Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0669755	12/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Drs Black & Benton, Psc	4741 N Broadway, Knoxville, TN	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Specimen Collection: Criteria for Rejection" policy, direct observation, and interview with the nursing supervisor, determined the laboratory failed to follow its policy for specimen labeling. The findings include: 1. Review of the laboratory's "Specimen Collection: Criteria for Rejection" policy stated, "Specimens must be labeled with patient's name." 2. Direct observation of one fingerstick specimen and one urine specimen on 12.15.2022 at approximately 8:40 a. m. revealed specimens were not labeled with patient's name. 3. Interview on 12.15.2022 at approximately 9:00 a.m. with the nursing supervisor confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's operator's manual, lack of documentation and interview with the nursing supervisor, the laboratory failed to monitor the humidity in the area where the complete blood count (CBC) instrument was located in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 12.15.2022 at 8:35 a.m. revealed the Cell-Dyn Emerald CBC instrument (serial #031016-006834) in use for patient testing. 2. Review of the manufacturer's specifications for operating revealed a maximum operating humidity range of 80% for temperatures up to 90 F (32 C). 3. There were no environmental records for monitoring of humidity for surveyor review. 4. Interview with the nursing supervisor on 12.15.2022 at approximately 9:00 a.m. confirmed the laboratory failed to monitor the humidity in the area where the CBC instrument was located in 2020, 2021 & 2022.