Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132503	09/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Brenda Tharian Md Pllc	129 Vision Park Blvd Ste 301, Shenandoah, 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 survey of the laboratory was conducted on 09/16/2025. 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observation, review of laboratory's policies/procedures and staff interview, the laboratory failed to ensure its policies were followed for patient sample labeling for eight of eight samples observed. Findings included: 1. Surveyor's observations on 09/16/2025 at 1100 hours in the laboratory revealed eight urine collection cups with patient samples sitting on the countertop. Three cups were labeled with only patients' first names and last names' initials and five cups were labeled with first and last names only. There was no second identifier annotated on the cup. 2. Review of laboratory's policy "1.6 Specimen Collection" (effective 01/01 /2025) revealed: "3. A urine sample must be collected in the following manner: ... b. In a pre-labeled collection cup with the patient's name, DOB, and date / time collection" 3. Review of laboratory's policy "3.3 Accessioning Protocol" (effective 01 /01/2025) revealed: "Labels must contain 2 unique identifiers: First, Last name and DOB." 4. In an interview on 09/16/2025 at 1100 hours in the laboratory, facility's Testing Person (as indicated on submitted Form CMS 209) confirmed the findings.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted test menu a sampling of laboratory's final reports and staff interview, the laboratory failed to ensure required information was included on final reports for two of three reports reviewed from August and September 2025. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory performed two tests in the laboratory a dipstick urinalysis and a laboratory developed Polymerase Chain Reaction (PCR) Molecular Microbiology Urine Panel. 2. Review of a sampling of laboratory's final reports for the above tests revealed: a. Urinalysis report for patient DOB 01/04/1961, collected and tested 09/16 /2025 had the section for Reference Ranges and time of collection left blank. b. PCR Molecular Microbiology Urine Panel report for patient 0005366, collected and tested 08/22/2025 did not include a complete list of analytes tested or the disclaimer identifying test methodology for the laboratory developed test. 3. In an interview on 09 /16/2025 at 1140 hours in the laboratory, facility's Testing Person (as indicated on submitted Form CMS 209) confirmed the findings. Key: DOB - Date of birth CMS - Centers for Medicare and Medicaid Services