Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463228	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Desoto Regional Health System	207 Jefferson Street, Mansfield, 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 May 17, 2021 through May 19, 2021 at DeSoto Regional Health System, CLIA ID # 19D0463228. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for two (2) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records for 2019, 2020, and 2021 revealed the Laboratory Director did not sign the attestation statements for the following two (2) of seven (7) events reviewed: a) 2021 Immunology /Immunohematology 1st event b) 2021 Hematology/Coagulation 1st event 2. In interview on May 17, 2021 at 15:33 pm, Personnel 2 confirmed the Laboratory Director did not sign the attestation statements for the above events.
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: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the performance evaluation form for one (1) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) PT records for 2019, 2020, and 2021 revealed the Laboratory Director did not sign the performance evaluation form for the following one (1) event: a) 2021 Hematology/Coagulation 1st event 2. In interview on May 17, 2021 at 15:33 pm, Personnel 2 confirmed the Laboratory Director did not sign the above identified PT event.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure that Blood Bank reagents were not used beyond their expiration dates. Findings: 1. Review of the laboratory's "Reagent Quality Control" policy revealed under "Complete the Reagent Identification section of the QC form" that "each day of testing, check all reagents to make sure none are outdated. If the reagent will expire during this shift, put a new lot into use at the time QC is performed and add new date /lot information to the right column". 2. Review of the laboratory's Blood Bank Reagent Quality Control Record from January 1, 2019 through May 17, 2021 revealed the laboratory documented the use of expired reagents for the following dates: a) On June 14, 2020 at 8:00 am, the laboratory documented the use of Thermofisher Blood Bank (BB) Saline (Lot 545477) with the expiration date of June 13, 2020 b) From March 13, 2021 at 8:00 am through March 14, 2021 at 8:00 am, the laboratory documented the use of Immucor Anti-A (Lot 104028-1) with the expiration date of March 12, 2021 3. In interview on May 18, 2021 at 1452 pm, Personnel 2 confirmed the laboratory documented the use of expired BB Saline and Anti-A for the dates cited above.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform corrective actions for the Ortho Workstation Incubator when temperature was outside of acceptable limits per laboratory policy for one (1) of three hundred sixty five (365) days reviewed. Findings: 1. Review of the laboratory's "Quality Control of Instruments" policy revealed under "Ortho Workstation Incubator" to "Daily record temperature on thermometer and record on temperature log. A check and initials will indicate an acceptable temperature: 37 +/- 2 degrees celsius". 2. Review of the laboratory's Ortho Workstation temperature logs from January 2019 through December 2019 revealed the Ortho Workstation Incubator temperature was not within the acceptable range for the following one (1) of three hundred sixty five (365) days reviewed: a) November 10, 2019: Temperature documented as 39.9 degrees celsius with no corrective action documented. 3. In interview May 18, 2021 at 15:03 pm, Personnel 2 confirmed that no corrective action was documented for the above cited unacceptable temperature.
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. Refer to D5417.
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 are reviewed by the appropriate staff. Findings: 1. The laboratory failed to ensure the Laboratory Director signed the attestation statement for two (2) of seven (7) proficiency testing (PT) events reviewed. Refer to D2009. 2. The laboratory failed to ensure the Laboratory Director signed the performance evaluation form for one (1) of seven (7) proficiency testing (PT) events reviewed. Refer to D2015.
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. Refer to D5785.
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 Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5417.
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. Refer to D5785.