel interviews and mycobacteriology quantiferon test record review on September 17, 2025 at 11:10 am, the laboratory failed to establish the statistical parameters for unassayed positive and negative quantiferon quality control materials over time through concurrent testing of quantiferon quality control materials having previously determined statistical parameters. Findings included: a. In the mycobacteriology section, it was the practice of the laboratory to perform and report patient quantiferon tests using Qiagen's QuantiFERON -TB Gold Plus test kits. To monitor patient quantiferon testing each day of testing, the laboratory pooled previously tested positive patient quantiferon specimens to use as the positive quantiferon quality control material, and pooled previously tested negative patient quantiferon specimens to use as the negative

quantiferon quality control material. b. On September 17, 2025 at 11:10 am, the general supervisor confirmed that the laboratory maintained no documentation to indicate that the statistical parameters for the pooled positive and negative quantiferon quality control materials, for which both quality control materials are considered unassayed quality control materials, had been established over time by the laboratory through concurrent testing of quantiferon quality control materials having previously determined statistical parameters. c. On September 17, 2025, the laboratory was using Qiagen's QuantiFERON-TB Gold Plus test kit lot number 57809306, expiration date 06/06/2027, to test patient quantiferon specimens. The general supervisor stated that the laboratory performed and reported approximately 100 patient quantiferon tests each week.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:  
Based on general supervisor interview and parasitology trichrome straining quality control record reivew on September 17, 2025 at 10:20 am, the laboratory failed to maintain documentation to indicate that, each day of use, trichrome stains were reviewed for intended reactivity to ensure predictable staining characteristic. Findings included: a. In the parasitology section of the laboratory, it was the practice of the laboratory to stain patient parasitology specimens using a trichrome stain. b. As confirmed by the general supervisor on September 17, 2025 at 10:20 am, although the laboratory maintained documentation to indicate that quality control materials were routinely tested, the laboratory maintained no documentation to indicate that the trichrome stains were reviewed for intended reactivity to ensure predictable staining characteristics. c. According to laboratory records, the laboratory performed and reported 83 patient parasitology specimen test results annually.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
1. Based on general supervisor and testing personnel interviews and mycobacteriology quantiferon test record review on September 17, 2025 at 11:10 am, the laboratory failed to document all quantiferon quality control procedures. Findings included: a. In the mycobacteriology section, it was the practice of the laboratory to perform and report patient quantiferon tests using Qiagen's QuantiFERON -TB Gold Plus test kits. To monitor patient quantiferon testing each day of testing, the laboratory pooled previously tested positive patient quantiferon specimens to use as the positive quantiferon quality control material, and pooled previously tested negative patient quantiferon specimens to use as the negative quantiferon quality control material. b. On September 17, 2025 at 11:10 am, the general supervisor confirmed that the

laboratory maintained no documentation to indicate which patient specimens were used for any pooled positive and negative quantiferon quality control materials used to monitor patient quantiferon testing. c. On September 17, 2025, the laboratory was using Qiagen's QuantiFERON-TB Gold Plus test kit lot number 57809306, expiration date 06/06/2027, to test patient quantiferon specimens. The general supervisor stated that the laboratory performed and reported approximately 100 patient quantiferon tests each week. 2. Based on general supervisor interview and bacteriology media quality control record review on September 17, 2025 at 01:30 pm, the laboratory failed to ensure that it had a record system that documented the results of all media quality control procedures performed had met the laboratory's criteria for acceptability before reporting patient bacteriology culture test results. Findings included: a. In the bacteriology section, for patient testing, it was the practice of the laboratory to use blood agar plates (BAP) for the growth of bacteria from patient specimens. Pursuant to 42 CFR 493.1256(e)(4), laboratory records indicated that each lot of BAP culture media the laboratory received had met the laboratory's criteria for acceptability. b. On September 17, 2025 at 01:30 pm, the general supervisor confirmed that, although each lot of BAP culture media had met the laboratory's quality control criteria for acceptability, the laboratory records did not indicate which lot of BAP culture media was used to culture bacteria from a patient specimen. c. For example, BAP lot numbers 289732 and 294940 were available for patient testing as of August 25, 2025. During the period of time these BAP lots were available for use, laboratory records did not indicate which specific BAP lot was used to culture bacteria from any specific patient specimen. d. According to the general supervisor, the laboratory received, cultured, and reported approximately 70 patient bacteriology specimens weekly using BAPs.

**D5783**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
Based on direct observation, review of the laboratory's quality control records, laboratory policies and procedures, test volume records, and confirmed in an interview with the Technical Supervisor (TS)-16, according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to take corrective action necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run after repeat Quality Control (QC) failures requiring recalibration on the Abbott Architect i2000, for 400 of 400 Human Immunodeficiency Virus (HIV) Antigen (Ag)/Antibody (Ab) tests run on July 17, 2024 and July 23, 2024. Findings Included: 1. In direct observation at 10:48 AM in the Serology department of the laboratory, two Abbott Architect i2000 instruments (iSR62994 #159898, iSR64032 #172661) were observed in use for HIV, Hepatitis C, and Hepatitis B CMIA testing. 2. Review of the laboratory's quality control records and Abbott Instrument Call Log revealed the following dates of QC failures requiring recalibration where evaluation of patient test results since the last acceptable test run was not performed: a. Date 7/18/2024, i2000 System serial number: 76101 10:36 AM

- Flag CNTL, 1-3s, HIV Ag/Ab\_Negative, Result 1.15 S/CO 08:53 AM - Flag CNTL, 1-3s, HIV Ag/Ab Negative, Result 4.69 S/CO 08:53 AM - Flag CNTL, 1-3s, HIV Ag/Ab Negative, Result 1.22 S/CO  
 Recalibration Results: Cal ID - Cal 1, Calibrator lot: 59496BE00 Mean RLU - 5289.0 Rep. 1 RLU - 5322 Rep. 2 RLU - 5202 Rep. 3 RLU - 5343 b. Date 7/24/2024, i2000 iSR62994 (#159896) Abbott Instrument Call Log  
 Description of Event: Multiple QC failures. Neg control is coming out positive for HIV. Occurred 2x on 7-18 and one time both 7-22 and 7-23. Recalibrated R1 & R2 Pipettors and Recalibrated Kits. Case No: 2052265 Recalibration Results: Cal ID - Cal 1, Calibrator lot: 59496BE00 Mean RLU - 5288.0 Rep. 1 RLU - 5387 Rep. 2 RLU - 5187 Rep. 3 RLU - 5290. 3. Review of test records revealed the following specimens in the last acceptable run reported, with no evaluation after QC failure(s) requiring recalibration: a. 7/17/2024 - 197 total HIV Ag/Ab tests run SIDS: N24H219357-01 (10:18 AM), N24H219358-01 (10:18 AM), N24H219359-01 (10:18 AM), N24H219360-01 (10:19 AM), N24H219361-01 (10:19 AM), N24H219362-01 (10:19 AM), N24H219363-01 (10:20 AM) [Sampling] ... b. 7/23/2024 - 203 total HIV Ag/Ab tests run SIDS: N24H226030-01 (11:02 AM), N24H226031-01 (11:02 AM), N24H226032-01 (11:02 AM), N24H226033-01 (11:03 AM), N24H226034-01 (11:03 AM), N24H226035-01 (11:03 AM), N24H226036-01 (11:04 AM) [Sampling] ... 4. Review of the laboratory's policies and procedures for the Serology section revealed no instruction on performing an evaluation to the last acceptable test run after QC failures requiring recalibrations. 5. Review of the laboratory's test volume revealed an annual test volume of 49,565 HIV Ag/Ab CMIA tests performed. 6. In an interview on 9/17/2025 at 10:55 AM in the Serology section of the laboratory, TS-16 confirmed that when recalibrations were performed after QC failures, patient evaluations to the last acceptable test run were not performed.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
 Based on general supervisor and testing personnel interviews and postanalytic systems quality assessment record reivev on September 17, 2025 at 09:45 am, the laboratory failed to establish written procedures for an ongoing mechnism to monitor, assess and when indicated correct problems identified in the postanalytic systems specified in 493.1291 pertaining to the review of pending workload and the reporting of patient test results. Findings included: a. In the serology section of the laboratory, it was the practice of the laboratory to review pending test workload records at the start and end of each work day to ensure all patient tests ordered were completed and patient test results were report within acceptable timeframes. b. As confirmed by the general supervisor on September 17, 2025 at 09:45 am, the laboratory maintained no written procedures detailing this quality assessment activity. c. According to laboratory records, the laboratory performs and reports 1,496,679 patient test results annually.