Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0997956	03/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monroe Surgical Hospital	2408 Broadmoor Boulevard, Monroe, 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 Validation survey was performed on March 13, 2023 through March 15, 2023 at Monroe Surgical Hospital, CLIA ID # 19D0997956. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 by surveyor, review of laboratory policies, manufacturer's instrument manual, donor questionnaires, normal patient mean study, and interview with personnel, the laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal donor mean studies. Findings: 1. Observation by the surveyor during the laboratory tour on March 13, 2023 at 09:59 am revealed the laboratory utilizes the Sysmex CA-600 coagulation analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) patient testing. 2. Review of the laboratory's policy for "Establishment of Reference Interval & Geometric Mean for PT/PTT" under "Requirements" revealed the following: * Donors must be from a healthy population (no known pathological condition) and unanticoagulated. * Donors taking interfering substances and medications should not be included in the study. The medical director will review the donor's medication list to approve those that can be included in the study. * A minimumof 20 donors with a reasonably even distribution of males and females should be included. * Donors should span the adult range. (NOTE: A separate range should be established for pediatric populations if necessary). * Testing should be performed over a period of

	several days and by different people, if possible, to minimize day to day variation. * A minimum of 4-6 specimens should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing of patient samples. * The test results from the donors should be analyzed statistically and a mean +/- 2sd or 95% confidence limit calculated. 3. Review of the Siemens Sysmex CA-600 analyzer manual under "Verification of Reference Interval" revealed the following: * Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients). * Donors should not hake any medications, including aspirin. * A minimum of 20 donors with a reasonably even distribution of males and females should be included. * Donors should span the adult age range. (NOTE: A separate range should be established for pediatric populations). The FDA defines "pediatric" as up to 21 years of age. * Testing should be performed over a period of several days and by different people, if possible, to allow for day to day variation. * A minimum of 4-6 specimens should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing of patient samples. * The test results from the donors should be analyzed statistically and a mean +/- 2sd or 95% confidence limit calculated. 4. Review of the laboratory's "Selection of Individuals for Reference Range Studies" revealed the following: * Do you consider yourself to be healthy? YES NO * Have you recently been ill? YES NO If YES, when _____ * Are you taking any prescribed or over the counter medications? YES NO * If YES, please list or attach list of all medications _____ 5. Review of laboratory's normal donor mean PT study (performed on 10/18/2022) and donor questionnaires for Innovin Lot 564616A revealed the laboratory utilized the following four (4) unacceptable donors: * Donor 524703: The donor answered question of "Do you consider yourself to be healthy? as NO * Donor 523819: The donor listed "Depo-provera" as a prescibed or over-the-counter medication * Donor 523925: The donor listed "Low-Dose Bayer Aspirin" as a prescribed or over-the-counter medication * Donor 526519: The donor listed "Warfarin" as a prescibed or over-the-counter medication 6. In interview on March 14, 2023 at 3:45 pm, the Techincal Consultant stated the Laboratory Director reviews medication lists and decides if donor can be utilized for the study. The Technical Consultant confirmed the laboratory utilized unacceptable donors for the normal mean PT study.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of laboratory policy manual and maintenance records as well as interview with personnel, the laboratory failed to perform corrective actions when the cuvette temperature was not within acceptable range as required by the manufacturer for the Siemens Dimension EXL Chemistry

	analyzer. Findings: 1. Observation by surveyor during the laboratory tour on March 13, 2023 at 9:59 am revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer for chemistry testing. 2. Review of the laboratory policy manual revealed the laboratory did not have a corrective action policy for unacceptable cuvette temperatures on the Siemens Dimension EXL chemistry analyzer. 3. Review of the Siemens Dimension EXL with LM chemistry analyzer maintenance log revealed the acceptable cuvette temperature range as 36.8 to 37.2 degrees celsius. 4. Further review of the laboratory's maintenance logs from January 1, 2022 through March 15, 2023 revealed the laboratory did not take corrective action when the cuvette temperature was out of acceptable range for the following one (1) of four hundred thirty nine (439) days reviewed: a) April 11, 2022 - temperature recorded as 37.3 degrees celsius 5. In interview on March 15, 2023 at 2:00 pm, the Technical Consultant confirmed the above identified cuvette temperature was unacceptable and that no corrective action was performed.
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 by surveyor, review of laboratory records for normal mean prothrombin time studies and policies, as well as interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal donor mean studies. Refer to D5411.
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 observation by surveyor, review of laboratory policies and temperature logs as well as interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to perform corrective actions when the cuvette temperature was not within acceptable range as required by the manufacturer for the Siemens Dimension EXL Chemistry analyzer. Refer to D5781.