

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0465387	<b>(X3) Date Survey Completed</b> 03/31/2023
<b>Name of Provider or Supplier</b> Chicot Memorial Medical Center	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory as well as interviews with laboratory staff, it was determined the laboratory had Airlife 0.45% sodium chloride solution available for use when it had exceeded its expiration date. Survey findings include: A) During a tour of the laboratory, conducted on 3/31/23 at 10:05 a.m., the surveyor observed 4 bottles of Airlife 0.45% sodium chloride solution (lot #21-2101019) which expired on 2023-01-11. B) During an interview at the time of the tour, Employee ( # 2 from the CMS-209 form) confirmed the sodium chloride solution was available for use when it had exceeded its expiration and the solution was used for dilutions required in microbiological sensitivity testing.</p>
<b>D5783</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:  
Through review of "Method Review quality control (QC)" reports for Thyroid Stimulating Hormone (TSH) for May 2022 and September 2022, "Communication and Corrective Action Logs" for the same time periods, patient result reports and interview with laboratory staff it was determined that the laboratory failed to evaluate patient test results back to the last successful QC when QC failure required actions which resulted in changes to the test system. Survey findings follow: A) Review of the "method review QC report" for May 2022 revealed that on 5/21/22 level 1 QC lot# EB2335 failed on five successive attempts on May 21, 2023 between 00:41 a.m. and 03:24 a.m. before being successful at 04:22 a.m. for TSH testing B) Review of the "method review QC report" for May 2022 revealed that on 5/21/22 level 3 QC lot# EB2335 failed on five successive attempts on May 21, 2023 between 00:41 a.m. and 03:24 a.m. before being successful at 04:22 a.m. for TSH testing. C) Review of the communication and corrective action log for 5/21./22 revealed that calibration of the test system was required to obtain acceptable QC results for TSH testing which reflects a change in the test system. D) Review of the method review QC report for May 2022 revealed that the last acceptable QC reported for TSH testing was 5/20/22 at 04:51 a.m. E) Review of patient result reports revealed that TSH testing was performed and reported on two patients (#s 1 and 2 on a separate patient identification list) on 5/20/22 at 10:13 a.m. and 03:49 p.m. respectively. F) In an interview on 3/30 /23 at 1:30 p.m., the laboratory staff member (#4 on the CMS 209 form) stated that the TSH results reported on 5/20/22 on the patients identified above had not been evaluated. G) Review of the "method review QC report" for September 2022 revealed that on 9/28/22 level 1 QC lot# FB3152 failed on six attempts on September 28 between 00:34 a.m. and 02:26 p.m. before being successful at 03:13 p.m. for TSH testing. H) Review of the communication and corrective action log for 9/28/22 revealed that calibration of the test system was required to obtain acceptable QC results for TSH testing which reflects a change in the test system. I) Review of the method review QC report for September 2022 revealed that the last acceptable QC reported for TSH testing was 9/27/22 at 00:51 a.m. J) Review of patient result reports revealed that TSH testing was performed and reported on one patient3 (#3 on a separate patient identification list) on 9/27/22 at 11:18 a.m. K) In an interview on 3/30 /23 at 1:30 p.m., the laboratory staff member (#4 on the CMS 209 form) stated that the TSH result reported on 9/27/22 on the patient identified above had not been evaluated.