Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0461975	(X3) Date Survey Completed 05/14/2021
Name of Provider or Supplier Allen Parish Hospital Lab	**Street Address, City, State** 108 6th Avenue, Kinder, 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	A Recertification survey was performed at Allen Parish Hospital, CLIA ID # 19D0461975, on May 10, 2021 through May 14, 2021. Allen Parish Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing, Technical Consultant 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing, Laboratory Director
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, proficiency testing records and interview with laboratory personnel, the laboratory failed to ensure that proficiency testing documents were signed by Testing Personnel for three (3) of fourteen (14) events reviewed. Findings: 1. Review of the laboratory's policy for Proficiency Testing (PT) revealed " The assigned testing personnel will also be required to sign and date the

	attestation statement. Attestation Statement will be signed by the Medical Director upon completion". 2. Review of the laboratory's 2019 American Proficiency Institute (API) proficiency testing (PT) records revealed the attestation statement was not signed by the Testing Personnel for the following events: a) 2019 Chemistry Miscellaneous 1st event b) 2019 Chemistry Core 2nd event c) 2019 Microbiology 2nd event 3. In interview on May 11, 2021 at 12:05 pm, Technical Consultant 2 confirmed that Testing Personnel did not sign attestation statements for the identified PT events. II. Based on review of laboratory policy and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to retain attestation statements and raw data for seven (7) of twenty six (26) proficiency testing events reviewed. Findings: 1. Review of the laboratory's policy for Proficiency Testing (PT) revealed "The assigned testing personnel will also be required to sign and date the attestation statement. Attestation Statement will be signed by the Medical Director upon completion. Copies of raw data, LIS data, and quality control data on day of testing MUST be remitted along with the PT paperwork to the Laboratory Manager to keep in the PT files". 2. Review of the laboratory's 2019 and 2020 American Proficiency Institute (API) proficiency testing records revealed the laboratory did not maintain copies of the attestation statements and/or raw data for the following seven (7) of twenty six (26) PT events reviewed: a) 2019 Chemistry Core 1st event: no attestation statement seen b) 2019 Chemistry Core 2nd event: no raw data seen c) 2019 Chemistry Miscellaneous 1st event: no raw data seen d) 2019 Hematology /Coagulation 1st event: no attestation statement or raw data seen e) 2019 Immunology /Immunohematology 1st event: no attestation statement seen f) 2019 Microbiology 1st event: no attestation statement seen g) 2020 Immunology/Immunohematology 3rd event: no attestation statement seen 3. In interview on May 11, 2021 at 12:05 pm, Technical Consultant 2 stated that the Laboratory Manager was informed that the above documents were missing from the PT binder in January of 2021. Technical Consultant 2 confirmed the above documents were not maintained as required.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-155D and American Proficiency Institute (API), the laboratory failed to successfully perform in

	proficiency testing as evidenced by: 1. The laboratory failed to achieve a satisfactory score for two of three Proficiency Testing events resulting in a non-initial unsuccessful performance in Compatibility Testing. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, Casper 155D report, and interview with personnel, the laboratory failed to achieve a satisfactory score for two (2) of three (3) Proficiency Testing events resulting in a non-initial unsuccessful performance in Compatibility Testing. Findings: 1. Review of the laboratory's Proficiency Testing (PT) records and the CMS 0155D report revealed the laboratory received the following scores for Compatibility Testing resulting in failure of two (2) out of three (3) events: a) 2020 Immunohematology Event 1 for Compatibility Testing: score of 80% b) 2020 Immunohematology Event 2 for Compatibility Testing: score of 100% c) 2020 Immunohematology Event 3 for Compatibility Testing: score of 80% 2. In interview on May 11, 2021 at 12:15 pm, Technical Consultant 2 confirmed the above events resulted in an unsuccessful performance.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control records, manufacturer's package inserts along with interview of laboratory personnel, the laboratory failed to retain raw data to support establishment of quality control means and ranges for the current lots of Chemistry quality controls. Findings: 1. Review of the laboratory's quality control (QC) records revealed the laboratory used the following BioRad QC materials for Chemistry testing: a) BioRad Liquid Unassayed Multiqual Level 1, Lot # 56661 Expiration 2/28/23 b) BioRad Liquid Unassayed Multiqual Level 3, Lot # 56663 Expiration 2/28/23 c) BioRad Liquichek Cardiac Marker Plus Level 1, Lot # 67611 Expiration 10/31/21 d) BioRad Liquichek Cardiac Marker Plus Level 3, Lot # 67613 Expiration 10/31/21 e) BioRad Liquichek Diabetes Level 1, Lot # 55731 Expiration 11/30/22 f) BioRad Liquichek Diabetes Level 3, Lot # 55733 Expiration 11/30/22 g) BioRad Liquichek Ethanol/Ammonia Level 1, Lot # 54341 Expiration 9/30/22 h) BioRad Liquichek Ethanol/Ammonia Level 3, Lot # 54343 Expiration 9/30/22 i) BioRad Liquichek Immunoassay Plus Level 1, Lot # 85241 Expiration 5/31/22 j) BioRad Liquichek Immunoassay Plus Level 3, Lot # 85243 Expiration 5/31/22 k) BioRad Liquichek Specialty Immunoassay Level 1, Lot # 60281 Expiration 6/30/22 l) BioRad Liquichek Specialty Immunoassay Level 3, Lot # 60283 Expiration 6/30/22 2. Review of the BioRad QC package inserts under "Assignment of Values" revealed "It is recommended that each laboratory establish its own acceptable ranges and use those

	provided only as guides". 3. Further review of the laboratory's quality control (QC) records revealed the laboratory used established ranges, not manufacturer ranges; however, the laboratory was unable to provide surveyor with QC data to support the laboratory's means and ranges of acceptability in use. 4. In interview on May 13, 2021 at 1:37 pm, Technical Consultant 2 confirmed the laboratory did not have supporting documentation of mean and range establishments for the above Chemistry QC lots in use.
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 the laboratory's personnel records and interview with personnel, the laboratory failed to follow written policy to assess competency for one (1) of four (4) General Supervisors. Findings: 1. Review of the laboratory's policy for competency assessment revealed the laboratory requires an annual competency for the duties and responsibilities of the General Supervisor. 2. Review of personnel records for General Supervisor 4 revealed no annual competency for 2020. 3. In interview on May 11, 2021 at 10:26 am, the Technical Consultant confirmed that documentation of an annual competency was not in the personnel records for General 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 review of proficiency testing results and interview with personnel, the laboratory failed to successfully verify the accuracy of Acetaminophen for three (3) of four (4) consecutive proficiency testing events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) results, the laboratory received the following scores in three of four events: a) 2020 Chemistry Core 1st event: score of 60% b) 2020 Chemistry Core 3rd event: score of 0% c) 2021 Chemistry Core 1st event: score of 60% 2. In interview on May 11, 2021 at 12:15 pm, Technical Consultant 2 confirmed the above scores for Proficiency Testing results.
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 observation by surveyor, 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 have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to perform platelet poor plasma checks every six (6) months as required by laboratory policy. Refer to D5401 II. 3. The laboratory failed to use normal donors to verify reference intervals and establish normal Prothrombin Time mean with each new lot of innovin as required by the manufacturer. Refer to D5411. 4. The laboratory failed to establish their own means and ranges for Siemens Dade Citrol Coagulation Level 1 Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469 I 5. The laboratory failed to establish their own means and ranges for Quality Control (QC) materials utilized for Chemistry testing. Refer to D5469 II. 6. The laboratory failed to take corrective action when one (1) of two (2) Quality Control (QC) values was unacceptable for Chemistry testing as required by laboratory policy. Refer to D5783 I. 7. The laboratory failed to ensure patient impact studies were reviewed by the laboratory director or manager as required by laboratory policy. Refer to D5783 II. 8. The laboratory failed to ensure their quality assessment (QA) program identified and corrected issues within the analytic system. Refer to D5793.
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: I. Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of policy and procedure manual revealed the laboratory did not include the following: a) Manual INR calculation check to include procedure and frequency of performance b) Laboratory Information System (LIS) validation procedure and frequency of performance 2. In interview on May 12, 2021 at 9:27 am, the Technical Consultant confirmed the laboratory's policy manual did not include the identified procedures. II. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to perform platelet poor plasma checks every six (6) months as required by laboratory policy. Findings: 1. Review of the laboratory's "Platelet Poor Plasma Study" policy revealed "Platelet Poor Plasma verification shall be performed at least every six months or as necessary when changes in centrifugation equipment are performed". 2. Review of the laboratory's platelet poor plasma records for 2020 revealed the laboratory performed the platelet poor plasma study on May 21, 2020; however, the laboratory did not have documentation of performance for platelet poor plasma check due in November 2020. 3. In interview on May 12, 2021 at 11:30 am, the Technical Consultant confirmed that the platelet poor plasma check was not performed as required by laboratory policy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of laboratory policy and manufacturer's package inserts, as well as interview with laboratory personnel, the laboratory failed to use normal donors to verify reference intervals and establish normal Prothrombin Time mean with each new lot of innovin as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on May 10, 2021 at 3:44 pm revealed the laboratory utilizes the Siemens Sysmex CA-660 analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the "Siemens Healthcare Diagnostics Sysmex CA-600 Series Verification of Reference Interval" insert revealed the following donor requirements: a) " Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) b) Donors should not take any medications, including aspirin c) Donors should span the adult age range. Note: A separate range should be established for pediatric populations) d) Testing should be performed over a period of several days and by different people if possible, to allow for day to day variation e) Samples should be drawn each testing day, following the established protocol for collection, storage and processing f) The test results from the donors should be analyzed statistically. Software that performs this calculation can be used." 3. Review of the laboratory's "Coagulation Reagent/QC Lot Roll-Over Procedure" revealed under "Verification of Reference Range" that twenty (20) normal individuals to include ten (10) males and ten (10) females, if possible spanning age ranges. Twenty (20) is the minimum requirement for a statistically valid study. NOTE: Each normal individual sample obtained must be accompanied by an acceptable Coagulation Normal Range Study Questionnaire. 4. Review of the laboratory's "Selection of Reference Individuals for Coagulation Studies" form revealed the following questions: a) Do you consider yourself to be healthy? YES____ NO_____ b) Are you taking any prescribed or over the counter medications that would affect your coagulation studies? Such as: Oral Contraceptives, Estrogen Therapy (HRT), Anticoagulants (Coumadin or Warfarin), Aspirin YES_____ NO_____ If yes, what? ____________________ 5. Review of the normal donor questionnaires utilized for the study revealed the following six (6) of nineteen (19) donors did not meet the accetable criteria per the manufacturer requirements: a) Donor 878519: taking Aspirin b) Donor 878524: do you consider yourself healthly? NO c) Donor 878542: taking Eliquis and Plavix d) Donor 878500: do you consider yourself healthy? no answer checked e) Donor 878513: taking Aspirin f) Donor 878528: do you consider yourself healthy? NO 6. In interview on May 12, 2021 at 10:20 am, General Supervisor 4 confirmed that the above donors should not have been utilized due to unacceptable criteria for normal donors. 7. Review of Task 1&3 form presented to surveyor revealed the laboratory performs 224 PT/INR tests annually.
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:
I. Based on observation, review of laboratory policy, quality control records and manufacturer package inserts as well as interview with laboratory personnel, the laboratory failed to establish their own means and ranges for Siemens Dade Citrol Coagulation Level 1 Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Findings: 1. Observation by surveyor during the laboratory tour on May 11, 2021 at 3:44 pm revealed the laboratory utilizes the Siemens Sysmex CA 660 analyzer for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) testing. 2. Review of the Dade Ci-Trol Coagulation Control package insert revealed "Since laboratory control materials are used for the effective monitoring of the performance of a coagulation test, each laboratory should establish its own level of performance to monitor quality assurance". 3. Review of the laboratory's Quality Control policy under "Establishing or Verifying QC Performance" revealed "Control limits should be set for analytes in new lot control materials. The mean/range will be established with a +/- 2SD (either historical SD or SD established with twenty point run used to establish acceptable range, with historical SD being the preferred method at Allen Parish Community Healthcare)". 4. Review of laboratory records for the Dade Citrol Coagulation controls revealed the last establishment of new lot of QC material was performed in June 2019 for the following: a) Dade Citrol Coagulation Control Level 1: Lot 564802 Expiration 6/23/22 b) Dade Citrol Coagulation Control Level 3: Lot 556515 Expiration 12/2/21 5. In interview on May 12, 2021 at 2:16 pm, General Supervisor 4 stated that the last establishment of new lots of Coagulation QC was from June 2019. General Supervisor 4 further stated that the laboratory was currently establishing a new lot of QC. 6. Review of the February 2021 QC records for Coagulation revealed the laboratory utilized a new lot of Dade Citrol Coagulation Control Level 1 (Lot 548094 Expiration 01/20/22) for PT testing and the old lot of Dade Citrol Coagulation Control Level 1 (Lot 564802 Expiration 6/23/22) for APTT testing. 7. Further review of the February 2021 QC records revealed the laboratory did not maintain any documentation to show new lot establishment for the Dade Citrol Coagulation control level 1 Lot 548094. 8. In interview on May 12, 2021 at 2:16 pm, General Supervisor 4 stated that there has not been a lot change for coagulation since June 2019. General Supervisor 4 further stated that she did not have an answer to why there was two (2) different QC level 1 lots in use for February 2021. 9. Review of the Task 1&3 form provided to surveyor revealed the laboratory performs 224 PT tests annually. II. Based on observation, review of laboratory policy, quality control records and manufacturer package inserts along with interview with laboratory personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) materials utilized for Chemistry testing. Findings: 1. Observation by surveyor during laboratory tour on May 10, 2021 at 3:44 pm revealed the laboratory utilizes the Siemens Dimension EXL analyzer for the following Chemistry tests and Quality Control (QC) materials to include: a) Amphetamine (AMPH), Barbituate (BARB), Benzodiazapine (BENZO), Cocaine (COC), Methamphetamine (METH), Opiate (OPI), Phencyclidine (PCP), Tetrahydrocannabinol (THC), Acetominaphen

	(ACTM), High Density Lipoprotein (HDL), Albumin (ALB), Alkaline Phosphatase (ALP), Amylase (AMY), Alanine Transaminase (ALT), Aspartate Transaminase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Cholesterol (CHOL), Creatine Kinase (CK), Carbamazapine (CRBM), Creatinine (CREA), Direct Bilirubin (DBIL), Digoxin (DIG), Carbon Dioxide (CO2), Alcohol (ETOH), Folate (FOLA), Free Thyroxine (FT4), Glucose (GLUC), Lactic Acid (LA), Lipase (LIP), Lithium (LI), Creatine Kinase-MB (CKMB), B-Type Natriuretic Peptide (BNP), Magnesium (MG), Phosphorus (PHOS), Dilantin (PTN), Salicylates (SAL), Total Bilirubin (TBIL), Triglyceride (TRIG), Troponin (TROP), Total Prostate Specific Antigen (TPSA), Thyroid Stimulating Hormone (TSH), Uric Acid (UA), Valproic Acid (VALP), Vancomycin (VANC), Vitamin B12 (VIT B12), Vitamin D (VIT D), Sodium (NA), Potassium (K), Chloride (CL) B) BioRad Multiqual Unassayed Control: Lot 56660 Expiration 2/28/23; BioRad Liquichek Cardiac Markers Control: Lot 67610 Expiration 10/31/21; BioRad Liquichek Diabetes Control: Lot 55730 Expiration 11/30 /22; BioRad Liquichek Ethanol/Ammonia Control: Lot 54340 Expiration 9/30/22; BioRad Liquichek Immunoassay Plus Control: Lot 85240 Expiration 5/31/22; BioRad Liquichek Specialty Immunoassay Control: Lot 60280 Expiration 6/30/22 2. Review of the BioRad QC package inserts under "Assignment of Values" revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides". 3. Review of the Laboratory Quality Control policy under "Setting Target Values" revealed "To establish target values, the new lots of control material must be analyzed for each analyte in parallel with the control material currently in use. Ideally, at least twenty (20) runs will give a reasonable estimate of the target value mean". 4. Review of the laboratory's QC establishment records revealed the laboratory utilizes the Unity Manufacturer Report for Siemens for setting acceptable mean and ranges for BioRad QC material. 5. In interview on May 13, 2021 at 1:37 pm, General Supervisor 4 stated that she consults with the Siemens field service representative when establishing and adjusting the BioRad QC materials means and ranges. 6. In further interview on May13, 2021 at 2:00 pm, Technical Consultant 2 confirmed the laboratory did not establish their own means and ranges for the above QC material.
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: I. Based on observation, review of the laboratory's policies and quality control records along with interview with laboratory personnel, the laboratory failed to take corrective action when one (1) of two (2) Quality Control (QC) values was unacceptable for Chemistry testing as required by laboratory policy. Findings: 1. Observation by surveyor during the laboratory tour on May 10, 2021 at 3:44 pm revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer for the following Chemistry tests to include: a) Amphetamine (AMPH), Barbituate (BARB), Benzodiazapine (BENZO), Cocaine (COC), Methamphetamine (METH), Opiate

(OPI), Phencyclidine (PCP), Tetrahydrocannabinol (THC), Acetominaphen (ACTM), High Density Lipoprotein (HDL), Albumin (ALB), Alkaline Phosphatase (ALP), Amylase (AMY), Alanine Transaminase (ALT), Aspartate Transaminase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Cholesterol (CHOL), Creatine Kinase (CK), Carbamazapine (CRBM), Creatinine (CREA), Direct Bilirubin (DBIL), Digoxin (DIG), Carbon Dioxide (CO2), Alcohol (ETOH), Folate (FOLA), Free Thyroxine (FT4), Glucose (GLUC), Lactic Acid (LA), Lipase (LIP), Lithium (LI), Creatine Kinase-MB (CKMB), B-Type Natriuretic Peptide (BNP), Magnesium (MG), Phosphorus (PHOS), Dilantin (PTN), Salicylates (SAL), Total Bilirubin (TBIL), Triglyceride (TRIG), Troponin (TROP), Total Prostate Specific Antigen (TPSA), Thyroid Stimulating Hormone (TSH), Uric Acid (UA), Valproic Acid (VALP), Vancomycin (VANC), Vitamin B12 (VIT B12), Vitamin D (VIT D), Sodium (NA), Potassium (K), Chloride (CL) 2. Review of the Laboratory Quality Control policy revealed "Chemistry - Dimension: Performed each day of patient testing for every analyte available on the analyzer. QC is good for twenty-four (24) hours. Patient testing may be performed anytime within the twenty-four (24) hour period". 3. Further review of the Laboratory Quality Control policy revealed "If an out-of-control situation arises, the testing personnel are to follow the 'Trouble Shooting Out Of Range QC' for out of range controls and document all corrective action on the QC Corrective Action Log. Patient results are reported only after quality control is verified to be within acceptable limits". 4. Review of the laboratory's "Trouble Shooting Out of Range QC" policy revealed when a QC analysis is found to be outside established limits, a systematic effort should be made to resolve the problem. The following steps should be followed for this purpose: a) Perform QC analysis again using the same control material b) If QC falls in an "out of control" situation again, either re-pour/reconstitute the QC material or open a new vial of QC material (depending on the quantity remaining in the vial) NOTE: If corrective action requires proceeding to steps 3 and/or 4, a patient impact study will be required. c) Open a "new well" on the reagent pack or place a new reagent pack on the analyzer, if applicable d) Calibrate the analyte. If the test values are still unacceptable, notify the Laboratory Manager 5. Review of Quality Control (QC) records for August 2020 revealed the laboratory did not take corrective action as required by laboratory policy for the following: a) On August 5, 2020 at 4:26 am, Acetaminophen (ACTM) Serum QC1 reported two (2) separate results as * 16.7 ug/ml which is acceptable (acceptable range of 15.8 - 20.6 ug/ml) * 23.7 ug/ml which is unacceptable (acceptable range of 15.8 - 20.6 ug/ml) b) On August 5, 2020 at 4:35 am, Acetaminophen (ACTM) Serum QC3 reported two (2) separate results as * 112.1 ug/ml which is acceptable (acceptable range of 110.0 - 118.6 ug/ml) * 120.6 ug/ml which is unacceptable (acceptable range of 110.0 - 118.6 ug/ml) c) On August 14, 2020 at 4:14 am, Prostate Specific Antigen (PSA) Serum QC1 reported two (2) separate results as * 0.29 ng/ml which is acceptable (acceptable range of 0.19 - 0.31 ng/ml) * 0.31 ng/ml which is unacceptable (acceptable range of 0.19 - 0.31 ng/ml) d) On August 20, 2020 at 5:35 am, Prostate Specific Antigen (PSA) Serum QC1 reported two (2) separate results as * 0.29 ng/ml which is acceptable (acceptable range of 0.19 - 0.31 ng/ml) * 0.32 ng/ml which is unacceptable (acceptable range of 0.19 - 0.31 ng/ml) e) On August 20, 2020 at 5:41 am, Prostate Specific Antigen (PSA) Serum QC3 reported two (2) separate results as * 17.03 ng/ml which is acceptable (acceptable range of 16.25 - 19.69 ng/ml) * 15.97 ng /ml which is unacceptable (acceptable range of 16.2 - 19.69 ng/ml) 6. In interview on May 13, 2020 at 1:37 pm, General Supervisor 4 stated she thought when two (2) results for the same test were resulted on QC printouts that testing personnel had rerun the test and it was acceptable. General Supervisor 4 further stated she did not know that the analyzer does not result two (2) QC results for an analyte at the same time and there were separate reagents on the analyzer. 7. In interview on May 13, 2020 at 1:37

pm, Technical Consultant 2 confirmed the above dates with unacceptable QC did not have corrective action performed. II. Based on review of the laboratory's policy manual, quality control (QC) records, as well as interview with laboratory personnel, the laboratory failed to ensure patient impact studies were reviewed by the laboratory director or manager as required by laboratory policy. Findings: 1. Review of the laboratory quality control policy under "Criteria for Calibration and/or QC Performance" revealed calibration and/or QC performance is required upon opening new lots of reagents and same lot with a different received date. Repeat calibration may be required when indicated by QC data, system manufacturer recommendation, or after a major maintenance/service event on an instrument. QC must be analyzed and verified as acceptable after calibration prior to patient testing. If an out-of-control situation arises, the testing personnel are to follow the "Trouble Shooting Out Of Range QC" section of this policy and document all corrective action on the "QC corrective action Log". Patient results are reported only after quality control is verified to be within acceptable limits. All incidents in which patient results have been affected will be reviewed immediately by the Laboratory Manager with Laboratory Director consultation, if applicable. 2. Review of the "Trouble Shooting Out Of Range QC" policy revealed when a QC analysis is found to be outside established limits, a systematic effort should be made to resolve the problem. The following steps should be followed for this purpose: a) Perform QC analysis again using the same control material b) If QC falls in an "out of control" situation again, either re-pour/reconstitute the QC material or open a new vial of QC material (depending on the quantity remaining in the vial) NOTE: If corrective action requires proceeding to steps c and/or d, a patient impact study will be required c) Open a "new well" on the reagent pack or place a new reagent pack on the analyzer, if applicable d) Calibrate the analyte. If the test values are still unacceptable, notify the Laboratory Manager 3. Review of the laboratory's QC records for January 2021 revealed the laboratory did follow the calibration and/or QC policy and performed a patient impact study; however, the Laboratory Manager and/or the Laboratory Director did not immediately review the patient impact studies performed for the following: a) Calibrated Triglyceride (TRIG) on January 4, 2021: Patient impact study performed on following patients with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879110 * Patient 879157 * Patient 879160 * Patient 879164 * Patient 879166 * Patient 879168 * Patient 879174 * Patient 879175 * Patient 879182 b) Calibrated Alcohol (ETOH) on January 5, 2021: Patient impact study performed on following patients with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879255 c) Opened new QC bottle and reran Salicylate (SAL) on January 5, 2021: Patient impact study performed on following patients with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879255 d) Calibrated Cholesterol (CHOL) on January 6, 2021: Patient impact study performed on following patients with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879133 * Patient 879290 e) Calibrated Free Thyroxine (FT4) on January 13, 2021: Patient impact study performed on following patients from January 14, 2021 through January 15, 2021 with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879509 * Patient 879401 * Patient 879436 * Patient 879545 * Patient 879571 f) Calibrated Thyroid Stimulating Hormone (TSH) on January 13, 2021: Patient impact study performed on following patients from January 14, 2021 through January 15, 2021 with no Laboratory Manager/Laboratory Director documentation of patient review: * Patient 879390 * Patient 879400 * Patient 879509 * Patient 879516 * Patient 879528 * Patient 879383 * Patient 879394 * Patient 879401 * Patient 879418 * Patient 879445 * Patient 879503 * Patient 879533 * Patient 879335 * Patient 879361 * Patient 879367 * Patient 879366 * Patient 879373 * Patient 879389 *

	Patient 879417 * Patient 879416 * Patient 879427 * Patient 879433 * Patient 879434 * Patient 879436 * Patient 879440 * Patient 879448 * Patient 879451 * Patient 879460 * Patient 879458 * Patient 879504 * Patient 879532 * Patient 879540 * Patient 879543 * Patient 879545 * Patient 879547 * Patient 879548 * Patient 879550 * Patient 879555 * Patient 879557 * Patient 879558 * Patient 879560 * Patient 879571 * Patient 879575 g) Calibrated Calcium (CA) on January 17, 2021: Patient impact study performed on following patients with no Laboratory Manager /Laboratory Director documentation of patient review: * Patient 879579 * Patient 879612 * Patient 879322 * Patient 879181 * Patient 879579 * Patient 879583 * Patient 879584 * Patient 879585 * Patient 879591 * Patient 879581 * Patient 879588 * Patient 879593 * Patient 879594 * Patient 879595 * Patient 879599 * Patient 879600 * Patient 879602 * Patient 879605 * Patient 879603 * Patient 879610 * Patient 879611 4. In interview on May 13, 2021 at 1:37 pm, Technical Supervisor 2 confirmed the Laboratory Manager and/or the Laboratory Director did not review the above patient impact studies per laboratory policy.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment forms, and interview with personnel, the laboratory failed to ensure their quality assessment (QA) program identified and corrected issues within the analytic system. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to perform platelet poor plasma checks every six (6) months as required by laboratory policy. Refer to D5401 II. 3. The laboratory failed to use normal donors to verify reference intervals and establish normal Prothrombin Time mean with each new lot of innovin as required by the manufacturer. Refer to D5411. 4. The laboratory failed to establish their own means and ranges for Siemens Dade Citrol Coagulation Level 1 Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469 I 5. The laboratory failed to establish their own means and ranges for Quality Control (QC) materials utilized for Chemistry testing. Refer to D5469 II. 6. The laboratory failed to take corrective action when one (1) of two (2) Quality Control (QC) values was unacceptable for Chemistry testing as required by laboratory policy. Refer to D5783 I. 7. The laboratory failed to ensure patient impact studies were reviewed by the laboratory director or manager as required by laboratory policy. Refer to D5783 II.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 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 ensure laboratory personnel performed testing as required. Refer to D6014. 2. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6016 3. The Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 4. The Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D6019. 5. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 6. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 76. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D6024. 8. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030. 9. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) 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 testing as required. Findings: 1. The laboratory failed to use normal donors to verify reference intervals and establish normal Prothrombin Time mean with each new lot of innovin as required by the manufacturer. Refer to D5411.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed

	to successfully verify the accuracy of Acetaminophen for three (3) of four (4) consecutive proficiency testing events reviewed. Refer to D5217.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. The laboratory failed to ensure that proficiency testing documents were signed by Testing Personnel for three (3) of fourteen (14) events reviewed. Refer to D2015 I. 2. The laboratory failed to retain attestation statements and raw data for seven (7) of twenty six (26) proficiency testing events reviewed. Refer to D2015 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to establish their own means and ranges for Siemens Dade Citrol Coagulation Level 1 Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469 I 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) materials utilized for Chemistry testing. Refer to D5469 II.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to ensure their quality assessment (QA) program identified and corrected issues within the analytic system. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Findings: 1. The laboratory failed to take corrective action when one (1) of two (2) Quality Control (QC) values was unacceptable for Chemistry testing as required by laboratory policy. Refer to D5783 I. 2. The laboratory failed to ensure patient impact studies were reviewed by the laboratory director or manager as required by laboratory policy. Refer to D5783 II.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 for assessing personnel competency were established and maintained. Findings: 1. The Technical Consultant failed to evaluate and document the performance of individual at least semi-annually duing the first year

	for one (1) of eleven (11) testing personnel reviewed. Refer to D6053. 2. The Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of eleven (11) testing personnel reviewed. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to perform platelet poor plasma checks every six (6) months as required by laboratory policy. Refer to D5401 II.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure participation in an HHS approved proficiency testing program. Refer to D6041 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. D6044. 5. The Technical Consultant failed to evaluate and document the performance of individual at least semi-annually during the first year for one (1) of eleven (11) testing personnel reviewed. Refer to D6053. 6. The Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of eleven (11) testing personnel reviewed. Refer to D6054.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform platelet poor plasma checks every six (6) months as required by laboratory policy. Refer to D5401 II. 2. The laboratory failed to use normal donors to verify reference intervals and establish normal Prothrombin Time mean with each new lot of innovin as required by the manufacturer. Refer to D5411.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure participation in an HHS approved proficiency testing program. Findings: 1. The laboratory failed to successfully verify the accuracy of Acetaminophen for three (3) of four (4) consecutive proficiency testing events reviewed. Refer to D5217.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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 observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish their own means and ranges for Siemens Dade Citrol Coagulation Level 1 Quality Control (QC) material utilized for Prothrombin Time (PT) testing. Refer to D5469 I 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) materials utilized for Chemistry testing. Refer to D5469 II.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the

	laboratory's policies occurred. Findings: 1. The laboratory failed to take corrective action when one (1) of two (2) Quality Control (QC) values was unacceptable for Chemistry testing as required by laboratory policy. Refer to D5783 I. 2. The laboratory failed to ensure patient impact studies were reviewed by the laboratory director or manager as required by laboratory policy. Refer to D5783 II.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individual at least semi-annually during the first year for one (1) of eleven (11) testing personnel reviewed. Findings: 1. Review of personnel records for Personnel 6 on May 11, 2021 at 9:00 am revealed an initial training performed prior to patient testing on 12/31/2019. Further review of personnel records for Personnel 6 revealed no documentation of a semi-annual assessment or an evaluation of testing had been performed. 2. In interview on May 11, 2021 at 10:26 am, the Technical Consultant confirmed that there was no documentation of a semi-annual evaluation for Personnel 6.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of eleven (11) testing personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of personnel records for Personnel 6 revealed documentation of a competency assessment being performed with Personnel 6's signature and date on the form for September 29, 2020; however, the competency assessment was not signed or dated by the Technical Consultant or the Laboratory Director. 3. In interview on May 11, 2021 at 10:26 am, the Technical Consultant confirmed the above documentation was not completed as required.
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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D6092. 2. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D6103.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Findings: 1. The laboratory failed to achieve a satisfactory score for two of three Proficiency Testing events resulting in a non-initial unsuccessful performance in Compatibility Testing. Refer to D2181.
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 follow written policy to assess competency for one (1) of four (4) General Supervisors. Refer to D5209