

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0660706	(X3) Date Survey Completed 02/05/2025
Name of Provider or Supplier Hardeman County Memorial Hospital	Street Address, City, State 402 Mercer St, Quanah, TX	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions, policies and procedures, quality control records patient test records and interview of facility personnel the laboratory failed to test a positive and negative control with each test run when testing 81 patient specimens for Rheumatoid Factor (RF) in 2024. The findings included: 1. Review of the manufacturer's instructions for use of the Arlington Scientific RF Direct Slide Test found on page 3 under the heading QUALITY CONTROL: "REACTIVE and NONREACTIVE CONTROLS should be included in each test run to confirm optimal reactivity of the LATEX REAGENT. If controls do not yield the expected response, the assay should be considered invalid and the assay repeated." 2. Review of the laboratory's own written procedure dated 02/09/2024 found under the heading QUALITY CONTROL: "REACTIVE and NONREACTIVE CONTROLS should be included in each test run to confirm optimal reactivity of the LATEX REAGENT. If controls do not yield the expected response, the assay should be considered invalid and the assay repeated." 3. Review of RF Quality control records found the laboratory tested reactive and nonreactive controls on the following dates in 2024: 01/31/2024 - lot 2J29D3 expiration 04/30/2024 02/29/2024 - lot 2J29D3 expiration 04/30/2024 04/01/2024 - lot 3P12D3 expiration 09/30/2025 05/01/2024 - lot 3P12D3 expiration 09/30/2025 05/31/2024 - lot 3P12D3 expiration 09/30/2025 07/01/2024 - lot 3P12D3 expiration 09/30/2025 08/01/2024 - lot 3P12D3 expiration 09/30/2025 08/31/2024 - lot 3P12D3 expiration 09/30/2025 09/24/2024 - lot 3P12D3 expiration 09/30/2025 10/01/2024 - lot 3P12D3 expiration 09/30/2025 11/01/2024 - lot 3P12D3 expiration 09/30/2025 11/08/2024 - lot L3L31DC expiration 10/31/2025 12/02/2024 - lot L3L31DC expiration 10/31/2025 4. Review of patient test records found the laboratory tested 81 patients without testing quality control materials with each test</p>

run as follows: 01/02/2024 - patient 10071050 01/15/2024 - patient 10071422 01/23/2024 - patient 10071676 01/25/2024 - patient 10071748 01/31/2024 - patient 10071943 02/01/2024 - patient 10071982 02/05/2024 - patient 10072196 02/06/2024 - patient 10072201 02/08/2024 - patient 10072266 02/13/2024 - patient 10072369 02/20/2024 - patient 10072519 02/21/2024 - patient 10072557 02/26/2024 - patient 10072668 02/27/2024 - patients 10072691 and 10072696 03/04/2024 - patient 10072917 03/08/2024 - patient 10073040 03/15/2024 - patient 10073199 03/21/2024 - patient 10073343 03/22/2024 - patient 10073396 03/28/2024 - 5 proficiency samples 04/05/2024 - patient 10073776 04/08/2024 - patients 10073856, 10073860 and 10073870 04/16/2024 - patient 10074030 04/23/2024 - patient 10074113 04/26/2024 - patient 10074289 04/29/2024 - patient 10074302 04/30/2024 - patients 10074339 and 10074352 05/15/2024 - patient 10074771 06/04/2024 - patient 10075253 06/07/2024 - patient 10075346 06/12/2024 - patient 10075417 06/19/2024 - patients 10075546 and 10075539 06/20/2024 - patient 10075571 06/26/2024 - patient 10075698 07/02/2024 - patients 10075904, 10075896 and 10075908 07/10/2024 - patient 10076079 07/18/2024 - patient 10076215 08/06/2024 - patient 10076796 08/08/2024 - patient 10076832 08/15/2024 - patient 10076979 08/23/2024 - patient 10077199 09/05/2024 - patients 10077590 and 10077600 09/17/2024 - patient 10077893 09/19/2024 - patient 10077923 09/24/2024 - patient 10078062 09/25/2024 - patients 10078073, 10078082 and 10078088 10/04/2024 - patient 10078390 10/10/2024 - patients 10078524 and 10078519 10/19/2024 - patient 10078581 10/23/2024 - patient 10078845 10/28/2024 - patients 10078931, 10078946 and 10078947 10/31/2024 - patient 10079056 11/07/2024 - patient 10079329 11/08/2024 - patient 10079372 11/18/2024 - patient 10079568 11/20/2024 - 5 proficiency samples 11/25/2024 - patients 10079754 and 10079781 5. During interview of the Technical Consultant conducted February 5, 2025 at 1:27 PM, she confirmed the laboratory did not test a reactive and nonreactive control with each test run when testing patient samples for RF.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(4)

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
 Review of policies and procedures, quality control records and interview of facility personnel found the technical consultant failed review and document the review of Hematology quality control (QC) reports monthly for 24 of 24 months as defined in their own policy. The findings included: 1. Review of the laboratory policy titled SYSMEX XN 550 (dated 05/23/2022) found on page 6 under the heading Frequency of Control Use and Review: "The supervisor reviews the following QC reports at the following intervals: Exception Report every month Summary Report every month Continuous Calibration Verification Certificate every month Detailed Daily Verification Report every month Parameter Report every month Traceability Report every month." 2. Review of quality control records for 2023 and 2024 found no monthly review of the six reports defined in the procedure. 3. During interview of the technical consultant conducted February 5, 2025 at 10:37 AM, she confirmed that she did not have documentation of the monthly reviews for 2023 and 2024.