Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461133	12/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Acadia-St Landry Hospital Pathology	810 South Broadway Street, Church Point, 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 CERTIFICATION SURVEY was performed at Acadia St Landry Hospital - Pathology - CLIA # 19D0461133 on December 3, 2018 through December 7, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation, record review, and interview with personnel, the laboratory failed to ensure patient samples for Routine Chemistry, General Immunology, and Endocrinology testing are processed according to Becton Dickinson Vacutainer Blood Collection System package instructions. Findings: 1. Observation by surveyor during the laboratory tour on December 3, 2018 revealed the laboratory utilized the Becton Dickinson (BD) Vacutainer Blood Collection Tubes for the collection of patient samples. 2. In interview on December 4, 2018 at 11:03 am, the laboratory assistant stated she receives the patient samples whether by collection or from an outside facility and then processes the physician's orders. The laboratory assistant further stated the collection time and the time spun are documented on the "ASLH SPIN DOWN LOG" along with a patient label which has the specific tests ordered. 3. Observation by surveyor revealed the laboratory received a yellow BD Vacutainer Serum Separator Blood Collection tube with the time collected documented on the "ASLH SPIN DOWN LOG" as 10:45 am and the time spun as 11:07 am with sample

being tested for a Basic Metabolic Panel (Basic Metabolic Panel includes Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, and Calcium) 4. Review of the BD Diagnostics-Preanalytical Systems package insert revealed "The minimum recommended clotting time for BD Vacutainer Serum Separator Tubes for patients without anticoagulant is 30 minutes". 5. In interview on December 4, 2018 at 11:19 am, Personnel 2 stated the laboratory does not document whether a serum or plasma specimen is received for patient testing. 6. Review of the laboratory's ASLH SPIN DOWN LOG for eight (8) days revealed the following fifty five (55) of ninety seven (97) patients with no documentation of specimen type received: October 2, 2018 a) Patient 5: Time Collected 07:38 - Time Spun 07:41 for Comprehensive Metabolic Panel testing (clotting time of three (3) minutes which is twenty seven (27) minutes less than the recommended clotting time) b) Patient 7: Time Collected 08:00 - Time spun 08:10 for Prostate Specific Ag (Clotting time of ten (10) minutes which is twenty (20) minutes less than the recommended clotting time) c) Patient 8: Time Collected 08:15 - Time Spun 08:20 for Basic Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) d) Patient 9: Time Collected 08:58 - Time Spun 09:00 for Lipid Panel (Clotting time of two (2) minutes which is twenty eight (28) minutes less than the recommended clotting time) e) Patient 15: Time Collected 11:47 - Time Spun 12:10 for Basic Metabolic Panel (Clotting time of twenty three (23) minutes which is seven (7) minutes less than the recommended clotting time) f) Patient 16: Time Collected 14:10 - Time Spun 14:16 for Thyroid Panel (Clotting time of six (6) minutes which is twenty four(24) minutes less than the recommended clotting time) October 29, 2018 g) Patient 18: Time Collected 13:32 - Time Spun 13:42 for Prealbumin (Clotting time of ten (10) minutes which is twenty (20) minutes less than the recommended clotting time) h) Patient 21: Time Collected 19:00 - Time Spun 19: 05 for Basic Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) October 30, 2018 i) Patient 22: Time Collected 03:30 - Time Spun 03:35 for Vancomycin (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) j) Patient 28: Time Collected 05:30 - Time Spun 05:36 for Prealbumin (Clotting time of six (6) minutes which is twenty four (24) minutes less than the recommended clotting time) k) Patient 29: Time Collected 05:29 - Time Spun 05:36 for Prealbumin (Clotting time of seven (7) minutes which is twenty three (23) minutes less than the recommended clotting time) l) Patient 30: Time Collected 07:00 - Time Spun 07:07 for Comprehensive Metabolic Panel (Clotting time of seven (7) minutes which is twenty three (23) minutes less than the recommended clotting time) m) Patient 31: Time Collected 07:33 - Time Spun 07:34 for Comprehensive Metabolic Panel (Clotting time of one (1) minute which is twenty nine (29) minutes less than the recommended clotting time) n) Patient 33: Time Collected 08:15 - Time Spun 08:15 for Prostate Specific Ag (Clotting time of zero (0) minutes which is thirty (30) minutes less than the recommended clotting time) November 19, 2018 o) Patient 36: Time Collected 10:20 - Time Spun 10:33 for Lipid Panel (Clotting time of thirteen (13) minutes which is seventeen (17) minutes less than the recommended clotting time) p) Patient 37: Time Collected 10:25 - Time Spun 10:33 for Thyroid Panel (Clotting time of eight (8) minutes which is twenty two (22) minutes less than the recommended clotting time) q) Patient 38: Time Collected 10:30 - Time Spun 10:33 for Thyroid Panel (Clotting time of three (3) minutes which is twenty seven (27) minutes less than the recommended clotting time) r) Patient 39: Time Collected 10:40 - Time Spun 10:44 for Thyroid Stimulating Hormone (Clotting time of four (4) minutes which is twenty six (26) minutes less than the recommended clotting time) s) Patient 43: Time Collected 11:45 - Time Spun 11:50 for Thyroid Stimulating Hormone (Clotting time of five (5) minutes which is twenty five (25) minutes less

than the recommended clotting time) t) Patient 45: Time Collected 11:50 - Time Spun 11:55 for Comprehensive Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) u) Patient 46: Time Collected 10:35 - Time Spun 11:00 for Basic Metabolic Panel (Clotting time of twenty five (25) minutes which is five (5) minutes less than the recommended clotting time) v) Patient 47: Time Collected 10:40 - Time Spun 11:00 for C-Reactive Protein (Clotting time of twenty (20) minutes which is ten (10) minutes less than the recommended clotting time) w) Patient 48: Time Collected 12:05 - Time Spun 12:10 for Basic Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) x) Patient 50: Time Collected 13:10 - Time Spun 13:19 for Basic Metabolic Panel (Clotting time of nine (9) minutes which is twenty one (21) minutes less than the recommended clotting time) y) Patient 51: Time Collected 13:02 - Time Spun 13:15 for Thyroid Panel (Clotting time of thirteen (13) minutes which is seventeen (17) minutes less than the recommended clotting time) z) Patient 52: Time Collected 16:10 - Time Spun 16:15 for Comprehensive Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) aa) Patient 53: Time Collected 18:50 - Time Spun 18:52 for Cardiac Enzymes (Clotting time of two (2) minutes which is twenty eight (28) minutes less than the recommended clotting time) bb) Patient 56: Time Collected 12:40 - Time Spun 12:44 for T3 Free (Clotting time of four (4) minutes which is twenty six (26) minutes less than the recommended clotting time) cc) Patient 59: Time Collected 14:00 - Time Spun 14:21 for Comprehensive Metabolic Panel (Clotting time of twenty one (21) minutes which is nine (9) minutes less than the recommended clotting time) dd) Patient 60: Time Collected 14:40 - Time Spun 14:45 for Basic Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) ee) Patient 61: Time Collected 14:40 - Time Spun 14:45 for Comprehensive Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) ff) Patient 62: Time Collected 20:10 - Time Spun 20:15 for Cardiac Enzymes (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) gg) Patient 61: Time Collected 14: 40 - Time Spun 14:45 for Comprehensive Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) November 2, 2018 hh) Patient 65: Time Collected 05:30 - Time Spun 05:38 for Prealbumin (Clotting time of eight (8) minutes which is twenty two (22) minutes less than the recommended clotting time) ii) Patient 66: Time Collected 05:00 - Time Spun 05:38 for Basic Metabolic Panel (Clotting time of eight (8) minutes which is twenty two (22) minutes less than the recommended clotting time) jj) Patient 67: Time Collected 05:25 - Time Spun 05:38 for Basic Metabolic Panel (Clotting time of thirteen (13) minutes which is seventeen (17) minutes less than the recommended clotting time) kk) Patient 73: Time Collected 05:20 - Time Spun 05:38 for Basic Metabolic Panel (Clotting time of eighteen (18) minutes which is twelve (12) minutes less than the recommended clotting time) November 14, 2018 ll) Patient 74: Time Collected 08:34 - Time Spun 08:44 for Comprehensive Metabolic Panel (Clotting time of ten (10) minutes which is twenty (20) minutes less than the recommended clotting time) mm) Patient 75: Time Collected 08:05 - Time Spun 08:10 for Digoxin Level (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) nn) Patient 76: Time Collected 10:30 - Time Spun 10: 38 for Lipid Panel (Clotting time of eight (8) minutes which is twenty two (22) minutes less than the recommended clotting time) oo) Patient 78: Time Collected 12: 00 - Time Spun 12:15 for Basic Metabolic Panel (Clotting time of fifteen (15) minutes which is fifteen (15) minutes less than the recommended clotting time) pp) Patient 79: Time Collected 14:20 - Time Spun 14:22 for T3 Free (Clotting time of two (2)

	minutes which is twenty eight (28) minutes less than the recommended clotting time) November 15, 2018 qq) Patient 83: Time Collected 06:15 - Time Spun 06:30 for Comprehensive Metabolic Panel (Clotting time of fifteen (15) minutes which is fifteen (15) minutes less than the recommended clotting time) rr) Patient 86: Time Collected 07:17 - Time Spun 07:20 for Comprehensive Metabolic Panel (Clotting time of three (3) minutes which is twenty seven (27) minutes less than the recommended clotting time) ss) Patient 87: Time Collected 08:40 - Time Spun 08:45 for Free T4 (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) tt) Patient 88: Time Collected 09:25 - Time Spun 09:30 for Comprehensive Metabolic Panel (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) uu) Patient 89: Time Collected 09:50 - Time Spun 09:58 for Prostate Specific Ag (Clotting time of eight (8) minutes which is twenty two (22) minutes less than the recommended clotting time) vv) Patient 90: Time Collected 09:55 - Time Spun 09:58 for Thryoid Panel (Clotting time of three (3) minutes which is twenty seven (27) minutes less than the recommended clotting time) ww) Patient 91: Time Collected 10: 55 - Time Spun 10:58 for Comprehensive Metabolic Panel (Clotting time of three (3) minutes which is twenty seven (27) minutes less than the recommended clotting time) December 4, 2018 xx) Patient 92: Time Collected 09:20 - Time Spun 09:25 for Vitamin D 25 OH (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) yy) Patient 93: Time Collected 09:58 - Time Spun 10:00 for Lipid Panel (Clotting time of two (2) minutes which is twenty eight (28) minutes less than the recommended clotting time) zz) Patient 94: Time Collected 10:20 - Time Spun 10:25 for Phosphorus Serum (Clotting time of five (5) minutes which is twenty five (25) minutes less than the recommended clotting time) aaa) Patient 95: Time Collected 10:45 - Time Spun 11:07 for Basic Metabolic Panel (Clotting time of twenty two (22) minutes which is eight (8) minutes less than the recommended clotting time) bbb) Patient 96: Time Collected 10:50 - Time Spun 11: 00 for Lipid Panel (Clotting time of ten (10) minutes which is twenty (20) minutes less than the recommended clotting time) ccc) Patient 97: Time Collected 11:23 - Time Spun 11:30 for Comprehensive Metabolic Panel (Clotting time of seven (7) minutes which is twenty three (23) minutes less than the recommended clotting time) 7. In interview on December 4, 2018 at 11:19 am, Personnel 2 confirmed the laboratory could not verify the above patients were processed according to the manufacturer's instructions.
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 detailed, written policy and procedure for addressing flags on Complete Blood Count reports. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for detailing the actions to be taken for Complete Blood Counts (CBC) with suspect, definitive and system flags reflecting that of the manufacturer requirements. 2. In interview on December 6, 2018 at 3:50 pm, Personnel 2 stated the laboratory follows the Sysmex XS-1000i Automated

Hematology Analyzer Quick Guide which contains the manufacturer's instructions for flag criteria. 3. Review of the Sysmex XS-1000i Quick Guide revealed the manufacturer's instructions for the following: WBC FLAGS a) Flag:WBC ABN Scattergram; Cause: WBC Abnormal Scattergram; Possible Action: Perform Manual Differential b) Flag: Neutropenia; Cause: Low neutrophil count; Possible Action: Review manual smear c) Flag: Neutrophilia; Cause: High neutrophil count; Possible Action: Review manual smear d) Flag: Lymphopenia; Cause: Low lymphocyte count; Possible Action: Review manual smear e) Flag: Lymphocytosis; Cause: High lymphocyte count; Possible Action: Review manual smear f) Flag: Monocytosis; Cause: High monocyte count; Possible Action: Review manual smear g) Flag: Eosinophilia; Cause: High eosinphil count; Possible Action: Review manual smear h) Flag: Basophila; Cause: High basophil count; Possible Action: Review manual smear i) Flag: Leukocytopenia; Cause: Low leukocyte (WBC) count; Possible Action: Review manual smear j) Flag: Leukocytosis; Cause: High leukocyte (WBC) count; Possible Action: Review manual smear k) Flag: Basts?; Cause: Presence of blasts possible; Possible Action: Perform manual differential m) Flag: Immature Gran?; Cause: Presence of immature granulocytes possible; Possible Action: Perform manual differential n) Flag: Left Shift?; Cause: Presence of "band" granulocytes possible; Possible Action: Perform manual differential o) Flag: Abn Lympho/Blasts?; Cause: Presence of atypical lymphoctes and/or blast possible; Possible Action: Perform manual differential p) Flag: NRBC?; Cause: Presence of nucleated RBC's possible; Possible Action: Verify presence on slide, correct WBC count if necessary q) Flag: Atypical Lymphocyte; Cause: Presence of atypical lymphocytes possible; Possible Action: Perform manual differential RBC FLAGS a) Flag: RBC ABN Distribution; Cause: Interfering particles in RBC histogram, i.e. Schistocytes, large platelets, platelet clumps, RBC clumps; Possible Action: Verify presence on slide. If RBC or platelet clumps present recollect sample if possible. b) Flag: Dimorphic population; Cause: Two different RBC sizes present in sample; Possible Action: Verify RBC morphology c) Flag: Anisocytosis; Cause: RDW CV and/or out of defined range. Multiple sizes of RBCs in sample; Possible Action: Verify RBC morphology d) Flag: Microcytosis; Cause: MCV lower limit range exceeded. Presence of small RBCs; Possible Action: Verify RBC morphology e) Flag: Hypochromia; Cause: MCHC lower limits exceeded; Possible Action: Verify RBC morphology f) Flag: Anemia; Cause: Hemoglobin lower limit exceeded; Possible Action: Verify RBC morphology g) Flag: Erythrocytosis; Cause: RBC upper limit exceeded; Possible Action: Verify RBC morphology h) Flag: RBC Agglutination?; Cause: Possible RBC or Platelet Clumps; Possible Action: Verify RBC morphology. Recollect sample if present. i) Flag: Turbidity/HGB Interference?; Cause: MCHC >36.5; Possible Action: Check sample for interfering substances, i.e. lipemia, icterus, cold agglutinin, and clotted sample. j) Flag: Iron Deficiency?; Cause: Sample Characteristic of iron deficiency anemia; Possible Action: Verify RBC morphology k) Flag: HGB Defect?; Cause: Sample characteristic of hemoglobin defect; Possible Action: Verify RBC morphology m) Flag: Fragments?; Cause: Presence of fragmented RBC's or large, Clumped platelets possible; Possible Action: Verify RBC morphology. If clumped platelets are present, recollect sample if possible. PLT FLAGS a) Flag: PLT Abn. Distribution; Cause: Presence of interfering particles in PLT histogram, i.e. Clumped platelets, fragmented RBC's or microcytic RBC's; Possible Action: Verify presence on slide. If RBC or platelet clumps present recollect sample if possible. Perform PLT estimate to confirm count. b) Flag: Thrombocytopenia; Cause: Low platelet count; Possible Action: Verify on slide. c) Flag: Thrombocytosis; Cause: High platelet count; Possible Action: Verify on slide d) Flag: PLT Clumps?; Cause: Presence of platelet clumps possible, specifically in Diff scattergrams; Possible Action: Verify on slide. Recollect sample if present. e) Flag: PLT Clumps (S)?; Cause: Presence of platelet

	clumps possible, specifically in platelet histogram; Possible Action: Verify on slide. Recollect if present. 3. Review of the laboratory's records for March 2018 revealed the laboratory did not address the flags on Complete Blood Count reports for the following seven (7) of three hundred thirty three (333) patients reviewed: a) Patient 98: Flag - PLT Clumps? b) Patient 99: Flag - Monocytosis; Leukocytopenia c) Patient 100: Flag - Monocytosis d) Patient 101: Flag - HGB Defect? e) Patient 102: Flag - Microcytosis; Iron Deficiency? f) Patient 103: Flag - Iron Deficiency?; PLT Abn Distribution g) Patient 104: Flag - Left Shift? 4. Interview with Personnel 2 on December 6, 2018 confirmed the laboratory did not have a policy for CBC flags. Personnel 2 further confirmed the above patients were not addressed for flags.
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, record review and interview with personnel, the laboratory failed to reconstitute STA-Liatest Control and STA-Coag Control as required by the manufacturer. Findings: 1. Observation by surveyor on December 3, 2018 revealed the laboratory utilized a Stago Satellite analyzer for Coagulation testing with STA-Liatest Control for D-Dimer testing and STA-Coag Control for Prothrombin Time (PT) and Activated Partial Thromboplastin (APTT) testing. 2. Review of the STA-Liatest Control and the STA-Coag Control package inserts under Reagent Preparation and Storage revealed "Reconstitute each vial of Reagent 1 or 2 with exactly 1 ml of distilled water". 3. Observation by surveyor on December 5, 2018 at 08:00 am revealed Personnel 9 utilized water from a specimen cup labeled with Millipore DI H2O when making Quality Control for coagulation. 4. In interview on December 5, 2018 at 08:06 am, Personnel 9 stated the laboratory utilizes the Millipore water to reconstitute the coagulation controls for PT, APTT, and D-Dimer testing. 5. In interview on December 6, 2018 at 08:38 am, Personnel 10 confirmed the laboratory routinely reconstitutes controls with 1ml of deionized water, not distilled water. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 1,058 Prothrombin Time (PT), 173 Partial Thromboplastin Time (PTT), and 48 D-Dimer tests annually.
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 observation, record review, and interview with personnel, the Laboratory

	Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure patient samples for Routine Chemistry, General Immunology, and Endocrinology testing are processed according to Becton Dickinson Vacutainer Blood Collection System package instructions. Refer to D5311. 2. The laboratory failed to have a detailed, written policy and procedure for addressing flags on Complete Blood Count reports. Refer to D5401. 3. The laboratory failed to reconstitute STA-Liatest Control and STA-Coag Control as required by the manufacturer. Refer to D5411.
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, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Routine Chemistry, General Immunology, and Endocrinology testing are processed according to Becton Dickinson Vacutainer Blood Collection System package instructions. Refer to D5311. 2. The laboratory failed to have a detailed, written policy and procedure for addressing flags on Complete Blood Count reports. Refer to D5401. 3. The laboratory failed to reconstitute STA-Liatest Control and STA-Coag Control as required by the manufacturer. Refer to D5411.