Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2135786	07/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sallie Astor Burdine Breast Foundation, The	730 Colonial Dr, Suite E, Baton Rouge, LA	

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
D0000	An INITIAL SURVEY was performed at THE SALLIE ASTOR BURDINE BREAST FOUNDATION - CLIA # 19D2135786 on July 23, 2018. THE SALLIE ASTOR BURDINE BREAST FOUNDATION was found not in compliance with the following CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patients serviced by the laboratory: 42 CFR 493.1230 CONDITION: General Laboratory Systems 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing, Technical Supervisor 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing, General Supervisor 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing, Testing Personnel Test Systems identified as Research or Laboratory Developed Tests are considered high complexity testing and are subject to the CLIA regulations for Establishment and verification of performance specifications (42 CFR 493.1253(b)(2) and all other high complexity CLIA requirements.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the laboratory failed to monitor and evaluate the overall quality of the General Laboratory

	System. Findings: 1. The laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Refer to D5203. 2. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 3. The laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Refer to D5207. 4. The laboratory failed to establish written policies to assess the competency of all employees. Please refer to D5209. 5. The laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Refer to D5217. 6. The laboratory failed to establish written policies and procedures for monitoring, assessing, and correcting problems identified in the General Laboratory Systems. Please refer to D5291.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Findings: 1. Review of Patient Final Reports revealed the laboratory performed and reported Lymphocyte Blastogenesis Assay" testing which included the following tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 2. Review of the Laboratory Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that ensures positive patient identification through specimen collection, labeling, accessioning, processing, (e.g., aliquoting), storage, testing, and reporting of results. Review the laboratory's system (policy and practices) for ensuring positive patient identification from specimen collection through reporting of results. 3. Interview with Personnel 2 on July 23, 2018 revealed he was unaware of all the policies and procedures that needed to be established. Personnel 2 confirmed the laboratory failed to establish written policies and procedure that would ensure positive identification and optimum integrity throughout the testing process. .
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems

	reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Findings: 1. Review of Patient Final Reports revealed the laboratory performed and reported Lymphocyte Blastogenesis Assay" testing which included the following tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for twice a year verification of the accuracy of Lymphocyte Blastogenesis Assay . 3. Interview with Personnel 2 on July 23, 2018 revealed he was unaware the laboratory needed to verify the Lymphocyte Blastogenesis Assay twice a year. Personnel 2 confirmed the laboratory did not verify Lymphocyte Blastogenesis Assay twice a year.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory failed to establish written policies and procedures for monitoring, assessing, and correcting problems identified in the General Laboratory Systems. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish policies and procedures for: a) The laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Refer to D5203. b) The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. c) The laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Refer to D5207. d) The laboratory failed to establish written policies to assess the competency of all employees. Please refer to D5209. e) The laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Refer to D5217. Further review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written polices and procedure for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements . 2. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to establish written policies and procedure for monitoring, assessing and correcting problems in General Laboratory Systems.

D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Refer to D5301. 2. The laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Refer to D5305. 3. The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. 4. The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. 5. The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. 6. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 7. The laboratory's Quality Assurance (QA) system failed to monitor, assess, and correct problems identified with the Pre-analytic system. Refer to D5391.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Findings: 1. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to obtain a written request from the physician for laboratory test orders of the following seven (7) patients: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. 2. Interview with Personnel 2 on July 23, 2018 confirmed the laboratory failed to obtain written requests for Lymphocyte Blastogenesis Assay testing for the seven (7) patients cited above.

D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not establish a written detailed test requisition policy and procedure that addresses the following required information:: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. h) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. 2. Interview with Personnel 2 on July 23, 2018 revealed he was unaware of the required information needed on a test requisition. 3. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to obtain a written request with the required information for laboratory test orders for the following nine (9) patients: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On March 15, 2018 Patient 4. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. On July 5, 2017 Patient 9. 2. Interview with Personnel 2 on July 23, 2018 confirmed the laboratory failed to obtain written requests containing all the required information for Lymphocyte Blastogenesis Assay testing for the nine (9) patients cited above.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on record review and interview with personnel, the laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to include written policies and procedures for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) to include: a) Patient preparation. b) Specimen collection. c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. d) Specimen storage and preservation. e) Conditions for specimen transportation. f) Specimen processing. g) Specimen acceptability and rejection. h) Specimen referral. 2. Interview with personnel 2 on July 23, 2018 revealed he was unaware of all the policies and procedures that were required. Personnel 2 confirmed the laboratory failed to have a complete policy and procedure manual. II. Based on observation record review and interview with personnel, the laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory Policy and Procedure Manual revealed under specimen collection and preparation that samples are stored at room temperature for a maximum of 48 hours. Further review of the Policy and Procedure Manual revealed if a sample is not separated within 48 hours of drawing, then the assay is not set up. The ordering physician is sent a report stating "Lymphocytes not separated from blood within 48 hours of being drawn so assay was not set up. It will be necessary for you to redraw blood and submit for LBA." 4. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had been performing this test since 1997. Personnel 2 stated he did not have any studies for the initial setup of the Lymphocyte Blastogenesis Assay. Personnel 2 stated he knew of no studies that were performed or kept. Personnel 2 stated he was unaware of the studies that need to be performed prior to patient testing. Personnel 2 confirmed the laboratory failed to have a specimen stability study performed. III. Based on observation, record review, and interview with personnel, the laboratory failed have a system in place for specimen referral for "Lymphocyte Blastogenesis Assay on Prostate Cancer Patients." Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay : Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23,

	2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory Policy and Procedure Manual revealed a Procedure Manual For "Lymphocyte Blastogenesis Assay on Prostate Cancer Patients". Under "Specimen Collection and Preparation" a procedure for drawing patient samples and processing the sample to be sent to Laboratory 2 for testing. 4. Interviews with Personnel 1 and 2 on July 23, 2018 revealed that samples for Prostate Cancer are all referred to Laboratory 2 for testing. Personnel 1 and 2 stated that no Prostate testing is performed in house. 5. Observation by surveyor on August 2, 2018 during a tour of Laboratory 2 found no laboratory equipment or patient samples for PSA testing. 6. Interview with Laboratory 2 representative on August 2, 2018 stated no laboratory testing is performed at their facility. There was no way to determine where laboratory 1 was sending their PSA patient tests.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not include policies and procedures for documenting the date and time for each specimen received into the laboratory. 2. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to document the date and time the following nine (9) patients were received into the laboratory: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On March 15, 2018 Patient 4. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. On July 5, 2017 Patient 9. 3. Interview with Personnel 2 on July 23, 2018 confirmed the laboratory failed to document the date and time each specimen is received into the laboratory. Review of the Task 1 and 3 Form submitted to surveyors on November 17, 2016 revealed the laboratory performed and reported the following annual volumes of testing without ensuring the time the patients specimen was received into the laboratory was documented: 9100 - Barb, 9100 - Benzo, 9100 - COC, 9100 - ETOH, 9100 - Meth, 9100 - OPI, 9100 - PCP, 9100 - THC and 9100 - Creat
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the Laboratory's Policy and Procedure Manual failed to include a manual for facilities that utilize the laboratory for Bacteriology, Parasitology, Virology and Histopathology testing with detailed instructions for: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. 2. Interview with personnel 2 on July 23, 2018 revealed the laboratory accepts samples for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from other locations. Personnel 2 revealed he was unaware that a Client Service Manual was required. Personnel 2 confirmed the laboratory did not have or provide a service manual to the outside facilities that they provide service to for maintaining the integrity of patient samples to ensure accurate and reliable testing.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish written quality assessment policies and procedures for monitoring, identifying and correcting problems identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish written quality assessment policies and procedure for monitoring, identifying and correcting problems identified with preanalytic systems. 2. Problems identified in the Preanalytic System found during the survey that failed to be addressed by the laboratory: a) The laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Refer to D5301. b) The laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Refer to D5305. c) The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. d) The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. e) The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. f) The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 3. Interview with personnel 2 on July 23, 2018 revealed he was unaware of the things that needed to be monitored. Personnel 2 confirmed the above 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 observatio, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. 2. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to have the policy and procedure manual approved, signed, and dated by the Laboratory Director. Refer to D5407. 4. The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417. 5. The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. 6. The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. 7. The laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427. 8. The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. 9. The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. 10. The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477. 11. The laboratory failed to take corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783. 12. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. 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:

	Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Test Requisitions: what mandated information needs to be on the test requisition: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. c) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. Twice a year verification of the Lymphocyte Blastogenesis Assay accuracy: a) What system are you going to use to meet the twice a year verification for the Lymphocyte Blastogenesis Assay accuracy. b) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place c) How to record results and who will score. d) What acceptability criteria will be used to score the verification. e) What records to maintain. f) What steps to take if corrective action is needed. Complaint policies and procedures. Communication policies and procedures. 2. Interview with personnel 2 on July 23, 2018 confirmed the policy and procedure manual was incomplete 2. Interview with personnel 2 on May 21, 2018 confirmed the policy and procedure manual was incomplete
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have detailed written policies and procedures for: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b) Microscopic examination, including the detection of inadequately prepared slides. c)) Step-by-step performance of the procedure, including test calculations and interpretation of results. d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. e) Calibration and calibration verification procedures. f)) The reportable range for test results for the test system as established. g) Control procedures. h) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. i) Limitations in the test methodology, including interfering substances. j) Reference intervals (normal values). k) Imminently life-threatening test results, or panic or alert values. l) Pertinent literature references. m) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. n) Description of the course of action to take if a test system becomes inoperable. 2. Interview with personnel 2 on July 23, 2018 revealed he was unaware of all the policies and procedures that were required. Personnel 2 confirmed the laboratory failed to have a complete policy and procedure manual.
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 record review and interview with personnel, the laboratory failed to have the policy and procedure manual approved, signed, and dated by the Laboratory Director. Findings: 1. Review of the laboratory's policy and procedure manual revealed, the manual was not signed by the Laboratory Director. 2. Interview with Personnel 2 on July 23, 2018 confirmed the Laboratory Director failed to sign, date and approve the policy and procedure manual.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, and interview with laboratory personnel, the laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on July 23, 2018 revealed the following expired items in place for patient testing: Seven (7) - 10 ml bottles Gibco Gentamycin Reagent Solution lot number 1806209 with an expiration date of 2018-06. Two (2) 500 ml bottles Quality Biologics DMEM High Glucose with L-Glutamine Sterile Filtered lot number 61181181 with an expiration date of Aug 2014. Two (2) 500 ml bottles Gibco MEM Alpha (1X) Minimum Essential Medium lot number 1810990 with an expiration date of 2017-08. One (1) 500 ml bottle Quality Biologics DMEM:F12 1:1 Dulbecco's Modified Eagles Medium lot number 721988 with an expiration date of 12/2017. Four (4) 500 ml bottles ATCC RPMI-1640 High Glucose with L-Glutamine with Hepes lot number 80224175 with an expiration date of Mar2018. Four (4) 500 ml bottles Promo Cell MEM D-Valine lot number W11172P with an expiration date of May 30, 2004. Three (3) 100 ml bottles Sigma Sodium Pyruvate lot number RNB06096 with an expiration date of 01/2017. Two (2) 100 ml bottles Sigma Red Blood Cell Lysing Buffer lot number 076K2358 with an expiration date of 07/2008. Thirty (30) Cell Treat Scientific Syringe Filters lot number 141009-052 with an expiration date of 2017/10 /09. One (1) 500 ml bottle Sigma-Aldrich Eosin Y Solution lot number 039K4342 with an expiration date of 2010-09. One (1) gallon HistoPrep 70% Denatured Ethyl Alcohol lot number 222769 with an expiration date of 04/2015. 2. Interview with personnel 2 on July 23, 2018 revealed that some of the items are only utilized for research. However Personnel 2 did state that both Research and Clinical items are all stored together. Personnel 2 confirmed by observation the items cited were expired and in place for patient testing.
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 observation, record review and interview with personnel the laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the

	laboratory. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed: a) The laboratory performed "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. b) The laboratory failed to establish written policies and procedures for Performance Specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. 4. Interview with personnel 2 on July 23, 2018 revealed the laboratory had been performing this test since 1997. Personnel 2 stated he did not have any studies for the initial setup of the Lymphocyte Blastogenesis Assay. Personnel 2 stated he knew of no studies that were performed or kept. Personnel 2 stated he was unaware of the studies that need to be performed prior to patient testing. Personnel 2 confirmed the laboratory failed to have studies for accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, reference intervals (normal values) and any other performance characteristic required for test performance (to include specimen stability). 5. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory for the following nine (9) patients: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On March 15, 2018 Patient 4. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. On July 5, 2017 Patient 9.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel the laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient

	samples for Lymphocyte Blastogenesis Assay. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope Hemocytometer 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed: a) The laboratory performed "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. b) The laboratory failed to establish written policies and procedures for Performance Specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. 4. Interview with personnel 2 on July 23, 2018 revealed the laboratory had been performing this test since 1997. Personnel 2 stated he did not have any studies for the initial setup of the Lymphocyte Blastogenesis Assay. Personnel 2 stated he knew of no studies that were performed or kept. Personnel 2 stated he was unaware of the studies that need to be performed prior to patient testing. Personnel 2 confirmed the laboratory failed to maintain studies to support calibration and control procedures performed for the Lymphocyte Blastogenesis Assay. 5. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay for the following nine (9) patients: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On March 15, 2018 Patient 4. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. On July 5, 2017 Patient 9.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel the laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the

	following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope Hemocytometer 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed: a) The laboratory performed "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. b) The laboratory failed to establish written policies and procedures for Performance Specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. 4. Interview with personnel 2 on July 23, 2018 revealed the laboratory had been performing this test since 1997. Personnel 2 stated he did not have any studies for the initial setup of the Lymphocyte Blastogenesis Assay. Personnel 2 stated he knew of no studies that were performed or kept. Personnel 2 stated he was unaware of the studies that need to be performed prior to patient testing. Personnel 2 confirmed the laboratory failed to maintain studies to support maintenance or function checks of all the equipment utilized in performing the Lymphocyte Blastogenesis Assay. 5. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay for the following nine (9) patients: On June 4, 2018 Patient 1. On May 15, 2018 Patient 2. On April 19, 2018 Patient 3. On March 15, 2018 Patient 4. On February 19, 2018 Patient 5. On January 18, 2018 Patient 6. On November 28, 2017 Patient 7. On September 6, 2017 Patient 8. On July 5, 2017 Patient 9.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA,

	HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed: a) The laboratory performed "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. b) The laboratory performed a positive and negative process control with each patient run; however the laboratory failed to establish written policies and procedures to include the performance of two levels of control materials for each of the tumor markers (TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) tested. 4. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to perform two levels of quality control for each marker tested for the following nine (9) patients: On June 4, 2018 Patient 1 for tumor markers: HTA, CA15-3, CEA ands CA125. On May 15, 2018 Patient 2 for tumor markers: HTA, CA15-3, CEA ands CA125. On April 19, 2018 Patient 3 for tumor markers: HTA, CA15-3, CEA ands CA125. On March 15, 2018 Patient 4 for tumor markers: HTA, CA15-3, CEA ands CA125. On February 19, 2018 Patient 5 for tumor markers: HTA HT-29, HTA SW480, CEA ands CA19-9. On January 18, 2018 Patient 6 for tumor markers: HTA, CA15-3, CEA ands CA125. On November 28, 2017 Patient 7 for tumor markers: HTA, CA15-3, CEA ands CA125. On September 6, 2017 Patient 8 for tumor markers: HTA HTB-38, HTA NCI-1640, CA15-3, CEA CA125 and CA19-9. On July 5, 2017 Patient 9 for tumor markers: HTA CRL5833, HTA HTB58 and CEA. 6. Interview with personnel 2 on July 23, 2018 revealed the laboratory performed a positive and negative control which he believed covered the quality control regulation. Personnel 2 stated he was unaware that each marker needed to include two levels of control materials for each marker each day of patient testing. Personnel 2 confirmed the laboratory did not perform and document two levels of control materials for each marker each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel the laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed: a) The laboratory performed "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. b) The laboratory performs a positive and negative process control utilizing PHA (T-cell mitogen) or PWN (B-cell mitogen). c) The laboratory failed to establish written policies and procedures for the establishment of Quality Control for each tumor marker tested to include when control materials provide quantitative results, the laboratory must maintain statistical parameters (mean and standard deviation) for each batch and lot number of control material. 4. Interview with Personnel 2 on July 23, 2018 confirmed the only quality control is the one (1) positive and one (1) negative controls to make sure that the process of the system is working correctly.
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 observation, record review, and interview with personnel, the laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for:

	TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed that process controls and patient prepared samples are suspended in the QBSF-56 media and then a sample from that suspension is taken and used as the sample to place in the 96 well plate for testing for at the tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. Further review of the Laboratory Policy and Manual revealed the laboratory failed to include written quality control policies and procedures for QBSF-56 Media to include: a). Checking each batch of media for sterility. b) Check the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. 3. Interview with personnel 2 on July 23, 2018 revealed he was unaware the laboratory had to perform and document any quality control procedures for QBSF-56 Medium. Personnel 2 stated the laboratory does not do any quality control for the QBSF-56 Media. 4. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to perform quality control on the QBSF-56 Media for following nine (9) patients: On June 4, 2018 Patient 1 for tumor markers: HTA, CA15-3, CEA ands CA125. On May 15, 2018 Patient 2 for tumor markers: HTA, CA15-3, CEA ands CA125. On April 19, 2018 Patient 3 for tumor markers: HTA, CA15-3, CEA ands CA125. On March 15, 2018 Patient 4 for tumor markers: HTA, CA15-3, CEA ands CA125. On February 19, 2018 Patient 5 for tumor markers: HTA HT-29, HTA SW480, CEA ands CA19-9. On January 18, 2018 Patient 6 for tumor markers: HTA, CA15-3, CEA ands CA125. On November 28, 2017 Patient 7 for tumor markers: HTA, CA15-3, CEA ands CA125. On September 6, 2017 Patient 8 for tumor markers: HTA HTB-38, HTA NCI-1640, CA15-3, CEA CA125 and CA19-9. On July 5, 2017 Patient 9 for tumor markers: HTA CRL5833, HTA HTB58 and CEA.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory

	had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. 3. Review of the Laboratory's Policy and Procedure Manual revealed under "Controls for LBA" that and acceptable value for the positive control would be a ratio that is greater that 2.00. The acceptable value for a negative control would be a ration that is less than 2.0. 4. Review of Patient Final Reports revealed that anything with a ratio > 1.50 is reactive (or positive). 5. Review of a random selection of Patient Test Records for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) from July 5, 2017 through June 4, 2018 revealed the laboratory failed to take corrective action for the following two (2) patients: On June 4, 2018 Patient 1 the negative control had a ration of 1.56. On April 19, 2018 Patient 3 the negative control had a ratio of 3.06.
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 observation, record review, and interview with personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. b) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. c) The laboratory failed to have the policy and procedure manual approved, signed, and dated by the Laboratory Director. Refer to D5407. d) The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417. e) The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. f) The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. g) The laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427. h) The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. i) The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. j) The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477. k) The laboratory failed to take corrective

	action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems. 3. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to identify and correct the issue cited above.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to meet the qualifications for a Laboratory Director of high complexity testing. D6078. 2. The Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6079 I. 3. The Laboratory Director failed to ensure that animal samples are collected, handled, processed, tested and reported separately from patient samples. Refer to D6079 II. 4. The Laboratory Director failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Lymphocyte Blastogenesis Assay. Refer to D6086. 5. The Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable test results. Please refer to D6087. 6. The Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6093. 7. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6094. 8. The Laboratory Director failed to ensure that the laboratory took corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D6096. 9. The 10. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6103. 11. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106. 12. The Laboratory Director failed to specify in writing the duties and responsibilities of personnel involved in all phases of testing. Refer to D6107.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory

	director 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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to meet the qualifications for a Laboratory Director of high complexity testing. Findings: 1. Review of personnel records revealed the laboratory failed to maintain copies of the Laboratory Director's education, experience and a copy of his current license issued by the State. 2. Interview with Personnel 2 on July 23, 2018 confirmed the laboratory failed to maintain copies of the Laboratory Director's education, experience and a copy of his current State license.
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 reapportions 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:

I. Based on record review and interview with laboratory personnel , the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Refer to D5203. 2. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 3. The laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Refer to D5207. 4. The laboratory failed to establish written policies to assess the competency of all employees. Please refer to D5209. 5. The laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Refer to D5217. 6. The laboratory failed to establish written policies and procedures for monitoring, assessing, and correcting problems identified in the General Laboratory Systems. Please refer to D5291. 7. The laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Refer to D5301. 8. The laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Refer to D5305. 9. The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. 10. The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. 11. The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. 12. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 13. The laboratory's Quality Assurance (QA) system failed to monitor, assess, and correct problems identified with the Pre-analytic system. Refer to D5391. 14. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. 15. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 16. The laboratory failed to have the policy and procedure manual approved, signed, and dated by the Laboratory Director. Refer to D5407. 17. The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417. 18. The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. 19. The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. 20. The laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427. 21. The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. 22. The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. 23. The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the

	manufacturer. Refer to D5477. 24. The laboratory failed to take corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783. 25. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791. II. Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure that animal samples are collected, handled, processed, tested and reported separately from patient samples. Findings: 1. Observation by the surveyor during the tour of the laboratory on July 23, 2018 revealed the laboratory utilized the following equipment for processing and reading results for Lymphocyte Blastogenesis Assay: Beckman Coulter LS 6500 Liquid Scintillation Counter Skatron Basic 96 Harvester Two (2) Panasonic CO2 Incubators Nikon Microscope Olympus Microscope Further observation of the laboratory during the tour revealed that all reagents, chemicals, solutions, controls, and filters are all maintained together. There was no separation of items based on research, animal testing vs patient testing. 2. Interview with Personnel 2 on July 23, 2018 revealed the laboratory had developed a test for "Lymphocyte Blastogenesis Assay" testing which includes tumor markers for: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA. Further interview with Personnel 2 revealed the laboratory receives both animal and patient samples, that both samples are tested and processed in the laboratory. 3. Review of the Laboratory's Policy and Procedure Manual revealed only one Policy and Procedure Manual that contained policies and procedures for Lymphocyte Blastogenesis Assay. Further review of the Policy and Procedure Manual revealed: a) The laboratory did not differentiate between animal and patient samples. b) The laboratory did not have policies and procedures for establishing systems to ensure accurate and reliable results when the different sample types are performed (i.e.; maintenance of equipment for possible interference or cross contamination of samples). 4. Interview with Personnel 2 on July 23, 2018 revealed he was unaware that items needed to be stored according to research, animal testing vs patient testing. Personnel 2 stated that all samples are treated the same and that there is no change in the processes when testing.
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 observation, record review and interview with personnel, the Laboratory Director failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Lymphocyte Blastogenesis Assay. Findings: 1. The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. 2. The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. 3. The laboratory failed to establish and verify

	performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable test results. Findings: 1. The laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Refer to D5217. 2. The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. 3. The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. 4. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 5. The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417.
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 laboratory policy and procedure manual, quality control and patient test records and interview with personnel, the Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. 2. The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. 3. The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of laboratory's policy and procedure manual, patient test records,and manufacturer's package inserts indicated systemic problems with the General Lab Systems, Preanalytic and Analytic system as follows: a) The laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Refer to D5203. b) The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. c) The laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Refer to D5207. d) The laboratory failed to establish written policies to assess the competency of all employees. Please refer to D5209. e) The laboratory failed to verify the accuracy of the performance of Lymphocyte Blastogenesis Assay at least twice annually. Refer to D5217. f) The laboratory failed to obtain a written request from the physician for seven (7) of nine (9) patients reviewed. Refer to D5301. g) The laboratory failed maintain test requisitions that included all the required information for nine (9) of nine (9) patients. Refer to D5305. h) The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. i) The laboratory failed to ensure that a specimen stability study was performed to support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. j) The laboratory failed to document the date and time specimens are received into the laboratory for nine (9) of nine (9) patients reviewed. Refer to D5313. k) The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. l) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. m) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. n) The laboratory failed to have the policy and procedure manual approved, signed, and dated by the Laboratory Director. Refer to D5407. o) The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417. p) The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. q) The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. r) The laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427. s) The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA

	15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. t) The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. u) The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477. v) The laboratory failed to take corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783. 2. Review of the Laboratory Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified with the General Laboratory System Preanalytic and Analytic systems. Refer to D5291, D5391 and 5791. 3. Interview with personnel 2 on July 23, 2018 confirmed the laboratory failed to identify the deficiencies cited during the survey.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory took corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of Personnel Records and interview with personnel, the Laboratory Director failed to ensure that testing personnel performing non-waived testing met the licensing, and educational requirements for qualify for performing high complexity testing. Findings: 1. The the Technical Supervisor failed to meet the licensing requirements for General Supervisor for one (1) of one (1) individuals functioning as the Technical Supervisor. Refer to D6111. 2. The General Supervisor met the educational and experience requirements for high complexity testing for one (1) of one (1) personnel. Refer to D6143. 3. The laboratory failed to ensure testing personnel met the qualifications for State Licensure to perform high complexity testing for one (1) of one (1) testing personnel. Refer to D6170.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have written personnel policies and procedures that detailed how and when a new employee was to have competency reviews performed and documented. The policy needs to include at a minimum a policy and procedure that includes assessments to be performed semi annually the first year and annually thereafter, but also includes the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with personnel 2 on July 23, 2018 confirmed there were no written policies and procedures which guided when and how evaluations were to be done, and who was responsible for the completion of the evaluations. Personnel 2 confirmed there were no written policies for identifying training or continuing education needs to improve skills.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: a) The laboratory failed to establish policies and procedures that would ensure positive identification and optimum integrity of patient samples for "Lymphocyte Blastogenesis Assay" testing. Refer to D5203. b) The laboratory failed to have established policies and procedures to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. c) The laboratory failed to have policies and procedures to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an

authorized person who orders or receives test results. Refer to D5207. d) The laboratory failed to establish written policies to assess the competency of all employees. Please refer to D5209. e) The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. f) The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. g) Test Requisitions: what mandated information needs to be on the test requisition: * The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. * The patient's name or unique patient identifier. * The sex and age or date of birth of the patient. * The test(s) to be performed. * The source of the specimen, when appropriate. * The date and, if appropriate, time of specimen collection. * Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. h) Performance specifications to include: * Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. * Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. i) Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: * Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. * Monitoring the recording and reporting or test results. * Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. * Direct observation of performance of instrument maintenance and function checks. * Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. * Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. j) Twice a year verification of the Lymphocyte Blastogenesis Assay accuracy: * What system are you going to use to meet the twice a year verification for the Lymphocyte Blastogenesis Assay accuracy. * How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place * How to record results and who will score. * What acceptability criteria will be used to score the verification. * What records to maintain. * What steps to take if corrective action is needed. k) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. l) Microscopic examination, including the detection of inadequately prepared slides. m) Step-by-step performance of the procedure, including test calculations and interpretation of results. n) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. o) Calibration and calibration verification procedures. p) The reportable range for test results for the test system as established. q) Control procedures. r) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for

	acceptability. s) Limitations in the test methodology, including interfering substances. t) Reference intervals (normal values). u) Imminently life-threatening test results, or panic or alert values. v) Pertinent literature references. w) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. x) Description of the course of action to take if a test system becomes inoperable. y) An ongoing mechanism to monitor, assess, and when indicated, correct problems identified with the General Laboratory System Preanalytic and Analytic systems. Refer to D5291, D5391 and 5791. 2. Interview with personnel 2 on July 23, 2018 revealed he was unaware of all the written policies and procedures needed in the laboratory. Personnel 2 confirmed the policy and procedure manual was incomplete
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to specify in writing the duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory failed to include written duties and responsibilities for personnel involved in all phases of testing to include: Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor and Testing Personnel. 2. Interview with Personnel 2 on July 23, 2018 revealed he was unaware they needed job descriptions for all the positions involved in the laboratory. Personnel 2 confirmed the laboratory failed to have detailed written job duties and responsibilities for all positions in the laboratory involved in all phases of testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to meet the qualifications and provide technical oversight for a Technical Supervisor of high complexity testing. Findings: 1. The Technical Supervisor failed to meet the licensing requirements for General Supervisor for one (1) of one (1) individuals functioning as the Technical Supervisor. Refer to D6111 2. The Technical Supervisor failed provide technical and scientific oversight for the laboratory. Refer to D6112.

D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is 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)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(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 (c)(1)(ii) Be certified in clinical pathology 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 (c)(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 (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(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 (d)(1)(ii) Be certified in clinical pathology 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 (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited

institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(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 (e)(1)(ii) Be certified in clinical pathology 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 (e)(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 (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology 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 (f)(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 (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an

accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(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 (g)(1)(ii) Be certified in clinical pathology 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 (g)(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 (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology 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 (h)(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 (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high

complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(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 (i)(1)(ii) Be certified in clinical pathology 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 (i)(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 (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology 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 (j)(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 (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the

individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology 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 (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology 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; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) 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-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology 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 (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) 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-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology 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 (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology 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 (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology 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 (n)(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 (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(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 (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(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 (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of

	paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology 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 (q)(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 (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor 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. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on record review and interview with personnel the Technical Supervisor failed to meet the licensing requirements for General Supervisor for one (1) of one (1) individuals functioning as the Technical Supervisor. Findings include: 1. Review of the Form CMS 209 submitted to the surveyor on July 23, 2018 revealed that personnel 2 was listed as the Technical Supervisor. 2. Review of Personnel 2's Personnel Record revealed the laboratory failed to maintain documentation of a current State license to qualify him as the Technical Supervisor, and failed to maintain documentation of laboratory training and experience in high complexity testing in the specialies /subspecialties of General Immunology and Routine Chemistry. 3. Interview with personnel 2 on July 23, 2018 revealed he was unaware that his State License as a Laboratory Assistant did not qualify him as the Technical Supervisor. Personnel 2 did reveal he had been working in the research laboratory since 1997; however he did confirm the laboratory failed to maintain a copy of his training and experience in high complexity testing.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Technical Supervisor failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to establish complete written policies and procedures addressing specimen submission, handling, and referral. Refer to D5311 I. 2. The laboratory failed to ensure that a specimen stability study was performed to

	support their policy that samples for Lymphocyte Blastogenesis Assay must be processed within 48 hours of collection. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 4. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 and D5403. 5. The laboratory failed to ensure that solutions, reagents, medium and filters are not used beyond their expiration dates. Refer to D5417. 6. The laboratory failed to establish and verify the Lymphocyte Blastogenesis Assay performed by the laboratory. Refer to D5423. 7. The laboratory failed to establish and verify performance specifications for Calibration and Quality Control procedures utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5425. 8. The laboratory failed to establish and verify performance specifications for Maintenance or Function Checks utilized for ensuring accurate and reliable test results for patient samples for Lymphocyte Blastogenesis Assay. Refer to D5427. 9. The laboratory failed to perform two levels of control materials each day of patient testing for "Lymphocyte Blastogenesis Assay" testing (which includes tumor markers: TAA, HTA, HTA HT-29, HTA SW480, HTA HTB-38, HTA NCI-1640, HTA CRL 5833, HTA HTB58, CA 15-3, CA 125, CA 19-9, and CEA) for nine (9) of nine (9) patients reviewed. Refer to D5447. 10. The laboratory failed to establish criteria for acceptability of all control materials for each test performed by the laboratory. Refer to D5469. 11. The laboratory failed to check each batch of QBSF-56 media for sterility, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477. 12. The laboratory failed to take corrective action when quality control was unacceptable for Lymphocyte Blastogenesis Assay performed by the laboratory for two (2) of two (2) patients requiring corrective action. Refer to D5783.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the laboratory failed to ensure the General Supervisor met the educational and experience requirements for high complexity testing for one (1) of one (1) personnel. Refer to D6143
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. 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). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the General Supervisors failed to meet the educational and experience requirements for one (1) of three (3) individuals functioning as the General Supervisor. Findings: 1. Review of FORM CMS 209 revealed that Personnel 2 was listed as the General Supervisor. 2. Review of Personnel 2's Personnel Record revealed the laboratory failed to maintain documentation of a current State license to qualify him as the General Supervisor, and failed to maintain documentation of laboratory training and experience in high complexity testing. 3. Interview with personnel 2 on July 23, 2018 revealed he was

	unaware that his State License as a Laboratory Assistant did not qualify him as the General Supervisor. Personnel 2 did reveal he had been working in the research laboratory since 1997; however he did confirm the laboratory failed to maintain a copy of his training and experience in high complexity testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications for State Licensure to perform high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications for State Licensure to perform high complexity testing for one (1) of one (1) testing personnel. Findings: 1. The laboratory failed to have a current license issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of one (1) testing persons performing high complexity testing. Refer to D6170. 2. Interview with Personnel 2 on July 23, 2018 revealed he was unaware that his Lab Assistant License would not allow him to do high complexity testing. Personnel 2 confirmed he failed to have a license that would allow him to do high complexity testing.