Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0674352	**(X3) Date Survey Completed** 03/13/2025
Name of Provider or Supplier Grimes St Joseph Health Center	**Street Address, City, State** 210 South Judson Street, Navasota, 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**
D0000	An announced validation survey of the laboratory was conducted on 03/13/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient reports, and confirmed in an interview with laboratory personnel, the laboratory failed to follow its policy for screening donors for two of two reagent lot roll overs, one in 2024 and one in 2025 (current study in progress). The findings were: 1. Review of the laboratory's policy titled, "COAG-05 System Lot Conversion and Correlation" under "Procedure: Full Validation - New Reference Range" it stated at #4: "Criteria for Donors: A. Age: Include ages that span the patient population B. Sex: Male or Female C. Drug HX: Donor excluded if taking estrogen, Coumadin, Heparin, LMWH, direct thrombin inhibitors, and antibiotics. D. Conditions: Donors excluded if they are pregnant or have any known immunological disease." 2. Review of patient reports found the following 10 patient samples were resulted for PT w/INR using the laboratory's current PT reagent: Specimen Id: 1205:HC41S Date: 12/05/2024 PT Result: 13.2 INR Result: 1.0 Specimen Id: 1204:HC82S Date:12/04/2024 PT Result: 12.8 INR Result: 1.0 Specimen Id: 1205:HC44S Date: 12/05/2024 PT Result: 14.4 INR Result: 1.1 Specimen Id: 1205:HC62S Date: 12/05/2024 PT Result: 13.2 INR Result: 1.0 Specimen Id: 1207:HC35S Date: 12/07/2024 PT Result: 13.7 INR Result: 1.1

	Specimen Id: 1209:HC39S Date: 12/09/2024 PT Result: 13.9 INR Result: 1.1 Specimen Id: 1210:HC55S Date: 12/10/2024 PT Result: 17.5 (flagged high) INR Result: 1.4 Specimen Id: 1210:HC66S Date:12/10/2024 PT Result: 13.4 INR Result: 1.0 Specimen Id: 1205:HC15R Date: 12/05/2024 PT Result: 38.2 (flagged high) INR Result: 3.9 Specimen Id: 1211:HC20R Date: 12/11/2024 PT Result: 27.3 (flagged high) INR Result: 2.5 3. The laboratory was asked to provide documentation of screening the donors for the previous lot roll and for the lot roll over in progress. No documentation was available for review. 4. The findings were confirmed in interview with General Supervisor 2 (as listed on CMS Form 209) on March 13, 2025 at 11:00 a. m. hours in the laboratory. She confirmed that screening was performed verbally. Key: LMWH - low molecular weight heparin PT - Prothrombin Time INR - International Normalized Ratio CMS - Centers for Medicare and Medicaid Services S - STAT R - Routine
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) (b) Each individual performing moderate complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, patient test records and interview of facility personnel, one of seven testing personnel performing Chemistry testing failed to follow the laboratory's procedure for testing patient specimens for Ammonia. The findings included: 1. Review of the laboratory's own written procedure titled AMMONIA (effective date 01/16/18) found on page 3 under the heading Procedure: " 4. Specimen Dilution procedure - A. The Abbott Architect c4000 has an automatic dilution feature; refer to Section 2 of the instrument specific operations manual located in the Architect workstation computer. B. Specimens with Ammonia values exceeding 500 ug/dL are flagged and will be diluted using the Automated Dilution Protocol. C. During the Automated Dilution Protocol, the system performs a 1:1.85 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor. If still no result is available, the test will be reported as >925 ug/dL. No other dilution will be performed." 2. Review of 19 patient specimens tested for Ammonia in 2024 found 2 of 19 specimens tested were diluted prior to testing. Specimen 0908:CS0062S - tested 09/08/2024, resulted as 48 with a comment of (Dilution X3) 16x3=48 Specimen 1007:CS00240S - tested 10/07 /2024, resulted as 40 with a comment of (Dilution X2) 920 x 2=40). 3. During interview of general supervisor 1 conducted March 13, 2025 at 1:07 PM, he confirmed that testing personnel failed to follow the laboratory's written instructions for testing patient specimens for Ammonia. Key: ug/dL - micrograms per deciliter
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based upon review of the Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel, the laboratory failed to perform competency assessments for 3 of 7 testing personnel in 2024. The findings included: 1. Review of the Laboratory Personnel Report found the laboratory defined seven testing personnel performing moderate and high complexity testing. 2. Review of the policy titled Employee Competency (Effective 08/20/18) found on page 3 under the heading Protocol: A(1)" Since standards for each position are continually increasing, all laboratory technical employees are required to complete a competency assessment: (a) Current employees are required to complete a competency assessment annually. (b) New employees are required to complete a competency assessment upon completion of their training and at six months and annually thereafter." 3. Review of personnel records found no competency assessments performed in 2023 for the following testing personnel: Testing person 1 - hire date 2009, one competency assessment dated 12/23/24 Testing person 2 - hire date 10/04/2019, one competency assessment dated 12/16/22 and one dated 11/7/24 Testing person 5 - hire date unknown, one competency assessment dated 10/21/22 and one dated 03/08/24 4. During interview of technical consultant 1 conducted March 12, 2025 at 11:18 AM, he confirmed that annual competency assessments were not completed in 2023 when personnel changes occurred.