

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0505487	<b>(X3) Date Survey Completed</b>  01/09/2020
<b>Name of Provider or Supplier</b>  Adc, Pllc, North Laboratory, The	<b>Street Address, City, State</b>  12221 North Mopac 4th Floor South, Austin, 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 to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with 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 the 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CLIA-FDA database, laboratory records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for Bleeding Time in 2018 and 2019. The findings were: 1. Review of the CLIA-FDA database revealed the Bleeding Time test is classified as moderate complexity. Therefore, the laboratory must perform perform twice annual accuracy. 2. Review of a Bleeding Time Test Count Report provided by the facility on January 7, 2020 revealed that the facility performed three patient Bleeding Time tests in 2018 and two patient Bleeding Time tests in 2019. Specimen ID: 8281092 Approval Date: 01-23-2018 Result: 3.5 minutes Specimen ID: 8352173 Approval Date: 02-21-2018 Result: 5 minutes Specimen ID: 8374720 Approval Date: 03-05-</p>

2018 Result: 8.5 minutes Specimen ID: 9004488 Approval Date: 01-23-2019 Result: 10 minutes Specimen ID: 9484036 Approval Date: 11-22-2019 Result: 10 seconds 3. A review of the laboratory's records revealed the facility failed to have documentation of performing twice annual accuracy assessment for Bleeding Time in 2018 and 2019. 4. An interview with Technical Supervisor 2 (as listed on Form CMS-209) on January 7, 2019 at 13:35 hours in his office confirmed the findings. Key: CLIA - Clinical Laboratory Improvement Amendments FDA - Food and Drug Administration CMS - Centers for Medicare and Medicaid Services

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of quality control records, patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for preparation of urine quality control. The findings were: 1. Review of the manufacturer's instructions for SPIFE Split Beta SPE Procedure (Pro. 137, 4/13/(4) under "Quality Control" it stated, " ...If desired, a control or patient sample may be diluted 1:7 with 0.85% saline (1 part sample + 6 parts saline) and run with urines and CSFs for qualitative comparison. Refer to the package insert provided with the control for assay values." 2. Review of quality control records from November and December 2019 revealed that when performing UPE w/Reflex to Immunofixation Random, the laboratory included one quality control per run. However, the laboratory used the serum control. The laboratory did not follow the manufacturer's instructions for preparation of a like matrix quality control. 3. Random review of patient results from November and December 2019 found the following patients were tested for UPE w/Reflex to Immunofixation Random when the laboratory failed to follow the manufacturer's instructions for preparation of a like matrix quality control material: Sample ID: 9480800 Approval Date: 11-19-2019 Sample ID: 9489997 Approval Date: 11-27-2019 4. The findings were confirmed in interview with Testing Personnel 16 (as listed on Form CMS-209) on January 9, 2020 at 13:45 hour in the laboratory. Key: SPE - serum protein electrophoresis UPE - urine protein electrophoresis CMS - Centers for Medicare and Medicaid Services

**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 observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in interview with facility personnel, the laboratory failed to define an acceptable room temperature according to manufacturer instructions from January 2018 through November 2019 for laboratory supplies stored in the laboratory storage room. The findings were: 1. Surveyor observation made in the laboratory on January 7, 2020 at 09:05 hours revealed the laboratory had a storage closet with a min/max hygrometer. Further, the laboratory had an environmental temperature log posted in the storage room used to document the room temperature of the storage closet. The temperature range on the logsheet revealed a range of 16 to 25 degrees Celsius. The following laboratory reagents were stored in the storage closet: IQ Lamina iChem Velocity Wash IRIS Diluent 2. Review of the manufacturer's instructions for IQ Lamina, iChem Velocity Wash, and IRIS Diluent located on the package labeling revealed the acceptable storage temperature for the reagents was 20 to 25 degrees Celsius. 3. The laboratory failed to establish an acceptable room temperature for the storage room where laboratory supplies are stored. 4. On interview with general supervisor #6 (as listed on CMS-209) on January 09, 2020 09:00 hours, outside the laboratory director's office, it was confirmed that the reagents were not stored at the proper temperature. He stated "It gets cold back here. We will need to turn the temperature up." Key C - Celsius CMS - Centers for Medicare and Medicaid Services

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, manufacturer's instructions and information, media quality control records and confirmed in interview of facility staff, the laboratory failed to before or concurrent with the initial use, check each batch of media for sterility, ability to support growth and, as appropriate select or inhibit specific organisms or produce a biochemical response for Nutrient Agar. The findings were: 1. Review of the laboratory's policy titled, "Processing of Media" approved by the laboratory director January 7, 2016 stated, "Procedure: Upon receipt of the media staff should examine the media packages and unopened sleeves with plates for obvious damage ..." The laboratory's policy failed to include instructions on how to monitor media for sterility, ability to support growth, and as appropriate select or inhibit specific organisms or produce a biochemical response before or concurrent with initial use. 2. Review of the manufacturer's instructions for BD's BBL Nutrient Agar (L007481, Rev. 10, September 2014) stated, "User Quality Control: Quality Control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices." 3. Review of BD customer letter dated August 2015 revealed Nutrient Agar was not listed on the

CLSI-exempt media list. 4. Random review of media quality control records from January 2019 to December 2019 revealed the following batches of media that was only checked for appearance and quality: Nutrient Agar Slants Lot Number Rec/Open Date Exp. Date 9045896 03-28-2019 2020-08-08 9161746 08-21-2019 2020-12-05 9157823 10-01-2019 2020-11-28 9295719 12-20-2019 2021-04-17 5. Interview with Technical Supervisor 3 (as listed on Form CMS-209) on January 7, 2020 at 10:00 hours in her office confirmed the findings. Key: BD - Becton Dickinson CLIA - Clinical Laboratory Improvement Amendments CLSI - Clinical Laboratory Standards Institute CMS - Centers for Medicare and Medicaid Services

D5545

HEMATOLOGY  
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on a review of laboratory policies, review of manufacturer's instructions, the laboratory's lot roll-over studies, and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer's instructions for calculation of the mean normal reference interval on the ACL Elite-Pro coagulation analyzer. The findings were: 1. Review of the laboratory's policy titled, "Quality Control and Calibration of PT/APTT" approved by the laboratory director on August 16, 2016 under, "H. Normal Reference Interval" it stated, "The interpretation of clinical laboratory data is a comparative decision-making process. For this process to occur, reference intervals are needed for all test systems. Since all results will be compared to the reference interval it is crucial that it be done correctly." The laboratory's policy did not include criteria to exclude donor participation the lot roll over studies. 2. Review of laboratory records revealed that the current lot number of RecombiPlasTin in use is N1081486. The lot number expires 10-31-2020 and was opened on February 28, 2019. 3. Review of the IL (Instrumentation Laboratory) manufacturer's instructions, "Changing Reagent or Lot Number of Reagent" (November 2012) under, "Establishing/Verifying a Normal Reference Interval" it stated, "...Either 120 or 20 normal donors following these screening guidelines: -Donors should be healthy and have no known pathological conditions. Don't use patients (they are at the hospital for a medical reason). -Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-dose aspirin, etc. -Donors should span the adult age range. Pediatric ranges should be established separately. -Donors should be equally divided between male/female. - Ensure there are less than  $10 \times 10^9/L$  platelets in the plasma." 4. Random review of the laboratory's "Patient Consent" forms revealed the following patients were included in the study when they answered "yes" to screening criteria. Patient "1" Do you take Aspirin daily? Yes Take Antibiotics? Yes Take Vitamin K? Yes Patient "14" Are you on oral anticoagulant therapy (i.e. Coumadin, Warfarin, "blood thinners")? Yes Do you take Aspirin daily? Yes Patient "18" Do you take Aspirin daily? Yes Are you on Estrogen Therapy? Yes Patient "22" Are you on oral anticoagulant therapy (i.e. Coumadin, Warfarin, "blood thinners")? Yes Do you take Aspirin daily? Yes Are you on Estrogen Therapy? Yes Patient "88" Are you on Estrogen Therapy? Yes Patient "99" Are you on Estrogen Therapy? Yes Patient "115" Are you on oral anticoagulant therapy (i.e. Coumadin, Warfarin, "blood thinners")? Yes Do you take Aspirin daily?

Yes 5. The following is a random sampling of patient reports that were tested when the laboratory failed to follow the manufacturer's instructions for exclusion criteria: See Patient Alias Report 6. The findings were confirmed in interview of General Supervisor 6 (as listed on Form CMS-209) on January 9, 2020 at 11:30 hours in the laboratory. Key: HRT - hormone replacement therapy CMS - Centers for Medicare and Medicaid Services

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures, patient test records and interview of facility personnel the laboratory failed to document the reactions of the control slides each day of use for nine of nine special stains used by the laboratory. The findings included: 1. Review of policies and procedures found the laboratory used nine special stains. Expected results for each of the stains were: a. AFB Stain, Kinyoun Acid-fast bacteria: Bright red Background: Light Blue b. Alcian Blue (pH 2.5) Stain Kit Acidic Sulfated Mucosubstances: Blue Hyaluronic Acid: Blue Sialomucins: Blue Nuclei: Red Background: Pink c. Gram Stain procedure, Hucker-Twort Gram-positive bacteria: Dark Blue Gram-negative bacteria: Red Cytoplasm and red blood cells: Shades of Green Nuclei: Red d. Mallory's Iron Stain, Gomori Prussian Blue Ferric Iron deposits: Bright blue Nuclei: Red Cytoplasm: Pink e. Periodic Acid Schiff's (PAS) with and without Amylase Digestion Glycogen: Magenta Nuclei: Blue Cytoplasm: Pale Pink f. Periodic Acid Schiff's stain with Hematoxylin Counterstain (PASH) Polysaccharides: Magenta Neutral Mucosubstances : Magenta Basement Membranes: Magenta Glycogen: Magenta Mucin: Magenta Nuclei: Blue g. Periodic Acid Schiff's for Fungus (PASf) Fungus: Bright Pink Background: Green-blue h. Gomori's Ammoniacal Silver Stain (GMS) Fungus: Black Background: Green i. Diff-Quik Giemsa Stain for H. Pylori H. Pylori: Dark Blue Other Bacteria: Blue Nuclei: Dark Blue Cytoplasm: Pink 2. Review of four patient test results( with use of special stains) found no documentation of reactions for each of the special stains used in the reports: a. Specimen S181820 report date 08/09/2018: " A PAS stain for fungi is negative. A GMS stain for fungi and amoeba is negative. An AFB stain for acid fast bacilli is negative." b. Specimen S190018 dated 01/08/2019: " Special Stains: Representative sections of the biopsy that has been stained for the presence of fungal organisms (GMS and PAS) are examined in the presence of an adequately and appropriately stained positive control slide for each slide. Frequent fungal hyphal elements and scattered yeast forms identified in the area of mucosal ulceration." c. Specimen S192185 dated 08/23/2019: "PAS and GMS are negative for microorganisms." d. Specimen S191633 dated 07/23/2019: "Special Stain: A representative section of the biopsy fragments that has been stained for the presence of Helicobacter pylori organisms (Giemsa Stain), is examined in the presence of an adequately and appropriately stained positive control slide. No helicobacter pylori organisms are seen." 3. Interview of the Laboratory Director conducted on January 9, 2020 at 10:17 AM confirmed that the laboratory did not document the reactions of each of the

special stains for each day of use. He confirmed that it was the laboratory's policy for testing personnel to dictate the reaction for special stains in each report.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on surveyor observation, laboratory policy, review of instrumentation verification documents, and confirmed in interview of facility personnel, the laboratory failed to perform instrument correlation studies between its two Sysmex XN-2000 hematology analyzers at least twice annually in 2018 and 2019. The findings were: 1. Surveyor observation made on January 7, 2020 at 11:15 hours in the laboratory during the initial tour of the facility revealed the laboratory had two Sysmex XN-2000 hematology analyzers in use. Serial Number: 24354 Serial Number: 24366 2. Review of the laboratory's policy titled, "Quality Assurance Program" approved by the laboratory director on 11/07/2016 under, "Correlating instruments that are used to perform same type of testing," it stated, "This QAI is overseen by section supervisor and performed by designated staff. Every six months 3-5 samples are run between instruments to insure they both produce same results." 3. Review of instrument verification documents, (Document number 62-1457 04/2018) under "Product Notification," it states, "Background: (Laboratory sites that use multiple analyzers to test for a given analyte should periodically check for comparability of results between analyzers as required by regulatory agencies.)" 4. Review of instrument correlation records from January 2018 through December 2019 revealed the laboratory failed to have documentation of performing instrument to instrument correlations for the its two Sysmex XN-2000 hematology analyzers in 2018 and 2019. 2018: no documentation of instrument to instrument correlation for 2018 2019: laboratory documentation revealed instrument to instrument correlation was performed once in 2019 (October 3, 2019). 5. An interview with general supervisor #5 (as listed on Form CMS-209) on 01/08/2020 at 08:20 hours in the office confirmed the facility did not have correlation of results between the two hematology instruments twice annually in 2018 and 2019. Key QA - Quality Assurance QAI - Quality Assurance Indicator CMS - Centers for Medicare and Medicaid Services

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of review of printed patient test records, review of patient results in the EMR, and staff interview, it was revealed the laboratory failed to provide reference ranges for tests performed on patient microbiology examinations. The

findings were: 1. A random review of printed patient test records from February 2019 to December 2019 identified the follow results which were reported without documentation of a reference range for the interpretation of patient results: Date Sample ID Test 09-16-2019 9425517 Group A Strep by DNA Amp 02-16-2019 9052790 Group A Strep by DNA Amp 05-04-2019 9195373 Isolate MIC 05-05-2019 9197326 Isolate MIC 05-11-2019 9217110 Group B Strep by DNA Amp 06-20-2019 9286204 Group A Strep by DNA Amp 12-03-2019 9498347 Group B Strep by DNA Amp 12-02-2019 9497040 C. Difficile Toxin by DNA Amp Fecal Leukocytes 12-03-2019 9498738 Group B Strep by DNA Amp 12-03-2019 9499588 Mycoplasma Pneumoniae Swab 12-04-2019 9500211 C. Difficile Toxin by DNA Amp 12-04-2019 9501351 C. Difficile Toxin by DNA Amp 12-08-2019 9505114 C. Difficile Toxin by DNA Amp 12-10-2019 9504021 C. Difficile Toxin by DNA Amp 12-10-2019 9507012 Pertussis by DNA Amp 2. Random review of the printed results through the provider view of the EMR additionally revealed no reference ranges were provided for interpretation of the patient results. 3. An interview with Technical Supervisor 3 (as listed on Form CMS-209) on January 7, 2020 at 12:25 hours in her office confirmed the findings. Key: EMR - electronic medical record Strep - Streptococcus DNA - deoxyribonucleic acid Amp - amplification MIC - minimum inhibitory concentration C. - Clostridium CMS - Centers for Medicare and Medicaid

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a qualified technical consultant performing a competency assessment on 1 of 29 testing personnel who required one in 2019. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a qualified technical consultant performing an annual competency assessment in 2019 for Testing Personnel 25 (as listed on Form CMS-209) who performed two moderate complexity Bleeding Time tests in 2019. 2. Review of the 2019 competency assessment performed on Testing Personnel 25 was performed by the phlebotomy supervisor. No records were provided as of the exit conference on January 9, 2020 that would qualify the phlebotomy supervisor as a Technical Consultant. 3. An interview with the laboratory manager on January 9, 2020 at 10:30 hours in his office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's submitted Form CMS 209, review of the

laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 29 testing personnel (refer to D6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 29 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on January 7, 2020 revealed the laboratory identified 29 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 1 of 29 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 25 3. The laboratory was asked to provide documentation of education to quality the identified testing personnel. No documentation was provided. 4. An interview with the laboratory manager on January 8, 2020 at 13:30 hours in his office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of personnel records, and confirmed in interview of facility personnel, the technical supervisor failed to perform two competency assessments the first year of testing for two testing persons who required them. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/07/2020) revealed the laboratory identified 28 testing personnel who performed high complexity testing. 2. Review of the laboratory's personnel records revealed Testing Personnel 6 (as listed on Form CMS-209) had a start date of July 2017. The testing person's records revealed a documentation of a competency assessment on 5-23-2018. There was no documentation of a 2nd competency

assessment during their 1st year of patient testing. 3. Review of the laboratory's personnel records revealed Testing Personnel 12 (as listed on Form CMS-209) had a start date of August 2017. The testing person's records revealed no documentation of two competency assessment during the 1st year of patient testing. 4. The findings were confirmed in interview of the laboratory manager on January 7, 2020 at 13:45 hours in his office. He confirmed the records could not be located. Key: CMS - Centers for Medicare and Medicaid Services

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing annual competency assessments on 3 of 28 testing personnel requiring one in 2019. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/07/2020) revealed the laboratory identified 28 testing personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment being performing in 2019 for high complexity testing for the following testing persons (as listed on Form CMS-209): Testing personnel number 1 Testing personnel number 7 Testing personnel number 24 3. The laboratory was asked to provide documentation of an annual competency assessment being performed in 2019. No documentation was provided. 4. An interview with the laboratory manager on January 9, 2020 at 14:00 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services