Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1001233	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Harper Branch Laboratory	5901 Harper Rd Ne, Albuquerque, NM	

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	The following standard deficiencies were cited as the results of a recertification survey on 01/25/2023, with an additional on-site visit on 03/02/2023. This facility was found to be IN compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed.
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 direct observation, review of the manufacturer's instructions, laboratory policy, laboratory records, patient records, and confirmed in staff interview, the laboratory failed to ensure Cryostat temperatures were within operating specifications according to the laboratory policy for 11 of 11 months (09/2021 through 12/2021 and 04/2022 through 10/2022). Findings included: 1. During a tour of the laboratory on 01/25/2023, at 3:00pm, one Cryostat (serial number 56579) was observed. 2. Review of the manufacturer's operation manual titled, "Microm HM550 Thermo Scientific CRYOSTAT MICROTOM" stated, "Technical Data ... Chamber temperature control -10C to -35C". 3. Review of the laboratory's policy titled "Frozen Sections of Fresh Tissue and Staining Procedure" (Reference: HIST 18, Effective: 07/11/2022, Version: 8.0) stated, "PROCEDURE ... B. Frozen Section Technique ... 5. The Cryostat temperature is verified. The range is: -30 to -20 C." 4. Review of the laboratory's "Northside PMG CryoStat Log" stated, "In Range Temp = -15 - -30C." The

	laboratory's daily log temperature upper limit of -15C exceeded the laboratory's upper limit of -20C, as specified in their policy. 5. Review of the laboratory's patient records from 09/2021 through 12/2021 and 04/2022 through 10/2022, revealed 2 of 16 days patient testing was performed when CryoStat temperatures exceeded the laboratory's specified upper limit of -20C: a. Patient 010826 09/09/2021 CryoStat temperature: -19 C b. Patient 010955 09/13/2021 CryoStat temperature: -17C Word key: C = degrees Celsius H&E = Hematoxylin-Eosin 6. During an interview on 03/02/2023 at 11:15 am in the conference room, after review of the above records, the technical consultant confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of laboratory policy/procedure, laboratory's quality control forms, and confirmed in staff interview, the laboratory failed to define the intended reactivity for the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for 4 months (January, February, April and December) in 2021 and 3 months (January, February and March) in 2022. Findings included: 1. Review of the policy/procedure titled, "Frozen Sections of Fresh Tissue and Staining Procedure" revealed the laboratory's policy/procedure failed to include the intended reactivity and the predicted staining characteristics for the H & E Quality Control (QC) slide. 2. Review of the laboratory's quality control forms revealed a checkmark under a column titled "Good", indicating the stain quality of the H&E Control slide. The laboratory's quality control forms indicated the QC for the H&E stain was performed on the following days in January, February, and April of 2021: 01/15/2021 01/20 /2021 02/02/2021 02/19/2021 04/06/2021 04/09/2021 04/16/2021 04/22/2021 The laboratory's quality control form indicated the QC for the H&E stain was performed on the following days in December (2021), January, February, and March of 2022: 12 /02/2021 12/09/2021 01/04/2022 01/13/2022 02/01/2022 02/10/2022 03/01/2022 The laboratory failed to define the intended reactivity for the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics. 3. In an interview on 1/25 /2023 at 3:09 pm, after review of the records, the Technical Consultant (TC#2), confirmed the findings.