Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465387	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chicot Memorial Medical Center	2729 S Hwy 65 & 82, Lake Village, AR	

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
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: Through a review of the Blood Bank Quality Control Data Sheet, a review of Microbiology Quality Control Logs, and interviews with laboratory staff, it was determined the laboratory used reagents when they exceeded their expiration date. Survey findings follow: A. A review of the Blood Bank Quality Control Data Sheets revealed the following which were documented in use past their expiration date: Reverse Grouping Cells (lot # 111167) expired 1/19/2018 but was documented in use on 1/20/2018; Screening Cells (lot # 46085) expired 1/19/2018 but was documented in use on 1/20/2018; Coombs Control Cells (lot # 46091) expired 1/19/2018 but was documented in use on 1/20/2018; B Reverse Typing Cells (lot # 113167) expired 1/19 /2018 but was documented in use on 1/20/2018; and Poly Anti IgG Cells (lot # 702022) expired 7/12/2018 but was documented in use on 7/13/2018 and 7/16/2018 through 7/20/2018. B. Through a review of the Micro Quality Control Logs for January through August of 2018 it was determined the laboratory documented using Coagulase Plasma (lot #C14132 expiration 12/31/2017) through 3/2/2018. C. In an interview on 9/6/2018 at 10:55 a.m. laboratory employee #3 (as listed on the form CMS-209) confirmed that reagents were used when they had exceeded their expiration date.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i)

	Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the Micro Quality Control Logs for January through August of 2018, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document quality control for each lot of coagulase plasma used in 2018. Survey findings follow: A. The Micro Quality Control Log included two different lots of Coagulase Plasma used in 2018. Lot #C14132 was documented in use until 3/2/2018. The new lot of Coagulase Plasma (lot #C15689) was documented in use starting on 3/6/2018. B. A review of the Micro Quality Control Log for January through August of 2018 revealed the laboratory did not document quality control on the new lot of Coagulase Plasma (lot # C15689) which was put in use on 3/6/2018. The laboratory failed to document quality control on one of two lots of Coagulase Plasma used in 2018. C. In an interview, at 10:36 on 9/6/2018, laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of documented quality control on the current lot of Coagulase Plasma.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of the Blood Bank Procedure Manual, a review of the Blood Transfusion Alarm Check Log, lack of documentation, and interviews with staff, it was determined the laboratory failed to inspect the alarm system as required by their written policies. Survey findings follow: A. A review of the Blood Bank Procedure Manual revealed the Alarm Check policy states that the blood bank alarm will be checked quarterly (four times per year). B. The Blood Transfusion Alarm Check Log is used to document four alarm checks each year. The Blood Transfusion Alarm Check Log includes spaces for alarm checks to be recorded in March, June, September, and December each year. C. A review of the Blood Transfusion Alarm Check Log revealed that the alarm check was only documented in two of four quarters in 2017. The alarm checks for 2017 were only documented on 3/16/2017 and 8/23 /2017. D. In an interview, at 11:01 on 9/6/2018, employee #3 (as listed on the form CMS-209) confirmed the laboratory did not document blood bank alarm checks each quarter of 2017.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Through a review of personnel files, lack of documentation, and interviews with laboratory staff, it was determined the technical supervisor failed to evaluate the competency of personnel at least semiannually the first year of testing. Survey findings follow: A. A review of eight personnel records revealed that employee #7 (as listed on the form CMS-209) had new employee training documented on 4/12/2017. The only competency evaluation documented for employee #7 was dated 10/25/2017. Although the employee has been testing over one year (16 months) there is only one documented competency. B. In an interview, at 9:31 a.m. on 9/5/2018, employee #3 (as listed on the form CMS-209) confirmed the competency of employee #7 had not been documented semiannually the first year that she tested patients.