

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0694079	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Sas Health Care Center	Street Address, City, State 700 Research Drive, Cary, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and technical consultant (TC) interview 6/8/21, the laboratory failed to discard 1 Sodium (NA) Citrate blood collection tube that had exceeded the expiration date. Findings: During tour of hallway phlebotomy station the surveyor observed a BD Vacutainer NaCitrate blood collection tube, Lot #0184337, with an expiration date of 4/30/21. Interview at approximately 9:00 a.m. with TC confirmed the blood collection tube was expired. She stated the phlebotomy station located in the hallway was not used often. The expired blood collection tube was disposed of at this time.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory procedure, review of 2019, 2020 and 2021 media quality control (QC) records and interview with TC 6/8/21, the laboratory failed to perform and document QC and sterility checks of the Healthlink Strep Select Agar media as required from April of 2019 until time of survey, approximately 360 patients were tested. Findings: Review of laboratory procedure "Strep Culture" revealed "... Quality Control...The lot/expiration information is maintained in a log book for each number of plates received, as well as a visual inspection of plates on receipt." Review of 2019, 2020 and 2021 media QC records revealed the laboratory had documented a visual inspection of the Healthlink Strep Select Agar media. The laboratory had also maintained the label documenting QC performed by the manufacturer for each lot number of media received, but had not performed and documented sterility checks or QC for the ability of the media to select or inhibit growth as required. Interview with TC at approximately 9:30 a.m. confirmed the laboratory had not performed sterility or QC on the media received. She stated the laboratory has only been checking for condition and they only perform QC on the Taxo A discs received.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of personnel records 6/8/21 and the deficiency cited at D6035, the laboratory failed to verify the TC met the minimum education requirements. Findings: See D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii)

Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with TC 6/8/21, the laboratory failed to verify the TC met the minimum education requirements. Findings: Review of personnel records revealed the TC has an associates degree in medical technology. Interview with TC at approximately 11:00 a.m. confirmed she had an associates degree in medical technology. She stated she was unaware that she would not qualify to serve as the TC when the position was offered by the laboratory.