Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2169206	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Signify Laboratory, Llc	935 Gravier St, Suite 550, New Orleans, 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 Signify Laboratory, LLC, CLIA ID 19D2169206, on October 7, 2020. Signify Laboratory, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical Supervisor
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Chemistry. Findings: 1. The laboratory failed to verify the accuracy of the performance of Hereditary Cancer screening testing at least twice annually. Refer to D5217. 2. The laboratory failed to have a system for ensuring specimens for Hereditary Cancer screening maintained the manufacturer's temperature requirements during transport. Refer to D5311. 3. The laboratory failed to ensure their client services manual reflected manufacturer's stability claims per their policy. Refer to D5317. 4. The laboratory failed to have a complete proficiency testing policy. Refer to D5401. 5. The laboratory failed to have complete quality control policies for Hereditary Cancer screening testing. Refer to D5403. 6. The laboratory failed to ensure the acceptable temperature range for refrigerators reflected the manufacturer's temperature requirements for the reagents stored in the refrigerators. Refer to D5413. 7. The laboratory failed to ensure reagents and supplies had not exceeded their expiration dates. Refer to D5417. 8. The laboratory failed to establish complete performance specifications for accuracy and specificity for Hereditary

	Cancer screening testing. Refer to D5423. 9. The laboratory failed to include on the report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by Signify Laboratory, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805. 10. The laboratory failed to notify clients of testing delays per laboratory policy. Refer to D5815.
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: I. Based on review of personnel records, policies, and interview with personnel, the laboratory failed to have documentation of initial training for testing personnel per laboratory policy for five (5) of ten (10) testing personnel reviewed. Findings: 1. Review of the laboratory's "Personnel Training and Competency" policy (effective September 1, 2019) revealed "It is the responsibility of the Technical Supervisor to ensure that staff are trained accordingly and to perform the initial six-month competency reviews and all following annual reviews. It is the responsibility of the Laboratory Director to review initial hire and annual competency reviews of all staff on an annual basis." 2. Review of the laboratory's competency records revealed the following document signed on "5/19/2020" by Technical Supervisor 1: " Signify personnel record were reviewed for completeness. Training policy was in place however training records were not. Since assuming the technical supervisor role on 2 /26/2020, I have implemented forms for training and competency for laboratory personnel. These forms are completed for all applicable personnel." 3. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) and competency records revealed the following current and previous testing personnel did not have initial training documentation: Current Testing Personnel: a) Technical Supervisor 1: no training documentation for data analysis b) General Supervisor: no training documentation for library preparation procedure Previous Testing Personnel: a) Technical Supervisor 2 (previously served as Testing Personnel): no training documentation for extraction and library enrichment preparation procedures b) Technical Supervisor 3: no training documentation for data analysis (terminated February 26, 2020) c) Technical Supervisor 4: no training documentation for data analysis (terminated February 26, 2020) 4. In interview on October 7, 2020 at 11:00 am, the General Supervisor confirmed the laboratory did not have an initial training document for her performing library preparation procedure. 5. In interview on October 7, 2020 at 11:00 am, Technical Supervisor 2 stated she performed the extraction and library preparation procedures for the patient samples tested in March. Technical Supervisor 2 further stated Testing Personnel 4 left before he signed off her training. 6. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated she did not know anything about Technical Supervisor 3 and Technical Supervisor 4. Technical Supervisor 2 confirmed the laboratory did not have the identified documents for Technical Supervisor 3 and Technical Supervisor 4. 7. In interview on October 7, 2020 at 1:29 pm, Technical Supervisor 1 stated Technical Supervisor 3 and Technical Supervisor 4 were previously hired to perform data analysis. Technical Supervisor 1 stated she would perform data analysis in house. 8. Review of final patient test reports revealed Technical Supervisor 1 reviewed and

	approved the test results for the following three (3) patients: Patient 200306101003 Patient 200306101004 Patient 200306101002 II. Based on review of personnel records, policies, and interview with personnel, the laboratory failed to ensure two (2) of four (4) Technical Supervisors had documentation of competency assessment performed by Laboratory Director for their duties as Technical Supervisor. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) and competency records revealed the following previously employed Technical Supervisors did not have documentation of competency assessment for their duties as Technical Supervisor. a)Technical Supervisor 3: terminated February 26, 2020 b) Technical Supervisor 4: terminated February 26, 2020 2. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated she did not know anything about Technical Supervisor 3 and Technical Supervisor 4. Technical Supervisor 2 confirmed the laboratory did not have the identified documents for Technical Supervisor 3 and Technical Supervisor 4.
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 Hereditary Cancer screening testing at least twice annually. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs hereditary cancer screening for the following genetic markers: ATM, BRCA 1, BRCA 2, CDH 1, MLH 1, MSH 2, MSH 6, and PTN 2. Review of the laboratory's revised "Proficiency Testing Policy" revealed "Assays for which no commercial proficiency testing program is available require alternate methods as deemed appropriate by the Laboratory Director. These methods may include: a) Blinded Samples analysis b) Split Sample Analysis with other laboratories performing this or similar assay c) Split sample analysis with an alternate in-house method d) Alternative PT programs are described (with acceptable criteria) in the individual test that use them" 3. Review of the laboratory's records revealed the laboratory did not have documentation of verification of the accuracy of the performance of hereditary cancer screening testing at least twice annually. 4. In interview on October 7, 2020 at 9:55 am, Technical Supervisor 1 stated the laboratory tried to do split sample testing with another laboratory; however, the other lab did not test or return the samples. Technical Supervisor 1 stated the laboratory did not verify the accuracy of performance of hereditary cancer screening. 5. Review of the laboratory's test menu revealed the laboratory performs 600 hereditary cancer screens annually. 6. In interview on October 7, 2020 at 9:36 am, Technical Supervisor 1 stated the laboratory has tested three (3) patient samples since opening.
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: Based on review of the laboratory's policies and procedures, manufacturer's package insert, and interview with personnel, the laboratory failed to have a system for ensuring specimens for Hereditary Cancer screening maintained the manufacturer's temperature requirements during transport. Findings: 1. Review of the ORAcollect-DX OCD-100 package insert revealed a 15 degrees Celsius to 25 degrees Celsius storage requirement. 2. Review of the laboratory's policies and procedures revealed the laboratory did not establish a system to ensure specimens during transport did not exceed the manufacturer's storage requirement. 3. In interview on October 7, 2020 at 11:30 am, Technical Supervisor 1 confirmed the laboratory did not monitor specimen temperature requirements during transport or upon receipt. 4. In interview on October 7, 2020 at 9:36 am, Technical Supervisor 1 stated the laboratory has tested three (3) patient samples since opening. 5. Review of patient final test reports revealed the laboratory received and tested the following three (3) patients : Patient 200306101003 Patient 200306101004 Patient 200306101002
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 review of the laboratory's Client Services Manual, , policies and procedure manual, manufacturer's package insert, and interview with personnel, the laboratory failed to ensure their client services manual reflected manufacturer's stability claims per their policy. Findings: 1. Review of the laboratory's "NEXTSEQ VERIFICATION REPORT November 6, 2019" under "Interfering Species, Sample Stability, and LOD" section revealed "Currently, Signify Laboratory adheres to all manufacturer's recommendations regarding sample collection, as well as reagent and patient sample storage expiration." 2. Review of the laboratory's "NEXTSEQ OCD-100 GENOTEK VALIDATION ADDENDUM May 10, 2020" revealed the laboratory did not include sample stability requirements. 3. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated the laboratory's stability requirements for samples are the same as the manufacturer's. 4. Review of the "ORAcollect-Dx OCD-100" package insert revealed the following storage requirement 15-25 degrees Celsius. 5. Review of the laboratory's client service manual effective "9/24/2020" revealed the following " Storage: 15 C-30 C (normal room temperature) for up to 30 days."
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 record review and interview with personnel, the laboratory failed to have a complete proficiency testing policy. Findings: 1. In interview on October 7, 2020 at 9: 55 am, Technical Supervisor 1 stated the laboratory had a policy in place for proficiency testing for Hereditary Cancer Screening testing. 2. Review of the laboratory's "Proficiency Testing Policy QA.01.014" revealed the laboratory did not include the following information: a) Frequency of performance of split sample testing b) Acceptability criteria and corrective action for results 3. In interview on October 7, 2020 at 2:54 pm, Technical Supervisor 2 stated the reviewed laboratory's proficiency testing policy had not been reviewed by the Laboratory Director.
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 policies and procedures, patient instrument data, and interview with personnel, the laboratory failed to have complete quality control policies for Hereditary Cancer screening testing. Findings: 1. Review of the laboratory's "Quality Control Monitoring for Hereditary CGx Screening" policy revealed the following controls for Hereditary Cancer: a) "Negative Controls: Negative Extraction Control (NEC) and No Template Control (NTC). NECs can count as NTCS, provided that they pass the quantification QC checkpoint and go through the entirety of library preparation. b) Positive controls: PhiX Control provided by Illumina must be included on every run. Previously characterized samples may also be run in addition to this PhiX control. c) Run Metrics: Percent Q30: > 75%, % PF: > 80%, Cluster density: 170-220, Alignment percentage, Error rate: 1%. For a run to be considered passing QC thresholds, the following metrics must be satisfied: Percent Q30 (%Q30), Error Rate (%), and Percent of Clusters passing filter (%PF)" 2. Review of the laboratory's patient run revealed the plate contained three (3) NEC and one (1) Positive control. 3. Further review of the laboratory's "Quality Control Monitoring for Hereditary CGx Screening" policy revealed the policy did not include the following: a) Specific negative and positive controls required for each patient run b) Parameters for quality control acceptability 4. In interview on October 7, 2020 at 2:00 pm, Technical Supervisor 1 and Technical Supervisor 2 stated PhiX and NEC controls

	were on the patient run plate. Technical Supervisor 1 confirmed the policy did not indicate what specific negative and positive controls were used by the laboratory. Technical Supervisor 1 and General Supervisor stated a previous employee developed the SOP they were unsure why those specific run metrics were chosen.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the laboratory failed to ensure the acceptable temperature range for refrigerators reflected the manufacturer's temperature requirements for the reagents stored in the refrigerators. Findings: 1. Direct observation by surveyor during the laboratory tour on October 7, 2020 at 10:00 am revealed the laboratory utilizes the following refrigerators: Kenmore Refrigerator "C" Kenmore Refrigerator "D" 2. Review of the laboratory's temperature logs for "Refrigerator C" and "Refrigerator D" revealed the laboratory utilizes "2C to 10C" as the acceptable temperature range. 3. Further direct observation by surveyor during laboratory tour on October 7, 2020 and review of manufacturers' storage requirements revealed the following reagents stored inside the refrigerators: a) Refrigerator C: Illumina AmpliSeq library equalizer: storage requirement 2-8 degrees Celsius AmPure XP: storage requirement 2-8 degrees Celsius Next Step High Output Flow Cell Cartridge v. 2.5: storage requirement 2-8 degrees Celsius b) Refrigerator D: Illumina AmpliSeq library equalizer: storage requirement 2-8 degrees Celsius Nextera DNA flex pre-environment: storage requirement 2-8 degrees Celsius 4. In interview on October 7, 2020 at 3:00 pm, the General Supervisor confirmed the laboratory's acceptable temperature range for refrigerators did not correspond with the reagents' storage requirements.
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 direct observation and interview with personnel, the laboratory failed to ensure reagents and supplies had not exceeded their expiration dates. Findings: 1. Direct observation by surveyor during laboratory tour at 10:00 am revealed the following expired items: AmpliSeq CD Indexes Set C, Lot 2023084, Expiration Date 2020-09-30, Quantity 1 plate Illumina HP3 2 N-NaOH, Lot 20351711, 200 uL tube, Expiration Date 2020/03/27, Quantity 1 tube AmpliSeq CD Indexes Set C, Lot 2023084, Expiration Date 2020-09-30, Quantity 6 plates AmpliSeq CD Indexes Set C,

	Lot 2037808, Expiration Date 2020-09-30, Quantity 8 plates 2. In interview on October 7, 2020 at 10:33 am, the General Supervisor stated the Illumina HP3 tube was from the validation and the identified plates were not in use. The General Supervisor confirmed the identified items were expired.
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 review of the laboratory's validation studies and interview with personnel, the laboratory failed to establish complete performance specifications for accuracy and specificity for Hereditary Cancer screening testing. Findings: 1. In interview on October 7, 2020 at 9:36 am, Technical Supervisor 1 stated the laboratory's initial validation in November 2019 was on dry swabs (Puritan Hydraflock). Technical Supervisor 1 stated the laboratory performed a bridging study comparing wet swabs (GenoTek OCD-100) to dry swabs, as wet swabs were utilized for the patient samples submitted. 2. Review of the laboratory's "NEXTSEQ VERIFICATION REPORT November 6, 2019" revealed the laboratory did not include the following information: a) Accuracy: reference laboratory's results to support accuracy claims b) Specificity (interfering substances): clinical reference utilized to support interfering substances claims 3. Review of the laboratory's "NEXTSEQ OCD-100 GENOTEK VALIDATION ADDENDUM May 10, 2020" revealed the laboratory performed accuracy and precision studies. 4. In interview on October 7, 2020 at 12:30 pm, Technical Supervisor 1 stated the laboratory did not have the reference laboratory's results for accuracy studies of the dry swabs. 5. In further interview on October 7, 2020 at 12:50 pm, Technical Supervisor 1 stated she did not know the clinical reference used for the interfering substances claim. 6. Review of the laboratory's patient final reports revealed the laboratory reported three (3) patient samples May 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of patient final reports and interview with personnel, the laboratory failed to include on the report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by Signify Laboratory, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration." Findings: 1. Review of the following three (3) patient final reports revealed the laboratory did not include the above disclaimer: Patient 200306101003 Patient 200306101004 Patient 200306101002 2. In interview on October 7, 2020 at 9:36 am, Technical Supervisor 1 stated the laboratory has tested three (3) patient samples since opening.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of patient final reports, policies and procedures, and interview with personnel, the laboratory failed to notify clients of testing delays per laboratory policy. Findings: 1. Review of the laboratory's "Turnaround Time of Genetic Tests" policy effective December 10, 2019, revealed the following: "For routine (daily) processing, the following turnaround time (TAT) guidelines apply: Hereditary Cancer Screening (CGx): Non-referred samples: 7-14 business days after the sample is delivered to the laboratory. NOTE: If, due to any circumstances, a delay in testing in inevitable and required TAT cannot be met, notify the appropriate personnel providing care to the patient. When results for certain tests are critically necessary for proper patient care, judgement must be exercised to determine alternatives." 2. Review of three (3) of three (3) patient final reports revealed the following testing delays: Patient 200306101003: Collection Date: 03/02/2020, Report Date: 05/19/2020 Patient 200306101004: Collection Date: 02/22/2020, Report Date: 05/19/2020 Patient 200306101002: Collection Date: 02/20/2020, Report Date: 05/19/2020 3. The laboratory did not have documentation that clients were notified regarding the delayed TAT. 4. In interview on October 7, 2020 at 9:56 am, Technical Supervisor 1 stated she did not notify clients of the delay. Technical Supervisor 2 stated she was told that clients were notified; however, she did not do the notification. Technical Supervisor 1 confirmed the laboratory did not have documentation that clients were notified of the delay.
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 direct observation, record review and interview with personnel, the

	Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to establish complete performance specifications for Hereditary Cancer screen testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable results. Refer to D6087. 3. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6093. 4. The Laboratory Director failed to ensure final reports included required pertinent information. Refer to D6098. 5. The Laboratory Director failed to ensure personal met state licensure and education requirements. Refer to D6102. 6. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D6103. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.
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 record review and interview with personnel, the Laboratory Director failed to establish complete performance specifications for Hereditary Cancer screen testing. Refer to D5423.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to verify the accuracy of the performance of Hereditary Cancer screening testing at least twice annually. Refer to D5217. 2. The laboratory failed to have a system for ensuring specimens for Hereditary Cancer screening maintained the manufacturer's temperature requirements during transport. Refer to D5311. 3. The laboratory failed to ensure the acceptable temperature range for refrigerators reflected the manufacturer's temperature requirements for the reagents stored in the refrigerators. Refer to D5413. 4. The laboratory failed to ensure reagents and supplies had not exceeded their expiration dates. Refer to D5417. 5. The laboratory failed to notify clients of testing delays per laboratory policy. Refer to D5815.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5403.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.
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 record review and interview with personnel, the Laboratory Director failed to ensure personal met state licensure and education requirements. Findings: 1. The laboratory failed to ensure two (2) of four (4) Technical Supervisors met education and state of Louisiana licensure requirements. Refer to D6111. 2. The laboratory failed to ensure two (2) of ten (10) testing personnel met state of Louisiana licensure requirements. Refer to D6170. 3. The laboratory failed to provide documentation that three (3) of ten (10) testing personnel met the educational qualification for performing high complexity testing. Refer to D6171.
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 maintained for assessing personnel

	competency. Findings: 1. The laboratory failed to have documentation of initial training for testing personnel per laboratory policy for five (5) of ten (10) testing personnel reviewed. Refer to D5209 I. 2. The laboratory failed to ensure two (2) of four (4) Technical Supervisors had documentation of competency assessment performed by Laboratory Director for their duties as Technical Supervisor. Refer to D5209 II.
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 policy and procedure manual review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.
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(s) failed to provide technical oversight for high complexity testing. Findings: 1. The laboratory failed to ensure two (2) of four (4) Technical Supervisors met education and state of Louisiana licensure requirements. Refer to D6111. 2. The Technical Supervisor(s) failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 3. The Technical Supervisor(s) failed to ensure the laboratory established complete performance specifications for Hereditary Cancer Screening. Refer to D6115. 4. The Technical Supervisor(s) failed to ensure that a quality control program was established to assure the quality of testing for Hereditary Cancer screening testing. Refer to D6117. 5. The Technical Supervisor(s) failed to have documentation of initial training/orientation for Testing Personnel per laboratory policy. Refer to D6120.
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 review of personnel records and interview with personnel, the laboratory failed to ensure two (2) of four (4) Technical Supervisors met education and state of Louisiana licensure requirements. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel previously served as Technical Supervisors: Technical Supervisor 3 (terminated February 26, 2020) Technical Supervisor 4 (terminated February 26, 2020) 2. Review of personnel records revealed no documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing and no documentation of education for the following Technical Supervisors: Technical Supervisor 3 Technical Supervisor 4 3. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated she did not know anything about Technical Supervisor 3 and Technical Supervisor 4. Technical Supervisor 2 confirmed the laboratory did not have the identified documents for Technical Supervisor 3 and Technical Supervisor 4.
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 personnel, the Technical Supervisor(s) failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to verify the accuracy of the performance of Hereditary Cancer screening testing at least twice annually. Refer to D5217. 2. The laboratory failed to have a system for ensuring specimens for Hereditary Cancer screening maintained the manufacturer's temperature requirements during transport. Refer to D5311. 3. The laboratory failed to have a complete proficiency testing policy. Refer to D5401. 4. The laboratory failed to ensure the acceptable temperature range for refrigerators reflected the manufacturer's temperature requirements for the reagents stored in the refrigerators. Refer to D5413. 5. The laboratory failed to ensure reagents and supplies had not exceeded their expiration dates. Refer to D5417. 6. The laboratory failed to notify clients of testing delays per laboratory policy. Refer to D5815.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures

	performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor(s) failed to ensure the laboratory established complete performance specifications for Hereditary Cancer Screening. Refer to D5423.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor(s) failed to ensure that a quality control program was established to assure the quality of testing for Hereditary Cancer screening testing. Refer to D5403.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor(s) failed to have documentation of initial training/orientation for Testing Personnel per laboratory policy. Refer to D5209 I.
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 review of personnel records and interview with personnel, the laboratory failed to ensure two (2) of ten (10) testing personnel met state of Louisiana licensure requirements. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel previously served as testing personnel: Technical Supervisor 3 (terminated February 26, 2020) Technical

	Supervisor 4 (terminated February 26, 2020) 2. In interview on October 7, 2020 at 1: 29 pm, Technical Supervisor 1 stated Technical Supervisor 3 and Technical Supervisor 4 were previously hired to perform data analysis. 3. Review of personnel records revealed no documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing for the following testing personnel: Technical Supervisor 3 Technical Supervisor 4 4. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated she did not know anything about Technical Supervisor 3 and Technical Supervisor 4. Technical Supervisor 2 confirmed the laboratory did not have the identified documents for Technical Supervisor 3 and Technical Supervisor 4.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

	control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation that three (3) of ten (10) testing personnel met the educational qualification for performing high complexity testing. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel previously served as testing personnel: Technical Supervisor 3 (terminated February 26, 2020) Technical Supervisor 4 (terminated February 26, 2020) Testing Personnel 5 (terminated September 27, 2019) 2. Review of personnel records revealed the laboratory did not maintain documentation of education for Technical Supervisor 3, Technical Supervisor 4, and Testing Personnel 5. 3. In interview on October 7, 2020 at 11:20 am, Technical Supervisor 2 stated Testing Personnel 5 was only at the laboratory for six (6) weeks. Technical Supervisor 2 confirmed the laboratory did not have documentation of education for Testing Personnel 5. 4. In interview on October 7, 2020 at 11:22 am, Technical Supervisor 2 stated she did not know anything about Technical Supervisor 3 and Technical Supervisor 4. Technical Supervisor 2 confirmed the laboratory did not have the identified documents for Technical Supervisor 3 and Technical Supervisor 4. 5. In interview on October 7, 2020 at 1:29 pm, Technical Supervisor 1 stated Technical Supervisor 3 and Technical Supervisor 4 were previously hired to perform data analysis.