

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0465641	<b>(X3) Date Survey Completed</b> 12/12/2024
<b>Name of Provider or Supplier</b> Magnolia Regional Health System Inc	<b>Street Address, City, State</b> 101 Hospital Drive, Magnolia, 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: Based on observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 12/12/24 at 1:16 pm, one (of three) BD Bactec Plus Aneorobic Culture Tube, (REF 442023, lot 4038374, expiration 11/15/2024) was observed in the laboratory, available for use beyond the expiration date. B) During a tour of the laboratory on 12/12/24 at 1:18 pm, two (of six) Finntip 250 Universals, (REF 9400260, lot 19156PO, expirations 06/2024 and 01/2022) were observed in the laboratory, available for use beyond the expiration date. D) In an interview on 12/12/24 at 1:20 pm Technical Supervisor #1 (as listed on the CMS-209 form), confirmed that the items, identified above, had exceeded the expiration date and were available in the laboratory.</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:

Based on a review of chemistry quality control (QC) results for May of 2024, and interviews with laboratory staff, it was determined that patients were reported when results of control material failed to meet the criteria for acceptability on two of thirty one days in May 2024. Survey findings follow: A) Review of the laboratory policy "General QC, Department Chemistry" (effective date 8/30/18, reviewed 3/4/20) revealed "In the event that daily QC does not come within acceptable limits (2 standard deviations (SD)), patients should not be reported for the day until QC is in range." B) Through a review of chemistry quality control results for May of 2024, it was revealed that on 5/14/24 the Biorad Multiquel Level 3 lot # 45933 Amylase was reported as 222 with an acceptable range of 237 to 252.2 and flagged as >2 SDI. The previous passing control was ran on 05/13/24 at 5:03 am. After calibration, a passing control was resulted on 5/14/24 at 8:20 am. C) Three patients (Medical Records #: 0047568,0044487, 0102186) had Amylase results reported between 5/13/24 at 5:03 am and 5/14/24 8:20am. D) Through a review of chemistry quality control results for May of 2024, it was revealed that on 5/18/24 the Biorad Multiquel Level 1 lot # 45931 Cholesterol was reported as 110.0 with an acceptable range of 98.94 to 109.06 and flagged as >2 SDI. The previous passing control was ran on 5/17/24 at 4:36 am. After calibration, a passing control was resulted on 5/18/24 at 4:53 am. E) Six patients (Medical Records #0015132, 0022083, 008493, 0104076, 0037875, 0045632) had Cholesterol results reported between 5/17/24 4:36am and 5/18/24 4:53 am. F) Through a review of chemistry quality control results for May of 2024, it was revealed that on 5/14/24 the Biorad Multiquel Level 3 lot # 45933 Glucose was reported as 316.0 with an acceptable range of 336.64 to 365.36 and flagged as >2 SDI. The previous passing control was ran on 5/13/24 at 04:06 am. After calibration, a passing control was resulted on 5/14/24 at 6:31 am. G) Twenty one patients (Medical Records #0072745, 0050792, 0025995, 0036809, 0017570, 0000727, 0023522, 0098173, 0025640, 0019859, 0044493, 003231, 0054455, 0049193, 0026656, 0082888, 0073894, 0001556, 0102186, 0029921, 0044487): ) had Glucose results reported between 05/13/24 at 5:03 am and 5/14/24 8:20am. C. In an interview at 9:55am on 12/12/24, Technical Supervisor #1 (as listed on the form CMS-209) confirmed the above patients were reported when the quality control results were outside of acceptable range and the results had not been evaluated.